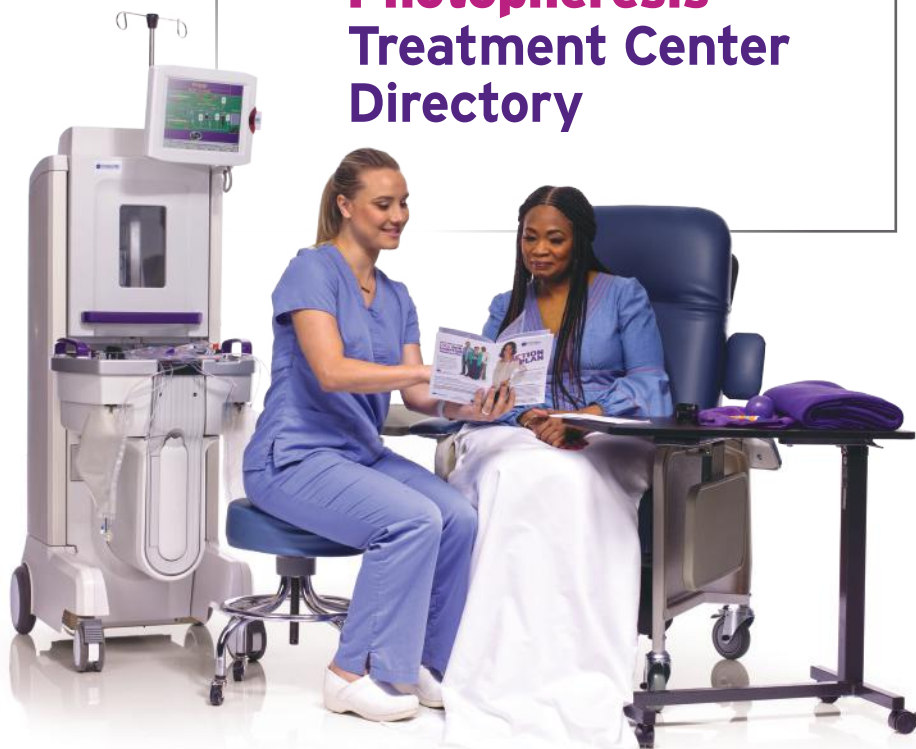


Extracorporeal Photopheresis Treatment Center Directory



INDICATIONS AND USAGE

UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® CELLEX® Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

IMPORTANT SAFETY INFORMATION

CAUTION: READ THE THERAKOS CELLEX PHOTOPHERESIS SYSTEM'S OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

UVADEX (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the THERAKOS CELLEX Photopheresis System. Please consult the CELLEX Operator's Manual before using this product.

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Find the treatment center offering photopheresis nearest to you



This is a directory of centers that offer photopheresis treatment, along with contact information for each center. The treatment centers are listed alphabetically by state for ease of reference. This resource is provided for informational use only and may not be comprehensive.

Extracorporeal photopheresis is available by prescription only.

Patients should always consult with their healthcare provider before initiating any treatment.

Treatment centers are independent, third-party facilities not owned or operated by Mallinckrodt.



Alabama

The Kirklin Clinic of University of Alabama at Birmingham Hospital

Jefferson Towers, 6th Floor
625 19th Street South
Birmingham, AL 35233

Contact: Outpatient Clinic
Contact Phone: 205-975-4026

<http://www.uabmedicine.org/locations/the-kirklin-clinic-of-uab-hospital>



Alaska

Katmai Oncology Group

3851 Piper Street, Suite U340
Anchorage, AK 99508

Contact Phone: 907-562-0321
<http://katmaioncology.com>



Arizona

Banner MD Anderson Cancer Center - Phoenix

2946 E. Banner Gateway Drive
Gilbert, AZ 85234

Contact Phone: 480-256-6444
<https://www.bannerhealth.com/banner-md-anderson>

Banner - University Medical Center Phoenix

Outpatient Infusion Center
1111 E. McDowell Road
Phoenix, AZ 85006

Contact Phone: 602-839-2000
<https://www.bannerhealth.com/locations/phoenix/banner-university-medical-center-phoenix>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

HonorHealth Scottsdale Shea Medical Center

9003 E Shea Boulevard
Scottsdale, AZ 85260

Contact: Dialysis/Apheresis Department
Contact Phone: 480-323-3035

Email: oncologynursenavigator@honorhealth.com
<https://www.honorhealth.com/locations/hospitals/scottsdale-shea-medical-center>

Mayo Clinic Hospital, Phoenix, Arizona

5777 E Mayo Boulevard, Suite 4E, Room 100
Phoenix, AZ 85054

Contact: Apheresis Department
Contact Phone: 480-342-0103

<https://www.mayoclinic.org/patient-visitor-guide/arizona/campus-buildings-maps/mayo-clinic-hospital>

St. Joseph's Hospital and Medical Center

Outpatient Infusion Suite
500 W Thomas Road, Suite 650
Phoenix, AZ 85013

Contact Phone: 602-406-3061

<https://www.dignityhealth.org/arizona/locations/stjosephs/services/outpatient-infusion-suite>

University of Arizona Cancer Center - North Campus

3838 N Campbell Avenue
Tucson, AZ 85719

Contact Phone: 520-694-2873
<https://cancercenter.arizona.edu/>



Arkansas

University of Arkansas for Medical Sciences

4301 W Markham Street, #823
Little Rock, AR 72205

Contact: Cell Therapy/Apheresis Department
Contact Phone: 501-686-7930

<https://clinlab.uams.edu/departments/>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.



California

Alta Bates Summit Cancer Services

2001 Dwight Way
Berkeley, CA 94704

Contact: Apheresis Department
Contact Phone: 510-204-6578

<https://www.sutterhealth.org/find-location/facility/alta-bates-summit-medical-center-herrick-campus#service-include-A-absmc>

Cedars-Sinai Medical Center

8700 Gracie Allen Drive, Street Level, South Tower, Room 1695
Los Angeles, CA 90048

Contact: Therapeutic Apheresis Unit
Contact Phone: 310-423-4867

<https://www.cedars-sinai.org/programs/blood-donor-services.html>

City of Hope National Medical Center - Comprehensive Cancer Center

1500 East Duarte Road
Duarte, CA 91010

Contact: Therapeutic Apheresis Department
Contact Phone: 626-218-5910

<http://www.cityofhope.org/homepage>

Keck Medicine of USC - Keck Hospital

1500 San Pablo Street
Los Angeles, CA 90033

Contact: Photopheresis Department
Contact Phone: 1-800-USC-CARE (1-800-872-2273)

<http://cancer.keckmedicine.org>

Ronald Reagan UCLA Medical Center

200 UCLA Medical Plaza, Suite 120
Los Angeles, CA 90095

Contact: Hematology/Oncology Department
Contact Phone: 310-206-6909

<https://www.uclahealth.org/ucla-medical-plaza>

Stanford Health Care - Infusion Center at Stanford Cancer Center

Advanced Medicine Center Building
875 Blake Wilbur Drive, 2nd Floor
Palo Alto, CA 94304

Contact: Apheresis Department
Contact Phone: 650-725-4656

<https://stanfordhealthcare.org/medical-clinics/infusion-center.html>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Sutter Cancer Center - Buhler Speciality Pavilion

2800 L Street, Room 215
Sacramento, CA 95816

Contact: Apheresis Service
Contact Phone: 916-453-3300, Ext. 4

<https://www.sutterhealth.org/find-location/facility/buhler-specialty-pavilion>

UC Davis Medical Center - Department of Pathology & Laboratory Medicine

2315 Stockton Boulevard
Sacramento, CA 95817

Contact: Apheresis Services
Contact Phone: 916-734-3732

https://health.ucdavis.edu/pathology/services/clinical/clinical_pathology/apheresis/

University of California Irvine Health Blood Donor Center

101 The City Drive South, Pavilion 3, Room 401
Orange, CA 92868

Contact Phone: 714-456-5433

<http://www.ucirvinehealth.org/locations/orange/blood-donor-center-medical-center>

University of California San Diego Health - La Jolla

9400 Campus Point Drive, 3rd Floor, Room 3-601
San Diego, CA 92037

Contact: Nephrology, Apheresis Department
Contact Phone: 858-249-3030

University of California San Diego Health - Hillcrest

UC San Diego Medical Center
200 W Arbor Drive
Lower-Level Room L-40
San Diego, CA 92103

Contact Phone: 858-249-3030

University of California San Francisco Health - Parnassus

UCSF Infusion Center
400 Parnassus Avenue, 4th Floor, A430
San Francisco, CA 94143

Contact: Parnassus Infusion Center
Contact Phone: 415-353-2421

<https://www.ucsfhealth.org/clinics/infusion-center>

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Colorado

Mercy Regional Medical Center - Infusion Center

1010 Three Springs Boulevard
Durango, CO 81301

Contact: Durango Nephrology
Contact Phone: 970-764-3825
<http://www.mercydurango.org/MDU/Home/#>

Presbyterian/St Luke's Medical Center

1721 E 19th Avenue, 1st Floor
Denver, CO 80218

Contact: Apheresis/Infusion Services
Contact Phone: 720-754-6842
<https://healthonecares.com/locations/presbyterian-st-lukes/>

UCHealth Anschutz Cancer Pavilion - Anschutz Medical Campus

1665 Aurora Court, 3rd Floor
Aurora, CO 80045

Contact: Dermatology Clinic
Contact Phone: 720-848-0500
<https://www.uchealth.org/services/dermatology>

UCHealth Cancer Outpatient Infusion Clinic - Memorial Hospital North

4050 Briargate Parkway, Suite C1100
Colorado Springs, CO 80920

Contact: Infusion Clinic
Contact Phone: 719-364-6708
<https://www.uchealth.org/locations/uchealth-outpatient-oncology-infusion-memorial-hospital-north/>



Connecticut

Yale New Haven Hospital - Dermatology Photopheresis Unit

15 York Street
Hunter 4, Room 4097
New Haven, CT 06510

Contact: Photopheresis Unit
Contact Phone: 203-688-2595
<https://medicine.yale.edu/dermatology/patient/services/photopheresis.aspx>



Delaware

ChristianaCare - Newark

4755 Ogletown-Stanton Road
Newark, DE 19718

Contact: Infusion Services at Christiana Hospital
Contact Phone: 302-733-1549
<https://www.christianacare.org>

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Florida

AdventHealth Orlando

2501 North Orange Avenue, 8th Floor
Orlando, FL 32804

Contact: Infusion Center
Contact Phone: 407-303-5600
<https://www.adventhealth.com/hospital/adventhealth-orlando>

H. Lee Moffitt Cancer Center

12902 USF Magnolia Drive
Tampa, FL 33612

Contact: Photopheresis Department
Contact Phone: 1-888-663-3488
<https://moffitt.org/>

Mayo Clinic - Jacksonville

4500 San Pablo Road, Mayo 3-104S
Jacksonville, FL 32224

Contact: Therapeutic Apheresis Department
Contact Phone: 904-956-3312
<https://www.mayoclinic.org/departments-centers/laboratory-medicine-pathology/overview/specialty-groups/transfusion-medicine>

Memorial Hospital West

603 North Flamingo Road
Pembroke Pines, FL 33028

Contact: Memorial Cancer Institute, 3 West
Contact Phone: 954-265-4325
<https://www.mhs.net/services/cancer>

University of Florida Health - Shands Cancer Hospital

UF Health Infusion Center - Medical Plaza
1549 Gale Lemerand Drive, 2nd Floor
Gainesville, FL 32608

Contact: Adult Infusion Center
Contact Phone: 352-265-0111
<https://ufhealth.org/uf-health-infusion-center-medical-plaza>

University of Miami Hospital - UHealth Outpatient Center

1295 NW 14th Street
Miami, FL 33125

Contact Phone: 305-243-7357
<https://umiamihealth.org/locations/uhealth-outpatient-center>

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Georgia

Augusta University Medical Center

1120 15th Street
BA 3654 Apheresis Department
Augusta, GA 30912

Contact: Apheresis Department
Contact Phone: 706-721-3695

<https://www.augustahealth.org/locations/medical-center>

Emory University Hospital

Emory Healthcare Hemapheresis Department
1364 Clifton Road, NE, Suite T4L08A
Atlanta, GA 30322

Contact: Hemapheresis Department
Contact Phone: 404-712-7028

<https://www.emoryhealthcare.org/locations/hospitals/emory-university-hospital/index.html>

Northside Hospital - Atlanta Blood Services at BMT Inpatient Unit

5670 Peachtree Dunwoody Road, Suite 1075
Atlanta, GA 30342

Contact: Apheresis Department
Contact Phone: 404-459-8744

<https://www.atlantabloodservices.com/services/other-services-offered/>



Idaho

St Luke's Cancer Institute: Boise

100 E Idaho Street
Boise, ID 83712

Contact: Oncology Infusion
Contact Phone: 208-381-2711

<https://www.stlukesonline.org/communities-and-locations/facilities/clinics/st-lukes-cancer-institute--boise>



Illinois

Loyola University Medical Center

2160 S 1st Avenue
Maywood, IL 60153

Contact: Apheresis Clinic
Contact Phone: 708-216-9376

<https://loyolamedicine.org/locations/lumc>

Midwestern Regional Medical Center - Cancer Treatment Centers of America

2520 Elisha Avenue
Zion, IL 60099

Contact Phone: 847-746-9990

<https://www.cancercenter.com/locations/chicago>

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Northwestern Memorial Hospital

Rube Walker Blood Center
250 E Superior Street, 5th Floor, Suite 2322
Chicago, IL 60611

Contact: Cutaneous Lymphoma Clinic
Contact Phone: 312-926-2342

<https://www.nm.org/locations/rube-walker-blood-center>

Rush University Medical Center - Rush Cancer Center

1725 W Harrison Street
Professional Building - Suite 1010
Chicago, IL 60612

Contact: Cancer Infusion Center
Contact Phone: 312-942-5904

<https://www.rush.edu/treatments/extracorporeal-photopheresis>

The University of Chicago Hospital

5758 S Maryland Avenue
DCAM 6H
Chicago, IL 60637

Contact Phone: 773-702-0236

University of Illinois Hospital - Institute for Transfusion Medicine

1740 W Taylor Street, Suite 1106
Chicago, IL 60612 (UIH)

Contact: Hemapheresis Center
Contact Phone: 312-996-6970

<https://vitalant.org/Home.aspx#>



Indiana

Franciscan Health Indianapolis

8111 S Emerson Avenue
Indianapolis, IN 46237

Contact Phone: 317-859-5252

<https://www.franciscanhealth.org/Indy>

IU Health University Hospital

550 N University Boulevard
Indianapolis, IN 46202

Contact: Apheresis
Contact Phone: 317-944-3921

<http://iuhealth.org/university>

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Iowa

University of Iowa Hospitals & Clinics

200 Hawkins Drive
Iowa City, IA 52242

Contact: DeGowin Blood Center
Contact Phone: 319-356-2058
<https://uihc.org/degowin>



Kansas

Ascension Via Christi St. Francis

929 N St Francis Street
Wichita, KS 67214

Contact Phone: 316-268-5000

The University of Kansas Hospital

3901 Rainbow Boulevard
Kansas City, KS 66160

Contact: Blood and Marrow Transplant Program/Apheresis Department
Contact Phone: 913-588-1725
<http://www.kumed.com>



Kentucky

Norton Healthcare - Norton Children's Hospital

411 E Chestnut Street
Louisville, KY 40202

Contact: Infusion Center
Contact Phone: 502-629-6993
<https://nortonhealthcare.com/location/hospitals/>

University of Kentucky

Chandler Hospital, Pavilion H
800 Rose Street
Lexington, KY 40536

Contact: Apheresis Unit
Contact Phone: 859-323-7737
<http://ukhealthcare.uky.edu/markey-cancer-center>

University of Louisville Brown Cancer Center

529 S Jackson Street
Louisville, KY 40202

Contact: Cancer Center
Contact Phone: 502-587-5481
<http://uoflbrowncancercenter.org/>

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Louisiana

Ochsner Medical Center

1514 Jefferson Highway
Jefferson, LA 70121

Contact: Hematology/Oncology
Contact Phone: 504-842-3910
<https://www.ochsner.org/services/melanoma-and-other-skin-cancers>

Tulane Medical Center

1415 Tulane Avenue
New Orleans, LA 70112

Contact: Apheresis Clinic
Contact Phone: 504-988-3613
<https://medicine.tulane.edu/node/3311>



Maine

Northern Light Eastern Maine Medical Center - Cancer Care

33 Whiting Hill Road
Brewer, ME 04412

Contact: Photopheresis Room
Contact Phone: 207-973-7478, Ext. 1
<https://northernlighthealth.org/cancercare>



Maryland

Johns Hopkins Outpatient Center - Baltimore

601 N Caroline Street, 8th Floor
Baltimore, MD 21287

Contact: Dermatology
Contact Phone: 410-955-5933
https://www.hopkinsmedicine.org/dermatology/specialty_areas/photomedicine/photopheresis.html

University of Maryland Medical Center

22 S Greene Street, 9th Floor
Baltimore, MD 21201

Contact: Marlene and Stewart Greenebaum Comprehensive Cancer Center
Contact Phone: 410-328-7508
<http://umm.edu/programs/cancer>



Massachusetts

Beth Israel Deaconess Medical Center - Infusion and Apheresis

330 Brookline Avenue
Boston, MA 02215

Contact: Infusion Apheresis Unit
Contact Phone: 617-667-1522
<https://www.bidmc.org/centers-and-departments/infusion-services>

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Boston Medical Center

Moakley Building
830 Harrison Avenue
Boston, MA 02118

Contact: Cancer Care Center
Contact Phone: 617-638-7131

<https://www.bmc.org/visiting-us/information-desk-moakley-building>

Brigham and Women's Hospital

Jimmy Fund Building, Room 122
75 Francis Street
Boston, MA 02115

Contact: Kraft Family Blood Donor Center
Contact Phone: 617-632-3394

<https://www.dana-farber.org/cutaneous-skin-cancer-treatment-center/our-approach/>

Massachusetts General Hospital

55 Fruit Street
Boston, MA 02114

Contact: Apheresis Unit
Contact Phone: 617-726-8164

http://www.massgeneral.org/pathology/clinical/blood_transfusion.aspx

Tufts Medical Center - The Neely Cell Therapy and Collection Center

800 Washington Street
Boston, MA 02111

Contact Phone: 617-636-6453

<https://www.tuftsmedicalcenter.org/>

Michigan

Henry Ford Hospital

2799 W Grand Boulevard
Detroit, MI 48202

Contact: Dermatology Cutaneous T-cell Lymphoma Clinic
Contact Phone: 888-734-5322

<https://www.henryford.com/services/skin-cancer/treatments/cutaneous-t-cell-lymphoma>

Karmanos Cancer Institute

4100 John R. Street
Detroit, MI 48201

Contact: Apheresis Facility
Contact Phone: 313-576-929

Email: info@karmanos.org

<https://www.karmanos.org/karmanos/karmanos-cancer-institute-detroit-home>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Michigan Blood

1036 Fuller Avenue NE
Grand Rapids, MI 49503

Contact: Therapeutic Apheresis

Contact Phone: 616-233-8569

Email: info@miblood.org

<https://www.versiti.org/medical-professionals/precision-medicine-expertise>

University of Michigan Hospital

Extracorporeal Photopheresis Treatment Center
1500 E Medical Center Drive
Ann Arbor, MI 48109

Contact: Extracorporeal Photopheresis Treatment Center
Contact Phone: 734-232-8891

<https://www.uofmhealth.org/>

Minnesota

Mayo Clinic Medical Center

200 First Street SW
Rochester, MN 55905

Contact: Apheresis Unit
Contact Phone: 507-284-2536

<https://www.mayoclinic.org/departments-centers/dermatology/sections/overview/ovc-20420526>

University of Minnesota

909 Fulton Street SE
Minneapolis, MN 55455

Contact: Dermatology Clinic
Contact Phone: 612-625-5656

<https://www.fairview.org/locations/university-of-minnesota-medical-center-east-bank-hospital/university-of-minnesota-health-clinics-and-surgery-center>

Mississippi

University of Mississippi Medical Center

2500 N State Street
Jackson, MS 39216

Contact: Apheresis Lab
Contact Phone: 601-815-1589

<https://www.umc.edu/>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.



Missouri

Barnes-Jewish Hospital - Siteman Cancer Center

Washington University Medical Center
4921 Parkview Place, 4th Floor, CAM, Suite 4E
St Louis, MO 63110

Contact: Apheresis Lab
Contact Phone: 314-454-8445
<https://siteman.wustl.edu>

Saint Louis University Cancer Center Saint Louis University Hospital - West Pavilion

3655 Vista Avenue
St Louis, MO 63110

Contact: Apheresis
Contact Phone: 314-577-8883
<https://www.ssmhealth.com/locations/saint-louis-university-hospital>

University of Missouri - Dermatology Center

1020 Hitt Street, 2nd Floor
Columbia, MO 65212

Contact Phone: 573-882-4800
<https://www.muhealth.org/conditions-treatments/dermatology>



Nebraska

American Red Cross - Nebraska & Southwest Iowa Region

3838 Dewey Avenue
Omaha, NE 68105

Contact: Apheresis Clinical Services
Contact Phone: 402-341-2723
<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>



Nevada

Vitalant (formerly United Blood Services)

6930 W Charleston Boulevard
Las Vegas, NV 89117

Contact Phone: 702-228-1111
<https://hospitals.vitalant.org/Products-Services/Clinical-Apheresis.aspx>



New Hampshire

Dartmouth-Hitchcock Medical Center

1 Medical Center Drive
Lebanon, NH 03756

Contact: Blood Donor Program
Contact Phone: 603-653-3775
<https://www.dartmouth-hitchcock.org/blood-donor-program.html>

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New Jersey

John Theurer Cancer Center at Hackensack University Medical Center

92 Second Street
Hackensack, NJ 07601

Contact: Apheresis Department
Contact Phone: 551-996-8326
<https://www.hackensackumc.org/services/cancer-care/>

Morristown Medical Center

100 Madison Avenue
Morristown, NJ 07960

Contact: Photopheresis Center
Contact Phone: 973-971-4192
<http://www.atlantichealth.org/morristown/our+services/photopheresis+center>

Robert Wood Johnson University Hospital - Clinical Academic Building

125 Paterson Street, 3rd Floor
New Brunswick, NJ 08901

Contact Phone: 732-235-8100, Ext. 225
<http://www.rwjuh.edu/rwjuh/therapeutic-apheresis.aspx>



New Mexico

Presbyterian Infusion Center and Apheresis Services

201 Cedar Avenue SE, Suite 4620
Albuquerque, NM 87106

Contact: Infusion Services
Contact Phone: 505-563-1309
<https://www.phs.org/doctors-services/services-centers/Pages/infusion-center.aspx>



New York

Memorial Sloan Kettering Cancer Center - Blood Donor Room

1250 First Avenue
New York, NY 10065

Contact Phone: 212-639-6178
<https://www.mskcc.org/cancer-care/patient-education/frequently-asked-questions-about-photopheresis>

Montefiore Medical Center

111 East 210th Street, Rosenthal SE, 2nd Floor
Bronx, NY 1046

Contact: Transfusion Medicine
Contact Phone: 718-920-4810
<http://www.montefiore.org/pathology-services-clinical>

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Mount Sinai Hospital

1468 Madison Avenue, Annenberg Building, 3rd Floor
New York, NY 10029

Contact: Apheresis Center
Contact Phone: 212-241-6104 or 212-241-2973
<https://icahn.mssm.edu/about/departments/pathology/clinical/transfusion-cellular>

New York Presbyterian Columbia

Harkness Building
180 Fort Washington Avenue, 4th Floor, Room 424
New York, NY 10032

Contact: Division of Transfusion Medicine and Cellular Therapy
Contact Phone: 212-305-4448
<https://www.pathology.columbia.edu/diagnostic-specialties/laboratory-medicine-division/transfusion-medicine-and-cellular-therapy>

Northwell Health

300 Community Drive, Apheresis Center Basement
Manhasset, NY 11030

Contact: Department of Dermatology
Contact Phone: 516-562-2368

Perlmutter Cancer Center - Langone Medical Center

160 East 34th Street
New York, NY 10016

Contact Phone: 212-731-6000
<http://nyulangone.org/conditions/cutaneous-t-cell-lymphoma-in-adults/treatments/photopheresis-for-cutaneous-t-cell-lymphoma>

Roswell Park Cancer Institute

Elm and Carlton Streets
Buffalo, NY 14263

Contact: Therapeutic Apheresis Unit
Contact Phone: 716-845-2385
<https://www.roswellpark.org>

Stony Brook University Hospital Cancer Center

101 Nicolls Road
Blood Bank Level 5, Suite 5000
Stony Brook, NY 11794

Contact Phone: 631-444-2634
<https://cancer.stonybrookmedicine.edu>

University of Rochester

601 Elmwood Avenue
Rochester, NY 1464

Contact: Wilmot Cancer Institute
Contact Phone: 585-275-7447
<https://www.urmc.rochester.edu/cancer-institute.aspx>

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Upstate University Hospital

750 E Adams Street
Syracuse, NY 13210

Contact Phone: 315-464-5540
<http://www.upstate.edu/nursing/units/downtown/apheresis10i.php>

Westchester Medical Center - Cancer Center

19 Bradhurst Avenue, Suite 2300
Hawthorne, NY 10532

Contact: Outpatient Infusion Center
Contact Phone: 914-493-2220
<http://www.wcmc.com/wmc/medical-services/408.aspx>



North Carolina

Atrium Health - Levine Cancer Institute

1021 Morehead Medical Drive
Charlotte, NC 28204

Contact Phone: 980-442-3830
<https://atriumhealth.org/medical-services/specialty-care/cancer-care/hematology-oncology-blood-disorders/transplant-cell-therapy>

Duke Blood and Marrow Transplant Clinic

2400 Pratt Street
Durham, NC 27705

Contact: Division of Hematologic Malignancies & Cellular Therapy
Contact Phone: 919-668-4360
<https://www.dukehealth.org/locations/duke-adult-blood-and-marrow-transplant-clinic>

UNC Health

101 Manning Drive
Chapel Hill, NC 27514

Contact: Transfusion Medicine/Blood Bank
Contact Phone: 919-966-4011
<https://www.unhealthcare.org/>

Wake Forest Baptist Health

Wake Forest Baptist Medical Center Comprehensive Cancer Center 3rd Floor
1 Medical Center Drive
Winston Salem, NC 27157

Contact: Apheresis Unit
Contact Phone: 336-713-5475
<https://www.wakehealth.edu/Locations/Clinics/a/Apheresis-Cancer-Center>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.



Ohio

Cleveland Clinic

Taussig Cancer Center, CA2
9500 Euclid Avenue
Cleveland, OH 44195

Contact: Apheresis
Contact Phone: 216-444-2633
<https://my.clevelandclinic.org/health/treatments/10252-photopheresis>

The Jewish Hospital - Mercy Health

4777 E Galbraith Road
Cincinnati, OH 45236

Contact: Outpatient Infusion Center
Contact Phone: 513-686-5260
<https://www.mercy.com/locations/hospitals/cincinnati/the-jewish-hospital-mercy-health>

The Ohio State University Comprehensive Cancer Center - The James

460 West 10th Avenue
Columbus, OH 43210

Contact: Apheresis Department, 1st Floor
Contact Phone: 614-293-8672
<https://cancer.osu.edu/cancer-specialties/cancer-care-and-treatment/cutaneous-lymphoma>

University Hospitals Seidman Cancer Center

1100 Euclid Avenue
Cleveland, OH 44106

Contact: Dermatology Services
Contact Phone: 216-539-1059
<https://www.uhhospitals.org/services/dermatology-services/conditions-and-treatments/skin-cancer-and-screenings>

University of Cincinnati Hoxworth Blood Center

3130 Highland Avenue
Cincinnati, OH 45267

Contact: Therapeutic Apheresis
Contact Phone: 513-558-1010 or 513-558-1333
<https://hoxworth.org/patient-services/photopheresis.html>



Oklahoma

Oklahoma Blood Institute

1001 N Lincoln Boulevard
Oklahoma City, OK 73104

Contact Phone: 405-297-5800
<https://obi.org/about-us/therapeutic-apheresis>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.



Oregon

American Red Cross Cascades Region

3131 N Vancouver Avenue
Portland, OR 97227

Contact Phone: 503-284-1234
<http://www.redcross.org/local/oregon>

Oregon Health & Science University

3181 SW Sam Jackson Park Road
Portland, OR 97239

Contact: Apheresis Department
Contact Phone: 503-494-0526
<https://www.ohsu.edu>



Pennsylvania

Allegheny Health Network

4800 Friendship Avenue
Pittsburgh, PA 15224

Contact: West Penn Hospital
Contact Phone: 412-578-1210
<https://www.ahn.org/cancer-institute/leukemia-lymphoma>

American Red Cross Penn Jersey Region

700 Spring Garden Street
Philadelphia, PA 19123

Contact Phone: 866-805-3500
<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

Geisinger Health System

100 Academy Avenue
Danville, PA 17822

Contact: Apheresis Clinic
Contact Phone: 570-271-8959
<https://www.geisinger.org/patient-care/find-a-location/geisinger-medical-center>

Geisinger Wyoming Valley Medical Center

1000 E Mountain Boulevard
Wilkes-Barre, PA 18702

Contact: Apheresis Clinic
Contact Phone: 570-808-7415
<https://www.geisinger.org/patient-care/find-a-location/geisinger-wyoming-valley-medical-center#>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Hospital of the University of Pennsylvania

3400 Civic Center Boulevard
West Pavilion, 2nd Floor
Philadelphia, PA 19104

Contact: Dermatology Department
Contact Phone: 215-662-7610

<https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/dermatology/photopheresis>

Temple University Hospital - Jeanes Campus

7600 Central Avenue
Philadelphia, PA 19111

Contact: Bone Marrow Transplant Outpatient
Contact Phone: 215-214-3100

<http://www.jeanes.com/content/default.htm>

Thomas Jefferson University Hospital

Therapeutic Apheresis Department
111 S 11th Street
Room 8230, Gibbon Building
Philadelphia, PA 19107

Contact Phone: 215-955-8911

University of Pittsburgh Medical Center PUH

Department of Dermatology
3459 Fifth Avenue, Unit 6 North East
Pittsburgh, PA 15232

Contact: Photopheresis
Contact Phone: 412-864-3681 or 412-648-6530

<http://dermatology.pitt.edu/centers-excellence>

Vitalant - Philadelphia

Philadelphia, PA

Contact: Clinical Apheresis Programs East of the Mississippi/Philadelphia
Contact Phone: 1-877-35-VITAL

<https://hospitals.vitalant.org/Products-Services/Clinical-Apheresis.aspx>

Vitalant - Pittsburgh

Pittsburgh, PA

Contact: Clinical Apheresis Programs East of the Mississippi/Pittsburgh
Contact Phone: 1-877-35-VITAL

<https://hospitals.vitalant.org/Products-Services/Clinical-Apheresis.aspx>



Rhode Island

Roger Williams Medical Center

Cancer Center
50 Maude Street
Providence, RI 02908

Contact: Outpatient Infusion Center
Contact Phone: 401-456-6404

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.



South Carolina

American Red Cross - South Carolina Region

Trident Medical Center
9330 Medical Plaza Drive North
Charleston, SC 29406

Contact: Apheresis Department
Contact Phone: 803-394-6005

<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

Bon Secours St. Francis Health System - Cancer Center

104 Innovation Drive
Greenville, SC 29607

Contact: Infusion Services
Contact Phone: 864-603-6200

<http://stfranciscancercenter.org/services/treatments/infusion-services>

Medical University of South Carolina

165 Ashley Ave, Suite EH870
Charleston, SC 29425

Contact: Hemapheresis Unit
Contact Phone: 843-792-4389

<https://web.musc.edu/>

Prisma Health - Greenville Memorial Hospital

Cancer Center, 2nd Floor
701 Grove Road
Greenville, SC 29605

Contact: Apheresis Department
Contact Phone: 864-455-5592

<https://prismahealth.org/hospitals/prisma-health-greenville-memorial-hospital>



South Dakota

Avera McKennan Hospital & University Health Center

1325 S Cliff Avenue
Sioux Falls, SD 57105

Contact: Hospital Infusion Center
Contact Phone: 605-322-8509

<http://www.avera.org/services/cancer-care>



Tennessee

Methodist Le Bonheur Healthcare - Methodist University Hospital

1265 Union Avenue, Shorb Tower, 2nd Floor
Memphis, TN 38104

Contact: Medical Oncology and Infusion Clinic
Contact Phone: 901-516-7000

<https://www.methodisthealth.org/locations/medical-oncology-infusion-clinic>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

TriStar Centennial Medical Center

Sarah Cannon Center for Blood Cancer
2410 Patterson Street, 5th Floor
Nashville, TN 37203

Contact: Oncology Services
Contact Phone: 615-342-7449 or 615-342-7457
<http://tristarcentennial.com/service/cancer-care>

Vanderbilt University Medical Center

The Vanderbilt Clinic, Room 2512A
1301 Medical Center Drive
Nashville, TN 37232

Contact: Apheresis/Photopheresis
Contact Phone: 615-322-9390
<https://www.vumc.org/pmi/transfusion-medicine-apheresis>

VA Tennessee Valley Healthcare System

1310 24th Avenue South
Nashville, TN 37212

Contact: Photopheresis
Contact Phone: 615-873-7353
<http://www.va.gov/directory/guide/facility.asp?id=95>



Texas

Baylor University Medical Center - T. Boone Pickens Cancer Hospital

Apheresis Unit, Suite 1030
3535 Worth Street
Dallas, TX 75246

Contact: Apheresis
Contact Phone: 214-865-1040
<https://www.bswhealth.com/locations/dallas/specialties/cancer-care/>

Carter BloodCare

5550 LBJ Freeway, Suite 350
Dallas, TX 75240

Contact: Clinical Apheresis Department
Contact Phone: 972-788-0650
<http://www.carterbloodcare.org>

Medical City Dallas Hospital

7777 Forest Lane
Dallas, TX 75230

Contact: Apheresis Unit
Contact Phone: 972-566-6755
<https://medicalcityhospital.com/hl/?/19881/Other-treatments>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Methodist Hospital of San Antonio

7700 Floyd Curl Drive
San Antonio, TX 78229

Contact: Apheresis Unit
Contact Phone: 972-566-6755
<https://sahealth.com/locations/methodist-hospital/>

Parkland

5201 Harry Hines Boulevard, 2nd Floor
Dallas, TX 75235

Contact: Oncology and Infusion Clinic
Contact Phone: 214-590-5582
<https://www.parklandhospital.com/locations/apheresis-179>

St. David's South Austin Medical Center

901 W Ben White Boulevard
Austin, TX 78704

Contact: Cancer Care Clinic
Contact Phone: 512-816-8611
<https://stdavids.com/locations/st-davids-south-austin-medical-center/>

The University of Texas Southwestern Medical Center

5939 Harry Hines Boulevard, 4th Floor, Suite 100
Dallas, TX 75390

Contact: Dermatology Clinic
Contact Phone: 214-645-2400
<https://utswmed.org/conditions-treatments/phototherapy/>

University of Texas MD Anderson Cancer Center

1515 Holcombe Boulevard
Houston, TX 77030

Contact: Apheresis
Contact Phone: 713-792-6404
<https://www.mdanderson.org/about-md-anderson/our-locations/texas-medical-center.html>



Utah

American Red Cross - Salt Lake Blood Donation Center

6616 South 900 East
Salt Lake City, UT 84121

Contact Phone: 801-892-4001
<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

Huntsman Cancer Institute

1950 Circle of Hope
Salt Lake City, UT 84112

Contact: Blood and Marrow Transplant Program
Contact Phone: 801-587-4652
<http://healthcare.utah.edu/huntsmancancerinstitute/patient-care/clinics-and-care-teams/blood-and-marrow-transplant/about-us>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.



Virginia

Inova Fairfax Hospital

3300 Gallows Road
Falls Church, VA 22042

Contact: Apheresis
Contact Phone: 703-776-2610
<https://www.inova.org/locations/inova-fairfax-medical-campus>

UVA Health - Emily Couric Clinical Cancer Center

1240 Lee Street, Room 4312, Pod 42-45
Charlottesville, VA 22903

Contact: Apheresis Department
Contact Phone: 434-243-6818
<https://uvahealth.com/locations/profile/emily-couric-clinical-cancer-center>

VCU Health - Main Hospital

Room 4800, 4th Floor Main
1250 E Marshall Street
Richmond, VA 23298

Contact: Apheresis Unit
Contact Phone: 804-828-0093
<https://maps.vcu.edu/mcv/mainhospital/>



Washington

Seattle Cancer Care Alliance

825 Eastlake Avenue E
Seattle, WA 98109

Contact Phone: 206-606-1024
<http://www.seattlecca.org/diseases-treatments.cfm>

Vitalant - Spokane

210 W Cataldo Avenue
Spokane, WA 99201

Contact: Clinical Apheresis West of the Mississippi/Washington
Contact Phone: 877-35-VITAL
<https://hospitals.vitalant.org/Products-Services/Clinical-Apheresis.aspx>



Washington, D C

MedStar Georgetown University Hospital

3800 Reservoir Road NW
Washington, DC 20007

Contact: Apheresis Department
Contact Phone: 202-444-3667
<https://www.medstargeorgetown.org/>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.



West Virginia

West Virginia University Cancer Institute - Mary Babb Randolph Cancer Center

1 Medical Center Drive
Morgantown, WV 26506

Contact Phone: 304-598-4500
<http://www.wvucancer.org>



Wisconsin

Froedtert & Medical College of Wisconsin - Froedtert Hospital

9200 W Wisconsin Avenue
Milwaukee, WI 53226

Contact: Apheresis Service
Contact Phone: 414-805-3000
<https://www.mcw.edu/departments/pathology-and-laboratory-medicine/patient-care/clinical-pathology/transfusion-services>

University of Wisconsin Hospital

600 Highland Avenue
Madison, WI 53792

Contact: Infusion Center
Contact Phone: 608-263-8369
<http://www.uwhealth.org/infusion-center/12230>

Versiti Blood Center of Wisconsin

638 North 18th Street
Milwaukee, WI 53233

Contact: Therapeutic Apheresis
Contact Phone: 414-937-6154
<https://www.versiti.org/ways-to-give/blood-donation/locations/milwaukee>



Canada

CancerCare Manitoba - MacCharles

675 McDermot Avenue
Winnipeg, MB R3E 0V9

Contact: Chemotherapy Department
Contact Phone: 204-787-2197
<http://www.cancercare.mb.ca/home>

Foothills Medical Centre

Special Services Building, Room 4748
1403 29 Street NW
Calgary, AB T2N 2T9

Contact: Apheresis Clinic
Contact Phone: 403-944-4712
<http://www.albertahealthservices.ca/fmc/fmc.aspx>

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Hôpital du Saint-Sacrement

1050 Ch Ste-Foy
Ville de Québec, QC G1S 4L8

Contact Phone: 418-649-0252, Ext. 87790
<http://www.chudequebec.ca/centre-hospitaliers/hopital-du-saint-sacrement.aspx>

Hôpital Maisonneuve - Rosemont

5415, boulevard de l'Assomption
Montréal, QC H1T 2M4

Contact: Apheresis Department
Contact Phone: 514-252-3400, Ext. 6589
<https://ciusss-estmtl.gouv.qc.ca/etablissement/hopital-maisonneuve-rosemont>

Royal University Hospital

103 Hospital Drive
Saskatoon, SK S7N 0W8

Contact: Apheresis Unit
Contact Phone: 306-655-2522
<https://www.saskatoonhealthregion.ca/patients/Pages/Outpatient-Care.aspx>

Royal Victoria Hospital - McGill University Health Centre

1001 Boulevard Décarie
Montréal, QC H4A 3J1

Contact: Apheresis Department
Contact Phone: 514-934-1934
<https://muhc.ca/>

The Ottawa Hospital - General Campus

501 Smyth Road
Weekdays: 7th Floor, Room 7410
Weekends: 5th Floor, Medical Day Care Unit West
Ottawa, ON K1H 8L6

Contact: Apheresis Program
Contact Phone: 613-798-5555, Ext. 73552
<http://www.ottawahospital.on.ca/en>

University Health Network - Toronto General Hospital Princess Margaret Cancer Centre

Peter Munk Building
610 University Avenue, 12th Floor
Toronto, ON M5G 2M9

Contact: Apheresis/Photopheresis Unit
Contact Phone: 416-340-3999
<https://www.uhn.ca/PrincessMargaret/Clinics/Apheresis>

Vancouver General Hospital - Leon Blackmore Pavilion

855 12th Avenue W
Vancouver, BC V5Z 1M9

Contact: Apheresis Unit
Contact Phone: 604-875-4626
http://www.vch.ca/Locations-Services/result?res_id=644

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Notes:

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

INDICATIONS AND USAGE

UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® CELLEX® Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

IMPORTANT SAFETY INFORMATION

CAUTION: READ THE THERAKOS CELLEX PHOTOPHERESIS SYSTEM'S OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

UVADEX (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the THERAKOS CELLEX Photopheresis System. Please consult the CELLEX Operator's Manual before using this product.

CONTRAINDICATIONS

UVADEX is contraindicated in:

- Patients exhibiting idiosyncratic or hypersensitivity reactions to methoxsalen, other psoralen compounds, or any of the excipients
- Patients possessing a specific history of a light-sensitive disease state, including lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism
- Patients with aphakia because of significantly increased risk of retinal damage
- Patients that have contraindications to the photopheresis procedure

WARNINGS AND PRECAUTIONS

- Patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents such as anthralin, coal tar or coal tar derivatives, griseofulvin, phenothiazines, nalidixic acid, halogenated salicylanilides (bacteriostatic soaps), sulfonamides, tetracyclines, thiazides, and certain organic staining dyes such as methylene blue, toluidine blue, rose bengal, and methyl orange may be at greater risk for photosensitivity reactions with UVADEX
- Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. Methoxsalen also causes DNA damage, interstrand cross-links and errors in DNA repair
- Methoxsalen may cause fetal harm when given to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant. If UVADEX is used during pregnancy, or if the patient becomes pregnant while receiving UVADEX, the patient should be apprised of the potential hazard to the fetus
- Severe photosensitivity can occur in patients treated with UVADEX. Advise patients to wear UVA absorbing, wrap-around sunglasses and cover exposed skin or use a sunblock (SPF 15 or higher), and avoid all exposure to sunlight for twenty-four (24) hours following photopheresis treatment
- After methoxsalen administration, exposure to sunlight and/or ultraviolet radiation may result in "premature aging" of the skin
- Since oral psoralens may increase the risk of skin cancers, monitor closely those patients who exhibit multiple basal cell carcinomas or who have a history of basal cell carcinomas
- Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of methoxsalen is exceeded or precautions are not followed
- Exposure to large doses of UVA light causes cataracts in animals. Oral methoxsalen exacerbates this toxicity
- Safety in children has not been established
- Thromboembolic events, such as pulmonary embolism and deep vein thrombosis, have been reported with UVADEX administration through photopheresis systems for treatment of patients with graft-versus-host disease, a disease for which UVADEX is not approved

Please see attached full Prescribing Information.

ADVERSE REACTIONS

- Side effects of photopheresis (UVADEX used with THERAKOS Photopheresis Systems) were primarily related to hypotension secondary to changes in extracorporeal volume (>1%)

For the THERAKOS® CELLEX® Photopheresis Procedure: INDICATIONS

The THERAKOS CELLEX Photopheresis System is indicated for use in the ultraviolet-A (UVA) irradiation, in the presence of the photoactive drug 8-methoxypsoralen (8-MOP®), of extracorporeally circulating leukocyte-enriched blood, in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL), in persons who have not been responsive to other forms of treatment.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

The THERAKOS CELLEX Photopheresis System is not designated, sold, or intended for use except as indicated. Certain underlying medical conditions contraindicate THERAKOS Photopheresis, including patients:

- who cannot tolerate extracorporeal volume loss during the leukocyte-enrichment phase
- exhibiting idiosyncratic or hypersensitivity reactions to 8-methoxypsoralen/psoralen compounds
- with coagulation disorders
- who have had previous splenectomy

WARNINGS AND PRECAUTIONS

- THERAKOS Photopheresis treatments should always be performed in locations where standard medical emergency equipment is available. Volume replacement fluids and/or volume expanders should be readily available throughout the procedure
- Patients who may not be able to tolerate the fluid changes associated with extracorporeal photopheresis should be monitored carefully
- Procedures, such as renal dialysis, which might cause significant fluid changes (and expose the patient to additional anticoagulation) should not be performed on the same day as extracorporeal photopheresis
- Individual patients may require a heparin dosage that varies from the recommended dose to prevent post-treatment bleeding or clotting during a treatment

ADVERSE REACTIONS

- Hypotension may occur during any treatment involving extracorporeal circulation. Closely monitor the patient during the entire treatment for hypotension
- Transient pyretic reactions, 37.7-38.9°C (100-102°F), have been observed in some patients within six to eight hours of reinfusion of the photoactivated leukocyte-enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction
- Treatment frequency exceeding labeling recommendations may result in anemia
- Venous access carries a small risk of infection and pain

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the THERAKOS Photopheresis System Operator's Manual.

Please see attached full Prescribing Information.



For more information, please contact a
Mallinckrodt Customer Service
Representative
by calling 1-877-566-9466, available
24 hours a day, 7 days a week.

For patients, please consult your
healthcare provider for more information.

Please see Important Safety Information on pages 30-31 and
attached full Prescribing Information.

UVADEX®

(Methoxsalen)

STERILE SOLUTION, 20 mcg/mL

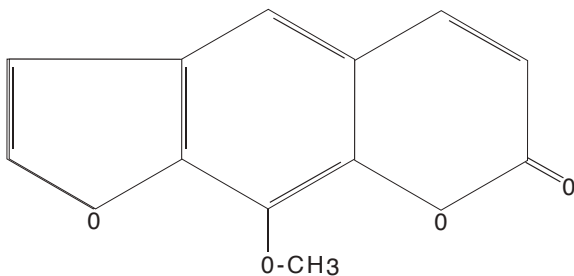
Rx ONLY.

CAUTION: READ THE THERAKOS® CELLEX® PHOTOPHERESIS SYSTEM OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

UVADEX® (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the THERAKOS® CELLEX® Photopheresis System. Please consult the CELLEX® Operator's Manual before using this product.

DESCRIPTION

Methoxsalen is a naturally occurring photoactive substance found in the seeds of the Ammi majus (Umbelliferae) plant. It belongs to a group of compounds known as psoralens or furocoumarins. The chemical name of methoxsalen is 9-methoxy-7H-furo[3,2-g][1]-benzopyran-7-one; it has the following structure:



Each mL of UVADEX® (methoxsalen, 8-methoxypsoralen) Sterile Solution contains methoxsalen 20 mcg, propylene glycol 50 mg, sodium chloride 8 mg, sodium acetate 1.75 mg, ethanol 40.550 mg, glacial acetic acid 1.260 mg, and Water for Injection q.s. to 1.0 mL. Glacial acetic acid and sodium hydroxide are used to adjust the pH of the solution if necessary. UVADEX® is a clear, colorless to pale yellow liquid.

UVADEX® is used in combination with the THERAKOS® CELLEX® Photopheresis System to extracorporeally treat leukocyte enriched buffy coat.

CLINICAL PHARMACOLOGY

Mechanism of action

The exact mechanism of action of methoxsalen is not known. The best-known biochemical reaction of methoxsalen is with DNA. Methoxsalen, upon photoactivation, conjugates and forms covalent bonds with DNA which leads to the formation of both monofunctional (addition to a single strand of DNA) and bifunctional adducts (crosslinking of psoralen to both strands of DNA). Reactions with proteins have also been described. The formation of photoadducts results in inhibition of DNA synthesis, cell division and epidermal turnover.

For the palliative treatment of Cutaneous T-Cell Lymphoma, Photopheresis consists of removing a portion of the patient's blood and separating the red blood cells from the white cell layer (buffy coat) by centrifugation. The red cells are returned to the patient and the UVADEX® Sterile Solution is then injected into the instrument and mixed with the buffy coat. The instrument then irradiates this drug-cell mixture with ultraviolet light (UVA light, 320–400 nm) and returns the treated cells to the patient. See the appropriate Operator's Manual for details of this process. Although extracorporeal phototherapy exposes less than 10% of the total body burden of malignant cells to methoxsalen plus light, some patients achieve a complete response. Animal studies suggest that the photopheresis may activate an immune-mediated response against the malignant T-cells.

Use of the THERAKOS® UVAR and UVAR XTS® Photopheresis Systems after oral administration of methoxsalen were previously approved for the treatment of Cutaneous T-Cell Lymphoma. Interpatient variability in peak plasma concentration after an oral dose of methoxsalen ranges from 6 to 15 fold. UVADEX® is injected directly into the separated buffy coat in the instrument in an attempt to diminish this interpatient variability and to improve the exposure of the cells to the drug.

Methoxsalen is reversibly bound to serum albumin and is also preferentially taken up by epidermal cells. Methoxsalen is rapidly metabolized in humans, with approximately 95% of the drug excreted as metabolites in the urine within 24 hours.

Systemic administration of methoxsalen followed by UVA exposure leads to cell injury. The most obvious manifestation of this injury after skin exposure is delayed erythema, which may not begin for several hours and peaks at 48–72 hours. The inflammation is followed over several days to weeks, by repair which is manifested by increased melanization of the epidermis and thickening of the stratum corneum.

The total dose of methoxsalen delivered in UVADEX® is substantially lower (approximately 200 times) than that used with oral administration. More than 80% of blood samples collected 30 minutes after reinfusion of the photoactivated buffy coat had methoxsalen levels below detection limits of the assay (<10 ng/ml), and the mean plasma methoxsalen concentration was approximately 25 ng/ml.

CLINICAL STUDIES

Three single-arm studies were performed to evaluate the effectiveness of photopheresis in the treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL). In the first study (CTCL 1), 39 patients were treated with the oral formulation of methoxsalen in conjunction with the UVAR Photopheresis System. The second study (CTCL 2) was a 5-year post approval follow-up of 57 CTCL patients that was conducted to evaluate long-term safety. This study also used the oral dosage formulation of methoxsalen. In the third study (CTCL 3), 51 patients were treated with the UVADEX® formulation of methoxsalen in conjunction with the UVAR Photopheresis System. In study CTCL 3, 86% of the patients were Caucasian, the median age was 62 years, and the average number of prior therapies was 4.3.

In study CTCL 1, prednisone up to 10 mg/day was permitted in addition to topical steroids. In CTCL 2, there was no concomitant medication restriction. In CTCL 3, topical steroids were permitted only for the treatment of fissures on the soles of the feet and the palms of hands. All other steroids, topical or systemic, were prohibited.

In all three studies, patients were initially treated on two consecutive days every four to five weeks. If the patient did not respond after four cycles, treatment was accelerated to two consecutive days every other week. If the patient did not respond after four cycles at the accelerated schedule, the patient was treated on two consecutive days every week. If the patient still did not respond after four cycles of weekly treatments, the schedule was increased to three consecutive days every week for three cycles. In study CTCL 3, 15 of the 17 responses were seen within six months of treatment. Only two patients responded to treatment after six months. Clinical experience does not extend beyond this treatment frequency and there is no evidence to show that treatment with UVADEX® beyond six months or using a different schedule provided additional benefit.

Overall skin scores were used in the clinical studies of photopheresis to assess the patient's response to treatment. The patient's baseline skin score was used for comparison with subsequent scores. A 25% reduction in skin score maintained for four consecutive weeks was considered a successful response to photopheresis therapy. Table 1 indicates the percent of successful

responses within six months of beginning therapy for all patients who received at least one course of photopheresis. Only patients with patch plaque, extensive plaque and erythrodermic disease were enrolled in these studies. No patients with disease in the tumor phase were treated. There are no data available regarding the efficacy of UVADEX® in patients with disease in the tumor phase.

Table 1: Percentage of Successful Responses Within Six Months of Beginning Therapy

Study	Response % Within Six Months
CTCL 3 (UVADEX®)	17/51 (33)
CTCL 2 (oral methoxsalen)	16/57 (28)
CTCL 1 (oral methoxsalen)	21/39 (54)

Although the response rate with UVADEX® in CTCL 3 was similar to with oral methoxsalen in CTCL 2, the possibility that UVADEX® is inferior in efficacy to oral methoxsalen cannot be excluded due to the design and size of the clinical trials. The higher response rate with oral methoxsalen in CTCL 1 may be partly due to patients receiving more treatments (mean of 64 in CTCL 1, 31 in CTCL 2, and 20 in CTCL 3), and to the administration of systemic steroids in CTCL 1.

Retrospective analyses of three clinical benefit parameters from the Body Area Severity Scores in CTCL 3 suggested a correlation between skin score response and improvement in edema, scaling and resolution of fissures.

INDICATIONS AND USAGE

UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® CELLEX® Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

CONTRAINDICATIONS

- UVADEX® (methoxsalen) Sterile Solution is contraindicated in patients exhibiting idiosyncratic or hypersensitivity reactions to methoxsalen, other psoralen compounds or any of the excipients. Patients possessing a specific history of a light sensitive disease state should not initiate methoxsalen therapy. Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum and albinism.
- UVADEX® Sterile Solution is contraindicated in patients with aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses.
- Patients should not receive UVADEX® if they have any contraindications to the photopheresis procedure.

WARNINGS

Concomitant Therapy

Patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents such as anthralin, coal tar or coal tar derivatives, griseofulvin, phenothiazines, nalidixic acid, halogenated salicylanilides (bacteriostatic soaps), sulfonamides, tetracyclines, thiazides, and certain organic staining dyes such as methylene blue, toluidine blue, rose bengal and methyl orange may be at greater risk for photosensitivity reactions with UVADEX®.

Carcinogenicity, Mutagenesis, Impairment of Fertility

Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. In a prospective study of 1380 patients given PUVA therapy for psoriasis, 237 patients developed 1422 cutaneous squamous cell cancers. This observed incidence of cutaneous carcinoma is 17.6 times that expected for the general population. Previous cutaneous exposure to tar and UVB treatment, ionizing radiation or arsenic increased the risk of developing skin carcinomas after PUVA therapy. Because the dose of methoxsalen with UVADEX® therapy is about 200 times less than with PUVA and the skin is not exposed to high cumulative doses of UVA light, the risk of developing skin cancer following UVADEX® therapy may be lower.

Methoxsalen was carcinogenic in male rats that were given the drug by oral gavage five days per week for 103 weeks at doses of 37.5 and 75 mg/kg. The 37.5 mg/kg dose is about 1900 times greater than a single human methoxsalen dose during extracorporeal photopheresis treatment on a body surface area basis. The neoplastic lesions in rats included adenomas and adenocarcinomas of the tubular epithelium of the kidneys, carcinoma or squamous cell carcinoma of the Zymbal gland and alveolar or bronchiolar adenomas. Topical or intraperitoneal methoxsalen is a potent photo-carcinogen in albino mice and hairless mice.

With S9 activation, methoxsalen is mutagenic in the Ames test. In the absence of S9 activation and UV light, methoxsalen is clastogenic in vitro (sister chromatid exchange and chromosome aberrations in Chinese hamster ovary cells). Methoxsalen also causes DNA damage, interstrand cross-links and errors in DNA repair.

Pregnancy

Methoxsalen may cause fetal harm when given to a pregnant woman. Doses of 80 to 160 mg/kg/day given during organogenesis caused significant fetal toxicity in rats. The lowest of these doses, 80 mg/kg/day, is over 4000 times greater than a single dose of UVADEX® on a mg/m² basis. Fetal toxicity was associated with significant maternal weight loss, anorexia and increased relative liver weight. Signs of fetal toxicity included increased fetal mortality, increased resorptions, late fetal death, fewer

fetuses per litter, and decreased fetal weight. Methoxsalen caused an increase in skeletal malformation and variations at doses of 80 mg/kg/day and above. There are no adequate and well-controlled studies of methoxsalen in pregnant women. If UVADEX® is used during pregnancy, or if the patient becomes pregnant while receiving UVADEX®, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

Photosensitivity

Severe photosensitivity can occur in patients treated with UVADEX®. Advise patients to wear UVA absorbing, wrap-around sunglasses and cover exposed skin or use a sunblock (SP 15 or higher), and avoid all exposure to sunlight for twenty-four (24) hours following photopheresis treatment. See **Precautions** section for additional information.

PRECAUTIONS

General

ACTINIC DEGENERATION

After methoxsalen administration, exposure to sunlight and/or ultraviolet radiation may result in "premature aging" of the skin.

BASAL CELL CARCINOMAS

Since oral psoralens may increase the risk of skin cancers, monitor closely those patients who exhibit multiple basal cell carcinomas or who have a history of basal cell carcinomas.

SERIOUS SKIN BURNS

Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of methoxsalen is exceeded or precautions are not followed. Advise patients to avoid all exposure to sunlight during the 24 hours following photopheresis treatment.

CATARACT FORMATION

Exposure to large doses of UVA light causes cataracts in animals. Oral methoxsalen exacerbates this toxicity. The concentration of methoxsalen in the human lens is proportional to the concentration in serum. Serum methoxsalen concentrations are substantially lower after extracorporeal UVADEX® treatment than after oral methoxsalen treatment. Nevertheless, if the lens is exposed to UVA light while methoxsalen is present, photoactivation of the drug may cause adducts to bind to biomolecules within the lens. If the lens is shielded from UVA light, the methoxsalen will diffuse out of the lens in about 24 hours.

Patients who use proper eye protection after PUVA therapy (oral methoxsalen) appear to have no increased risk of developing cataracts. The incidence of cataracts in these patients five years after their first treatment is about the same as that in the general population.

Instruct patients emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after UVADEX[®] treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window.

VENOUS AND ARTERIAL THROMBOEMBOLISM

Thromboembolic events, such as pulmonary embolism and deep vein thrombosis, have been reported with UVADEX[®] administration through photopheresis systems for treatment of patients with graft-versus-host disease, a disease for which UVADEX[®] is not approved.

Information for Patients

Patients should be told emphatically to wear UVA-absorbing, wrap-around sunglasses and cover exposed skin or use a sunblock (SP 15 or higher) for the twenty-four (24) hour period following treatment with methoxsalen, whether exposed to direct or indirect sunlight in the open or through a window glass.

Drug Interactions

See **Warnings** Section.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

See **Warnings** Section.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methoxsalen is administered to a nursing woman.

Pediatric Use

Safety in children has not been established. Potential hazards of long-term therapy include the possibilities of carcinogenicity and cataractogenicity as described in the **Warnings** Section as well as the probability of actinic degeneration which is also described in the **Warnings** Section.

Patients with Renal or Hepatic Impairment

UVADEX[®] has not been evaluated in patients with renal or hepatic impairment

Renal impairment

Although renal transplant recipients with poor renal function have been treated with photopheresis using UVADEX[®], little additional information is available on the use of UVADEX[®] in patients with varying degree of renal impairment. No reduction of dose or prolongation of UV light protection were reported in the renal transplant recipients who have undergone photopheresis treatment.

Hepatic impairment

No specific information is available on the use of photopheresis with UVADEX[®] in patients with hepatic impairment. In view of the very low systemic exposure to methoxsalen, it is unlikely that patients with severe hepatic

impairment will be at greater risk than patients with normal hepatic function. However, the potential benefits of photopheresis treatment should be weighed against any possible risk before embarking on the procedure.

ADVERSE REACTIONS

Side effects of photopheresis (UVADEX[®] used with THERAKOS[®] Photopheresis Systems) were primarily related to hypotension secondary to changes in extracorporeal volume (>1%). In study CTCL 3 (UVADEX[®]), six serious cardiovascular adverse experiences were reported in five patients (5/51, 10%). Five of these six events were not related to photopheresis and did not interfere with the scheduled photopheresis treatments. One patient (1/51, 2%) with ischemic heart disease had an arrhythmia after the first day of photopheresis that was resolved the next day. Six infections were also reported in five patients. Two of the six events were Hickman catheter infections in one patient, which did not interrupt the scheduled photopheresis. The other four infections were not related to photopheresis and did not interfere with scheduled treatments.

POSTMARKETING

Adverse reactions reported from postmarketing experience include nausea, dysgeusia, photosensitivity reaction, pyrexia and hypersensitivity reactions including anaphylaxis and rash.

OVERDOSAGE

In the event of overdosage, the patient should be kept in a darkened room for at least 24 hours.

DRUG DOSAGE AND ADMINISTRATION

Each UVADEX[®] treatment involves collection of leukocytes, photoactivation, and reinfusion of photoactivated cells. UVADEX[®] (methoxsalen) Sterile Solution is supplied in 10 mL vials containing 200 mcg of methoxsalen (concentration of 20 mcg/mL). The THERAKOS[®] CELLEX[®] Photopheresis System Operator's Manual should be consulted before using this product. UVADEX[®] should not be diluted. The contents of the vial should be injected into the THERAKOS[®] CELLEX[®] Photopheresis System immediately after being drawn up into a syringe. Do not inject directly into patients. The UVADEX[®] vial is for single use only. Any UVADEX[®] that is not used during a procedure should be immediately discarded. UVADEX[®] can adsorb onto PVC and plastics, therefore only THERAKOS[®] CELLEX[®] photopheresis procedural kits supplied for use with the instrument should be used to administer this medicinal product. Once UVADEX[®] is drawn into a plastic syringe it should be immediately injected into the photoactivation bag. UVADEX[®] exposed to a plastic syringe for more than one hour should be discarded.

During treatment with the THERAKOS® CELLEX® Photopheresis System, the dosage of UVADEX® for each treatment will be calculated according to the treatment volume.

- The prescribed amount of UVADEX® should be injected into the recirculation bag prior to the Photoactivation Phase using the formula:

TREATMENT VOLUME × 0.017 = mL of UVADEX®
for each treatment

Example: Treatment volume of 240 mL × 0.017 =
4.1 mL of UVADEX®

Frequency/Schedule of Treatment

Normal Treatment Schedule

Treatment is given on two consecutive days every four weeks for a minimum of seven treatment cycles (six months).

Accelerated Treatment Schedule

If the assessment of the patient during the fourth treatment cycle (approximately three months) reveals an increased skin score from the baseline score, the frequency of treatment may be increased to two consecutive treatments every two weeks. If a 25% improvement in the skin score is attained after four consecutive weeks, the regular treatment schedule may resume. Patients who are maintained in the accelerated treatment schedule may receive a maximum of 20 cycles. There is no clinical evidence to show that treatment with UVADEX® beyond six months or using a different schedule provides additional benefit. In study CTCL 3, 15 of the 17 responses were seen within six months of treatment and only two patients responded to treatment after six months.

HOW SUPPLIED

UVADEX® (methoxsalen) Sterile Solution 20 mcg/mL in 10 mL amber glass vials (NDC 64067-216-01), and cartons of 12 vials (NDC 64067-216-01). One vial of 10 mL contains 200 micrograms methoxsalen. The drug product must be stored between 59°F (15°C) and 86°F (30°C)

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