INDICATIONS AND USAGE
UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® UVAR XTS® or 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 UVAR XTS or THERAKOS CELLEX PHOTOPHERESIS SYSTEMS’ 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 UVAR XTS or THERAKOS CELLEX Photopheresis System. Please consult the appropriate Operator’s Manual before using this product.

Please see additional Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Find the closest treatment center offering photopheresis near 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

University of Alabama at Birmingham Hospital
625 19th Street South
Birmingham, AL 35233
Contact: Apheresis Department
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
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
1111 E. McDowell Road
Phoenix, AZ 85006
Contact Phone: 602-839-2000
https://www.bannerhealth.com/locations/phoenix/banner-university-medical-center-phoenix

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Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
American Red Cross - Pomona Blood Donation Center

100 Red Cross Circle  
Pomona, CA 91768

Contact: Donor Center  
Contact Phone: 909-859-7281  
http://www.redcrossblood.org/locations/pomona-donor-center

Cedars-Sinai Medical Center

8700 Beverly Boulevard  
Los Angeles, CA 90048

Contact: Transfusion Medicine Division  
Contact Phone: 310-423-8981  
https://www.cedars-sinai.edu/Patients/Programs-and-Services/Pathology-and-Laboratory-Medicine-/Consultation-Services/Transfusion-Medicine-.aspx

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

1500 San Pablo Street  
Los Angeles, CA 90033

Contact Phone: 323-442-8363  
http://cancer.keckmedicine.org

Ronald Reagan UCLA Medical Center

200 Medical Plaza, Suite 670  
Los Angeles, CA 90095

Contact: Hemapheresis Unit  
Contact Phone: 310-794-7177  
https://www.uclahealth.org

Stanford Health Care - Stanford Cancer Center Palo Alto - Infusion Center

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

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

UC Davis Medical Center - Department of Pathology & Laboratory Medicine

2315 Stockton Blvd  
Sacramento, CA 95817

Contact: Apheresis Services  
Contact Phone: 916-734-3732  
http://ucdmc.ucdavis.edu/pathology/services/clinical/clinical_pathology/apheresis

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
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 System - Hillcrest
9400 Campus Point Drive
3rd Floor, Room 3-601
San Diego, CA 92037
Contact: Apheresis Program
Contact Phone: 858-249-3030
Email: apheresis@ucsd.edu
https://health.ucsd.edu/specialties/apheresis/Pages/photopheresis.aspx

University of California, San Francisco Medical Center
UCSF Medical Center - Infusion Services
400 Parnassus Ave. Fourth Floor, A430
San Francisco, CA 94143
Contact: Cutaneous Lymphoma Clinic
Contact Phone: 415-353-2421
https://www.ucsfhealth.org/clinics/cutaneous_lymphoma

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 - Colorado Blood Cancer Institute
1719 E. 19th Avenue
Denver, CO 80218
Contact: Infusion Services
Contact Phone: 303-839-6394
http://bloodcancerinstitute.com/services

University of Colorado Cancer Center - Anschutz
Anschutz Cancer Pavilion
1665 Aurora Court, 3rd Floor
Aurora, CO 80045
Contact: Dermatology Clinic
Contact Phone: 720-848-0500
https://www.uchealth.org/services/dermatology/

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
**Connecticut**

Yale New Haven Hospital - Dermatology Photopheresis Unit  
Hunter 4, Room 4097  
15 York Street  
New Haven, CT 06510  
Contact: Department of Dermatology  
Contact Phone: 203-688-6445  
https://medicine.yale.edu/dermatology/patient/services/photopheresis.aspx

**Delaware**

Christiana Care Health System - Helen F. Graham Cancer Center & Research Institute  
4701 Ogletown-Stanton Road  
Newark, DE 19713  
Contact: Ambulatory Infusion Center  
Contact Phone: 302-623-4500  
http://www.christianacare.org/lymphoma

**Florida**

Florida Hospital Cancer Institute  
2501 North Orange Ave  
Orlando, FL 32804  
Contact: Florida Hospital Orlando Infusion Center  
Contact Phone: 407-303-5865  
http://www.floridahospitalcancer.com

H. Lee Moffitt Cancer Center  
12902 USF Magnolia Drive  
Tampa, FL 33612  
Contact Phone: 1-888-663-3488  
https://moffitt.org/cancers/lymphomas-hodgkin-and-non-hodgkin

Larkin Community Hospital - Florida Academic Dermatology Center at Larkin  
7031 S.W. 62nd Avenue  
South Miami, FL 33143  
Contact Phone: 305-284-7516  
http://www.larkinhospital.com/site

Mayo Clinic - Jacksonville  
4500 San Pablo Road  
Mayo 3-104S  
Jacksonville, FL 32224  
Contact: Therapeutic Apheresis Department  
Contact Phone: 904-956-3312  
http://www.mayoclinic.org/diseases-conditions/cutaneous-t-cell-lymphoma/home/ovc-20179742

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Memorial Hospital West
801 North Flamingo Road
Pembroke Pines, FL 33028
Contact: Memorial Cancer Institute
Contact Phone: 954-276-5365

OneBlood
10100 Dr Martin Luther King Jr. Street N.
St. Petersburg, FL 33716
Contact: Therapeutic Apheresis
Contact Phone: 727-568-1111
https://www.oneblood.org

University of Florida Health - Shands Cancer Hospital
1515 S.W. Archer Road
Gainesville, FL 32608
Contact Phone: 352-265-0111
https://ufhealth.org/uf-health-shands-cancer-hospital

University of Miami Hospital - Miller School of Medicine
University of Miami Hospital South Bldg, Suites K-M
1295 N.W. 14th Street
Miami, FL 33136
Contact: Department of Dermatology & Cutaneous Surgery
Contact Phone: 305-243-7357
http://dermatology.med.miami.edu

Georgia
Emory University Hospital
Emory Healthcare Hemapheresis Department D627
1364 Clifton Road, N.E.
Atlanta, GA 30322
Contact: Hemapheresis Department
Contact Phone: 404-712-7028
http://www.emoryhealthcare.org/dermatology/lymphoma.html

Augusta University Medical Center
1120 15th Street
Augusta, GA 30912
Contact: Apheresis Department
Contact Phone: 706-721-3695
http://www.augustahealth.org/dermatology/dermatology-services-page

Northside Hospital - Atlanta Blood Services at BMT Inpatient Unit
5670 Peachtree Dunwoody Road, Suite 1075
Atlanta, GA 30342
Contact Phone: 404-459-8744
http://www.northside.com/BMT-Facilities

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Idaho

St. Luke's Mountain States Tumor Institute: Boise
100 E. Idaho Street
Boise, ID 83712
Contact: Oncology Infusion
Contact Phone: 208-381-2918
https://stlukesonline.org/health-services/procedures/extracorporeal-photopheresis

Illinois

Loyola University Medical Center
2160 S. 1st Avenue
Maywood, IL 60153
Contact: Dermatology Services
Contact Phone: 708-327-2609
https://www.loyolamedicine.org/dermatology/dermatology-services

Midwestern Regional Medical Center
2520 Emmaus Avenue
Zion, IL 60099
Contact: Stem Cell Laboratory
Contact Phone: 847-731-4177
http://www.cancercenter.com/midwestern

Northwestern Memorial Hospital
Rube Walker Blood Center
201 East Huron Street, 11th Floor, Suite 105
Chicago, IL 60611
Contact: Cutaneous Lymphoma Clinic
Contact Phone: 312-695-8106
https://www.nm.org/locations/rube-walker-blood-center

Rush University Medical Center - Dermatology Patient Services
1725 W. Harrison Street, Suite 264
Chicago, IL 60612
Contact: Cutaneous T-Cell Lymphoma Clinic
Contact Phone: 312-942-2195
https://www.rush.edu/services/dermatology

The University of Chicago Hospital - Duchossois Center for Advanced Medicine
5758 S. Maryland Avenue, Suite 3A
Chicago, IL 60637
Contact: Dermatology Clinic
Contact Phone: 773-702-1611
http://www.uchospitals.edu/visitor/directions/maps/dcam.html

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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

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

American Red Cross - Kansas Capital Area Chapter
707 N. Main Street
Wichita, KS 67203
Contact: Apheresis Services
Contact Phone: 316-268-9071
http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis

The University of Kansas Hospital
3901 Rainbow Boulevard
Kansas City, KS 66160
Contact: Blood and Marrow Transplant Program/Apheresis Services
Contact Phone: 913-588-1725
http://www.kumed.com

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
**Kentucky**

Norton Healthcare - Norton Healthcare Pavilion
411 E. Chestnut St.
Louisville, KY 40202
Contact: Outpatient Medical Unit
Contact Phone: 502-629-6993
[https://nortonhealthcare.com/services-and-conditions/cancer-care/services/skin-cancers/](https://nortonhealthcare.com/services-and-conditions/cancer-care/services/skin-cancers/)

University of Kentucky
1000 S. Limestone
Lexington, KY 40536
Contact: UK Markey Cancer Center
Contact Phone: 859.257.4488
[http://ukhealthcare.uky.edu/markey-cancer-center](http://ukhealthcare.uky.edu/markey-cancer-center)

University of Louisville Hospital - James Graham Brown Cancer Center
529 S. Jackson Street
Louisville, KY 40202
Contact: Cancer Center
Contact Phone: 502-681-1359

**Louisiana**

LSU Health Shreveport
1501 Kings Highway
Shreveport, LA 71103
Contact: Feist-Weiller Cancer Center
Contact Phone: 318-675-5972
[http://www.feistweiller.org](http://www.feistweiller.org)

Ochsner Medical Center
1514 Jefferson Highway
Jefferson, LA 70121
Contact: Hematology/Oncology Department
Contact Phone: 504-842-3910
[https://www.ochsner.org/services/melanoma-and-other-skin-cancers](https://www.ochsner.org/services/melanoma-and-other-skin-cancers)

Tulane University School of Medicine
1415 Tulane Avenue, 5th Floor
New Orleans, LA 70112
Contact: Apheresis Clinic
Contact Phone: 504-988-3613
[http://www2.tulane.edu/som/departments/dermatology/index.cfm](http://www2.tulane.edu/som/departments/dermatology/index.cfm)

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**Maine**

Eastern Maine Medical Center Cancer Care
33 Whiting Hill Road
Brewer, ME 04412
Contact: Photopheresis Room
Contact Phone: 207-973-7895
[https://www.emmc.org/Cancer-Care.aspx](https://www.emmc.org/Cancer-Care.aspx)

**Maryland**

Johns Hopkins Hospital - Outpatient Center
601 N. Caroline Street, 8th Floor
Baltimore, MD 21287
Contact: Dermatology
Contact Phone: 410-955-5933
[http://www.hopkinsmedicine.org/dermatology](http://www.hopkinsmedicine.org/dermatology)

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](http://umm.edu/programs/cancer)

**Massachusetts**

Brigham and Women's Hospital - Dana-Farber Cancer Institute
Jimmy Fund Building, Room 122
450 Brookline Avenue
Boston, MA 02215
Contact: Kraft Family Blood Donor Center
Contact Phone: 617-632-3394

Boston Medical Center
Boston Medical Center Moakley Building
830 Harrison Avenue
Boston, MA 02118
Contact: Cancer Care Center
Contact Phone: 617-638-7131
[https://www.bmc.org/cutaneous-lymphoma](https://www.bmc.org/cutaneous-lymphoma)

Beth Israel Deaconess Medical Center - Infusion and Apheresis
330 Brookline Avenue
Boston, MA 02215
Contact: Infusion Apheresis Unit
Contact Phone: 617-667-1522

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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: The Neely House
Contact Phone: 617-636-6453
https://www.tuftsmedicalcenter.org/

Michigan

Karmanos Cancer Institute
4100 John R Street
Detroit, MI 48201
Contact: Apheresis Department
Contact Phone: 313-576-9259
Email: info@karmanos.org
http://www.karmanos.org/cancer-care

Michigan Blood
1036 Fuller N.E.
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/ transfusion-medicine

University of Michigan Hospital - C&W Mott Hospital
Extracorporeal Photopheresis Clinic 8-951
1500 E. Medical Center Drive
Ann Arbor, MI 48109
Contact: Extracorporeal Photopheresis Clinic 8-891
Contact Phone: 734-232-8891
http://www.mcancer.org/lymphoma

Minnesota

Mayo Clinic Medical Center
200 First Street S.W.
Rochester, MN 55905
Contact: Dermatology Department
Contact Phone: 507-284-2536
http://www.mayoclinic.org/diseases-conditions/cutaneous-t-cell-lymphoma/ home/ovc-20179742

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Nevada

United Blood Services
6930 W. Charleston Blvd
Las Vegas, NV 89117
Contact Phone: 702-228-1111
https://www.vitalant.org/Home.aspx

New Hampshire

Dartmouth-Hitchcock Medical Center
1 Medical Center Drive
Lebanon, NH 03756
Contact: Norris Cotton Cancer Center
Contact Phone: 603-653-3775
Email: bmtransplant@hitchcock.org
https://cancer.dartmouth.edu/blood-marrow.html

New Jersey

Hackensack University Medical Center
92 Second Street
Hackensack, NJ 07601
Contact: John Theurer Cancer Center and Apheresis Department
Contact Phone: 551-996-8326 or 551-996-4018
https://www.hackensackumc.org/services/cancer-care/services/blood-marrow-stem-cell

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 Patterson Street
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 Ave. S.E.
Albuquerque, NM 87106
Contact: Infusion Services
Contact Phone: 505-563-1309
https://www.phs.org/doctors-services/services-centers/Pages/infusion-center.aspx

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New York

Columbia University Medical Center
Herbert Irving Pavilion
161 Fort Washington Avenue
New York, NY 10032

Contact: Cutaneous Lymphoma Center
Contact Phone: 212-305-5550
http://www.cumc.columbia.edu/lymphoma/cutaneous-lymphoma

Memorial Sloan Kettering Cancer Center - Blood Donor Room
1250 First Avenue
New York, NY 10065

Contact Phone: 212-639-6178

Montefiore Medical Center
111 East 210th Street
Bronx, NY 10467

Contact: Montefiore Einstein Center for Cancer Care
Contact Phone: 718-920-4818
http://www.montefiore.org/pathology-services-clinical

Mount Sinai Hospital
1450 Madison Avenue
New York, NY 10029

Contact: Apheresis Center
Contact Phone: 212-241-8810

Northwell Health
1991 Marcus Avenue
Lake Success, NY 11042

Contact: Department of Dermatology
Contact Phone: 516-719-3376
https://www.northwell.edu/find-care/locations/department-dermatology-0

Perlmutter Cancer Center - Langone Medical Center
160 East 34th Street
New York, NY 10016

Contact Phone: 646-929-7845

Roswell Park Cancer Institute
Elm and Carlton Streets
Buffalo, NY 14263

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

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Stony Brook University Hospital Cancer Center
101 Nicolls Road
Stony Brook, NY 11794
Contact Phone: 631-444-2630
https://cancer.stonybrookmedicine.edu

University of Rochester
601 Elmwood Avenue
Rochester, NY 14642
Contact: Wilmot Cancer Institute
Contact Phone: 585-275-7447
https://www.urmc.rochester.edu/cancer-institute.aspx

Upstate University Hospital
750 E. Adams Street
Syracuse, NY 13210
Contact Phone: 315-464-6720
http://www.upstate.edu/nursing/units/downtown/apheresis10i.php

Westchester Medical Center - Cancer Center
19 Bradhurst Avenue, Suite 2300N
Hawthorne, NY 10532
Contact: Outpatient Infusion Center
Contact Phone: 914-493-2220
http://www.wcmc.com/wmc/medical-services1/408.aspx

North Carolina
Atrium Health – Carolinas HealthCare System – Apheresis Department
1000 Blythe Boulevard, Suite 04M200
Charlotte, NC 28203
Contact Phone: 704-446-9750

Duke Blood and Marrow Transplant Clinic
2400 Pratt Street, Suite 1100D
Durham, NC 27710
Contact: Division of Hematologic Malignancies & Cellular Therapy
Contact Phone: 919-668-4360

UNC Health Care
101 Manning Drive
Chapel Hill, NC 27514
Contact: Transfusion Medicine/Blood Bank
Contact Phone: 919-966-4011
http://www.uncmedicalcenter.org/uncmc/care-treatment/dermatology

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Ohio

Cleveland Clinic

9500 Euclid Avenue
Cleveland, OH 44195

Contact: Apheresis M12
Contact Phone: 216-444-2633
http://my.clevelandclinic.org/health/treatments_and_procedures/hic_Photopheresis

Jewish Kenwood

4777 E Galbraith Rd
Cincinnati, OH 45236
(513) 686-3000

Contact: The Jewish Hospital-Mercy Health Blood Cancer Center
Contact Phone: 513-686-5250

The Ohio State University Wexner Medical Center - The James Cancer Hospital

460 West 10th Avenue
Columbus, OH 43210

Contact: Apheresis Department, 1st Floor
Contact Phone: 614-293-8672

University Hospitals Case Medical Center

11100 Euclid Avenue
Cleveland, OH 44106

Contact: Seidman Cancer Center
Contact Phone: 216-844-3951
http://www.uhhospitals.org/seidman

University of Cincinnati Hoxworth Blood Center

3130 Highland Avenue
Cincinnati, OH 45267

Contact: Department of Pathology, Microbiology, and Immunology
Contact Phone: 513-558-1333
http://www.hoxworth.org/patient-services.html

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Oklahoma

Oklahoma Blood Institute
1001 N. Lincoln Boulevard
Oklahoma City, OK 73104
Contact Phone: 405-297-5800
https://obi.org/about-us/therapeutic-apheresis

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, Mail Code: CR145
Portland, OR 97239
Contact: Apheresis Dept
Contact Phone: 503-494-0526
http://www.ohsu.edu/xd/health/services/dermatology/our-services/specialty-services/phototherapy.cfm

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 Eastern Pennsylvania Region
2221 Chestnut Street
Philadelphia, PA 19103
Contact Phone: 866-805-3500
http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis

Geisinger Health System
100 North Academy Avenue
Danville, PA 17822
Contact Phone: 570-214-8162
https://www.geisinger.org/patient-care/conditions-treatments-specialty/2017/03/21/16/33/cancer

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Geisinger Wyoming Valley Medical Center
1000 E. Mountain Boulevard
Wilkes-Barre, PA 18702
Contact Phone: 570-808-7415
https://www.geisinger.org/patient-care/find-a-location/geisinger-wyoming-valley-medical-center#

Hospital of the University of Pennsylvania
3400 Civic Center Boulevard, Suite 1-330
Philadelphia, PA 19104
Contact: Photopheresis Department
Contact Phone: 215-662-2737
https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/dermatology/photopheresis

Jeanes Hospital
7600 Central Avenue
Philadelphia, PA 19111
Contact: Bone Marrow Transplant Outpatient
Contact Phone: 215-214-3100
http://www.jeanes.com/content/default.htm

The Institute for Transfusion Medicine
3636 Blvd of the Allies
Pittsburgh, PA 15213
Contact: Therapeutic Apheresis Department
Contact Phone: 412-209-7433
https://www.vitalant.org/Home.aspx

Thomas Jefferson University Hospital
1014 College Building
1025 Walnut Street
Philadelphia, PA 19107
Contact: Oncology Department
Contact Phone: 215-955-8874

University of Pittsburgh Medical Center Shadyside - Cancer Center
5115 Centre Avenue, 3rd and 4th Floors
Pittsburgh, PA 15232
Contact: General Dermatology
Contact Phone: 412-864-7610
Email: bloodcancers@upmc.edu
http://www.upmccancercenter.com/one-team/#1

Washington Health System Greene
350 Bonar Avenue
Waynesburg, PA 15370
Contact Phone: 724-627-3101
http://southwestregionalmedical.com

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Rhode Island

Roger Williams Medical Center - Cutaneous Lymphoma Clinic

Cancer Center
50 Maude Street
Providence, RI 02908

Contact: General Dermatology
Contact Phone: 401-456-5793
http://www.rwmc.org/services/dermatology-services

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

Greenville Health System

Cancer Center 2nd Floor
900 West Faris Road
Greenville, SC 29605

Contact: Apheresis Department
Contact Phone: 864-455-5592
http://www.ghs.org/healthcareservices/cancer

Medical University of South Carolina

165 Ashley Ave, Suite 201
Charleston, SC 29425

Contact: Hemapheresis Unit
Contact Phone: 843-792-4389
http://www.muschealth.org/dermatology/index.html

Bon Secours St. Francis Cancer Center

104 Innovation Drive
Greenville, SC 29607

Contact Phone: 864-603-6200
http://stfranciscancercenter.org/services/treatments/infusion-services

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.averas.org/services/cancer-care

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Tennessee

HCA TriStar Centennial Medical Center
Sarah Cannon Center for Blood Cancer At TriStar Centennial Medical Center
2410 Patterson Street, 5th Floor
Nashville, TN 37203
Contact: Oncology Services
Contact Phone: 615-342-7457
http://tristarcentennial.com/service/cancer-care

Methodist Le Bonheur Healthcare
1265 Union Avenue
3rd Floor – Crews Wing
Memphis, TN 38104
Contact Phone: 901-516-8695
http://www.methodisthealth.org/locations/methodist-university-radiology-department

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://ww2.mc.vanderbilt.edu/vmcpathology/43053

VA Tennessee Valley Healthcare System
1310 24th Avenue South
Nashville, TN 37212
Contact: Photopheresis
Contact Phone: 615-327-4751
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

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Medical City Dallas Hospital
7777 Forest Lane
Dallas, TX 75230
Contact Phone: 972-566-6755
http://medicalcityhospital.com/hl/?/19881/Other-treatments

Methodist Hospital of San Antonio
7700 Floyd Curl Drive
San Antonio, TX 78229
Contact: Apheresis
Contact Phone: 210-575-4681
http://sahealth.com/hl/?/33753/Lymphoma-Center----Non-Hodgkin-s-Lymphoma

Parkland Memorial Hospital
5201 Harry Hines Boulevard
Dallas, TX 75235
Contact: Hematology and Oncology Clinic
Contact Phone: 214-590-5582

St. David’s South Austin Medical Center
901 W. Ben White Boulevard
Austin, TX 78704
Contact: Oncology Department
Contact Phone: 512-816-7612
http://stdavids.com/service/cancer-care

University of Texas MD Anderson Cancer Center
1515 Holcombe Boulevard
Houston, TX 77030
Contact: Cutaneous T-Cell Lymphoma Clinic
Contact Phone: 713-792-6404

The University of Texas Southwestern Medical Center
5939 Harry Hines Boulevard
Dallas, TX 75390
Contact: General Dermatology
Contact Phone: 214-645-8300
http://www.utswmedicine.org/conditions-specialties/dermatology/general/phototherapy.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

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Huntsman Cancer Institute
1950 Circle of Hope
Salt Lake City, UT 84112
Contact: Blood and Marrow Transplant Program
Contact Phone: 801-587-4652

Virginia

Inova Fairfax Hospital
3300 Gallows Road
Falls Church, VA 22042
Contact: Inova Schar Cancer Institute
Contact Phone: 703-776-2610 or 571-472-4724
https://www.inova.org/cancer/treatments/apheresis

Virginia Commonwealth University
The Gateway Building, 6th Floor
1200 East Marshall Street
Richmond, VA 23298
Contact: Department of Pathology
Contact Phone: 804-828-0256
http://www.pathology.vcu.edu

Washington

Inland Northwest Blood Center
210 W. Cataldo Avenue
Spokane, WA 99201
Contact Phone: 800-423-0151 ext. 4444
http://inbcsaves.org

Seattle Cancer Care Alliance
825 Eastlake Avenue E
Seattle, WA 98109
Contact Phone: 206-288-2167
http://www.seattlecca.org/diseases-treatments.cfm

Washington, DC

MedStar Georgetown University Hospital
3800 Reservoir Road N.W.
Washington, DC 20007
Contact: Apheresis Department
Contact Phone: 202-444-3667
http://www.medstargeorgetown.org/our-services/cancer-care/blood-cancer/conditions/lymphoma/#q={}

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Hôpital Maisonneuve - Rosemont
5415 Boulevard de l'Assomption
Montréal, QC H1T 2M4
Contact: Apheresis Department
Contact Phone: 514-252-3400 ext. 6589

Hôpital du Saint-Sacrement
1050 Ch Ste-Foy
Ville de Québec, QC G1S 4L8
Contact Phone: 418-649-0252 ext. 87790

The Ottawa Hospital
501 Smyth Road
Ottawa, ON K1H 8L6
Contact: Apheresis Department
Contact Phone: 613-798-5555 ext. 70933
http://www.ottawahospital.on.ca/en

Royal University Hospital
103 Hospital Drive
Saskatoon, SK S7N 0W8
Contact: Apheresis Services
Contact Phone: 306-655-2522
https://www.saskatoonhealthregion.ca/locations_services/locations/ruh/Pages/Home.aspx

Royal Victoria Hospital - McGill University Health Centre
1001 Boulevard Décarie
Montréal, QC H4A 3JI
Contact: Apheresis Department
Contact Phone: 514-934-1934
https://muhc.ca/mission/hematology

University Health Network - Toronto General Hospital
Princess Margaret Cancer Centre
610 University Avenue
Toronto, ON M5G 2M9
Contact: Apheresis Unit
Contact Phone: 416-340-3999
http://wwwuhn.ca/PrincessMargaret/PatientsFamilies/Clinics_Tests/Apheresis

Vancouver General Hospital - Centennial Pavilion
855 12th Avenue W
Vancouver, BC V5Z 1M9
Contact: Apheresis Unit
Contact Phone: 604-875-4626
http://www.vch.ca/locations-and-services/find-health-services/?program_id=12960

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Notes:

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
INDICATIONS AND USAGE
UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® UVAR XTS® or 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 UVAR XTS or THERAKOS CELLEX PHOTOPHERESIS SYSTEMS’ 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 UVAR XTS or THERAKOS CELLEX Photopheresis System. Please consult the appropriate 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 should not initiate methoxsalen therapy.

Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism.

UVADEX 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 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. 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. It is not known whether this drug is excreted in human milk.
- 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.
- Patients should be advised to avoid all exposure to sunlight during the 24 hours following photopheresis treatment.
- Exposure to large doses of UVA light causes cataracts in animals. Oral methoxsalen exacerbates this toxicity. 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.
- Instruct patients emphatically to wear UVA-absorbing, wrap-around sunglasses for 24 hours after UVADEX treatment.
- 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.

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

For the THERAKOS® UVAR XTS®/CELLEX® Photopheresis Procedure:

INDICATIONS
The THERAKOS UVAR XTS Photopheresis System/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.

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
The THERAKOS UVAR XTS or THERAKOS CELLEX Photopheresis Systems are 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 erythrodema 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 appropriate THERAKOS Photopheresis System Operator's Manual.
For more information, please contact a Mallinckrodt Customer Service Representative by calling 1-877-566-9466, 24/7.

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

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.
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:

![Chemical structure of methoxsalen]

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® UVAR XTS® and THERAKOS® CELLEX® Photopheresis Systems 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 UVAR and UVAR XTS® 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:

<table>
<thead>
<tr>
<th>Study</th>
<th>Response % Within Six Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTCL 3 (UVADEX®)</td>
<td>17/51 (33)</td>
</tr>
<tr>
<td>CTCL 2 (oral methoxsalen)</td>
<td>16/57 (28)</td>
</tr>
<tr>
<td>CTCL 1 (oral methoxsalen)</td>
<td>21/39 (54)</td>
</tr>
</tbody>
</table>

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® UVAR XTS® or 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

PHOTOSENSITIVITY: 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.
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.

Pregnancy:
Pregnancy Category D. 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 the THERAKOS® Photopheresis System) 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: An analysis of postmarketing data shows the following events occurred with an incidence of <0.01%: rash, allergic reaction, pyrexia, nausea, dysgeusia.

OVERDOSAGE
There are no known reports of overdosage with extracorporeal administration of methoxsalen. However, 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® UVAR XTS® or 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® UVAR
XTS® or THERAKOS® CELLEX® Photopheresis System immediately after being drawn up into a syringe. Do not inject directly into patients. The UVAX® vial is for single use only. Any UVAX® that is not used during a procedure should be immediately discarded. UVAX® can adsorb onto PVC and plastics, therefore only THERAKOS® UVAR XTS® or THERAKOS® CELLEX® photopheresis procedural kits supplied for use with the instrument should be used to administer this medicinal product. Once UVAX® is drawn into a plastic syringe it should be immediately injected into the photoactivation bag. UVAX® exposed to a plastic syringe for more than one hour should be discarded.

During treatment with the THERAKOS® UVAR XTS® or THERAKOS® CELLEX® Photopheresis System, the dosage of UVAX® for each treatment will be calculated according to the treatment volume.
• The prescribed amount of UVAX® should be injected into the recirculation bag prior to the Photactivation Phase using the formula:

\[
\text{TREATMENT VOLUME} \times 0.017 = \text{mL of UVAX® for each treatment}
\]

Example: Treatment volume of 240 mL \(\times 0.017 = 4.1\) mL of UVAX®

**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 UVAX® 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**

UVAX® (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)

**REFERENCES**


3. National Study Commission on Cytotoxic Exposure- Recommendations for Handling Cytotoxic Agents. Available from Louis P. Jeffrey, ScD., Chairman, National Study Commission on Cytotoxic Exposure, Massachusetts College of Pharmacy and Allied Health Sciences, 179 Longwood Avenue, Boston, Massachusetts 02115.

4. Clinical Oncological Society of Australia, Guidelines and Recommendations for Safe Handling of


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