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 on pages 29-30 and attached full Prescribing Information.
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.

<table>
<thead>
<tr>
<th>State</th>
<th>Center Name</th>
<th>Address</th>
<th>Contact Phone</th>
<th>Contact Email</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>University of Alabama at Birmingham Hospital</td>
<td>625 19th Street South, Birmingham, AL 35233</td>
<td>205-975-4026</td>
<td>Apheresis Department</td>
<td><a href="http://www.uabmedicine.org/locations/the-kirklin-clinic-of-uab-hospital">www.uabmedicine.org/locations/the-kirklin-clinic-of-uab-hospital</a></td>
</tr>
<tr>
<td>Alaska</td>
<td>Katmai Oncology Group</td>
<td>3851 Piper Street, Suite U340, Anchorage, AK 99508</td>
<td>907-562-0321</td>
<td></td>
<td><a href="http://katmaioncology.com">katmaioncology.com</a></td>
</tr>
<tr>
<td>Arizona</td>
<td>Banner MD Anderson Cancer Center</td>
<td>2946 E. Banner Gateway Drive, Gilbert, AZ 85234</td>
<td>480-256-6444</td>
<td>Cell Therapy/Apheresis Department</td>
<td><a href="http://www.bannerhealth.com/banner-md-anderson">www.bannerhealth.com/banner-md-anderson</a></td>
</tr>
<tr>
<td></td>
<td>Banner - University Medical Center Phoenix</td>
<td>1111 E. McDowell Road, Phoenix, AZ 85006</td>
<td>602-839-2000</td>
<td></td>
<td><a href="http://www.bannerhealth.com/locations/phoenix/banner-university-medical-center-phoenix">www.bannerhealth.com/locations/phoenix/banner-university-medical-center-phoenix</a></td>
</tr>
<tr>
<td>Arkansas</td>
<td>University of Arkansas for Medical Sciences</td>
<td>4301 W. Markham Street, #823, Little Rock, AR 72205</td>
<td>501-686-7930</td>
<td></td>
<td><a href="http://uamshealth.com">uamshealth.com</a></td>
</tr>
<tr>
<td>California</td>
<td>Alta Bates Summit Medical Center - Comprehensive Cancer Center</td>
<td>2001 Dwight Way, Berkeley, CA 94704</td>
<td>510-204-6578</td>
<td>Apheresis Department</td>
<td><a href="http://www.altabatessummit.org/cancer/ccc">www.altabatessummit.org/cancer/ccc</a></td>
</tr>
</tbody>
</table>

Please see Important Safety Information on pages 29-30 and attached full Prescribing Information.
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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

AdventHealth Orlando (formerly Florida Hospital Cancer Institute)
2501 North Orange Ave
Orlando, FL 32804
Contact: AdventHealth Orlando Infusion
Contact Phone: 407-303-1392
https://www.adventhealthcancerinstitute.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

Mayo Clinic - Jacksonville
4500 San Pablo Road
Mayo 3-1045
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

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

Please see Important Safety Information on pages 29-30 and attached full Prescribing Information.
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

University of Illinois, Chicago ITxM Diagnostics
1740 W Taylor St. Suite #1106
Chicago, IL 60612 (UIH)
Contact Phone: 312-996-6970
Email: mkeller@itxm.org or mkelle34@uic.edu
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

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
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/

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

University of Louisville Hospital - James Graham Brown Cancer Center
529 S. Jackson Street
Louisville, KY 40202
Contact: Cancer Center
Contact Phone: 502-681-1359
http://www.kentuckyonehealth.org/browncancercenter-cancer-care

Louisiana

LSU Health Shreveport
1501 Kings Highway
Shreveport, LA 71103
Contact: Feist-Weiller Cancer Center
Contact Phone: 318-675-5972
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

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

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

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

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

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

Beth Israel Deaconess Medical Center - Infusion and Apheresis
330 Brookline Avenue
Boston, MA 02215
Contact: Infusion Apheresis Unit
Contact Phone: 617-667-1522
Please see Important Safety Information on pages 29-30 and attached full Prescribing Information.
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

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

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
1100 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

Please see Important Safety Information on pages 29-30 and attached full Prescribing Information.
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Vitalant – Pittsburgh (formerly The Institute for Transfusion Medicine)
3636 Blvd of the Allies
Pittsburgh, PA 15213
Contact: Therapeutic Apheresis Department
Contact Phone: 412-209-7290
https://www.vitalant.org/Home.aspx

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

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.aver.org/services/cancer-care

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: 972-786-0650
http://www.carterbloodcare.org

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

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

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

University of Virginia Health System
1215 Lee Street
Charlottesville, VA 22903
Contact: Therapeutic Apheresis Department
Contact Phone: 434-924-9333
https://uvahealth.com/

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

Please see Important Safety Information on pages 29-30 and attached full Prescribing Information.
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 3J1
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://www.uhn.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

Notes:
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, variagate 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 “precocious 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 extracorporeal circulation of 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 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 methoxsalen/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, 37.3-38.9°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 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 on pages 29-30 and attached full Prescribing Information.