

ECP Patients FAQ

- What is ECP and how does it work?
- How do I get ready for treatment?
- Where do I go to get treatment and does someone need to come with me?
- How often are treatments?
- How long are treatments?
- How do I care for myself after treatment?
- When can I go back to work?
- How long will I be on this therapy?
- When can I expect to see benefits?
- What are the side effects?
- How effective was this therapy for other patients?
- How does ECP fit with the other medications I am on or other conditions that I have?

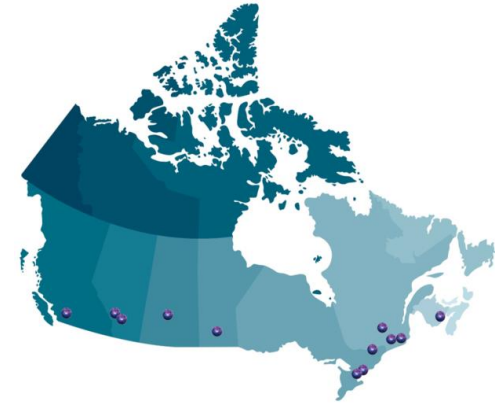
Patients should consult with their healthcare provider for more information.

Please see the full product monograph for the appropriate 8-methoxypsoralen formulation for important information related to adverse reactions, drug interactions, and dosing.

1. Therakos (UK) Ltd. Data on file. September 2020. 2. NCI 2015 – National Cancer Institute: Mycosis Fungoides and Sézary Syndrome Treatment (PDQ®) 2017 (available at https://www.cancer.gov/types/lymphoma/hp/mycosis-fungoides-treatment-pdq#section/_73). 3. EDF 2014 – Knobler R, et al. Guidelines on the use of extracorporeal photopheresis. *J Eur Acad Dermatol Venereol.* 2014;28 Suppl 1:1-37. 4. ASFA – Schwartz J, et al. – Guidelines on the Use of Therapeutic Apheresis in Clinical Practice-Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Seventh Special Issue. *J Clin Apher.* 2016;31(3):149-162. 5. NCCN 2014 – National Comprehensive Cancer Network: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Available at: <http://www.nccn.org/about/nhl.pdf>. 6. USCLC 2011 – Olsen EA, et al. Sézary syndrome: immunopathogenesis, literature review of therapeutic options, and recommendations for therapy by the United States Cutaneous Lymphoma Consortium (USCLC). *J Am Acad Dermatol.* 2011;64(2):352-404. 7. UKPS 2014 – Das-Gupta E, et al. Extracorporeal photopheresis for treatment of adults and children with acute GVHD: UK consensus statement and review of published literature. *Bone Marrow Transplant.* 2014;49(10):1251-1258. 8. EORTC 2017 – Trautinger F, et al. European Organisation for Research and Treatment of Cancer consensus recommendations for the treatment of mycosis fungoides/Sézary syndrome – Update 2017. *Eur J Cancer.* 2017;77:57-74. 9. Knobler et al. European Dermatology Forum S1-guideline on the diagnosis and treatment of sclerosing diseases of the skin, Part 1: localized scleroderma, systemic sclerosis and overlap syndromes. *JEADV.* 2017. 10. Knobler et al. European dermatology forum S1-guideline on the diagnosis and treatment of sclerosing diseases of the skin, Part 2: Scleromyxedema, scleredema and nephrogenic systemic fibrosis. *JEADV.* 2017. 11. Therakos, Inc. Operator's Manual. THERAKOS™ CELLEX™ Photopheresis System.



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THERAKOS™ Photopheresis

Referral Guide



Therakos™ Quick Facts

- Therakos™ Photopheresis collects and separates a small fraction of white blood cells for light-activated therapy to **help create an immunomodulatory response**^{1*}
- Therakos has **30 years** of clinical evidence and experience¹
- Therakos is an established, **guideline-recommended** therapy for indicated immune-mediated conditions²⁻¹⁰
- Therakos is used by **more than 300 treatment centers in over 30 countries**¹
- The Therakos Photopheresis system is **available in tertiary care centres across Canada**¹
- Therakos Photopheresis average treatment times are **less than 2 hours**:¹¹
 - Single-needle mode: **103.0mins**
 - Double-needle mode: **74.4mins**

*The exact mechanism by which extracorporeal photopheresis (ECP) exerts its clinical effect is unknown and under continual investigation.

Therakos™ Photopheresis Treatment Center Directory

Find the closest treatment center offering Photopheresis near you

This is a directory of Centers that offer Therakos Photopheresis treatment. This resource is provided for informational use only, is subject to change, and may not be comprehensive.

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



Vancouver General Hospital – Centennial Pavilion

855 12th Avenue W
Vancouver, BC V5Z 1M9
Contact: Apheresis Unit
Phone: 604-875-4626
<http://www.vch.ca/locations-services>

Foothills Medical Centre

Special Services Building, Room 4748
1403 29 Street N.W.
Calgary, AB T2N 2T9
Contact: Apheresis Clinic
Phone: 403-944-4712
<http://www.albertahealthservices.ca/fmc/fmc.aspx>

Royal University Hospital

103 Hospital Drive
Saskatoon, SK S7N 0W8
Contact: Apheresis Department
Phone: 306-655-1169
https://www.saskatoonhealthregion.ca/locations_services/Services/Outpatient-Services/Pages/Medical-Day-Care.aspx

Cancer Care Manitoba – MacCharles

675 McDermot Avenue
Winnipeg, MB R3E 0V9
Contact: Chemotherapy Department
Phone: 204-787-2197 **Toll Free:** 1-866-561-1026
<http://www.cancercare.mb.ca/home>

Toronto General & Princess Margaret Cancer Center

610 University Avenue
Toronto, ON M5G 2M9
Contact: Apheresis Unit
Phone: 416-340-3999
http://www.uhn.ca/PrincessMargaret/PatientsFamilies/Clinics_Tests/Apheresis

The Ottawa Hospital

501 Smyth Road
Ottawa, ON K1H 8L6
Contact: Hematology Department
Phone: 613-737-8899 ext. 78822
<http://www.ottawahospital.on.ca/en>

Hôpital Enfant-Jésus

1401 18e Rue
Ville de Québec, QC G1J 1Z4
Phone: 418-525-4444
<https://www.chudequebec.ca/centre-hospitaliers/hopital-de-l-enfant-jesus.aspx>

Hôpital Maisonneuve - Rosemont

5415 Boulevard de l'Assomption
Montréal, QC H1T 2M4
Contact: Apheresis Department
Phone: 514-252-3400
<https://ciusssestmtl.gouv.qc.ca/etablissement/hopital-maisonneuve-rosemont>

MUHC – Royal Victoria Hospital

1001 Boulevard Décarie
Montréal, QC H4A 3J1
Contact: Apheresis Department
Phone: 514-934-1934
<https://muhc.ca/glen>

St. John Regional Hospital

400 University Avenue
Saint John, NB E2L 4L2
Phone: 506-648-600
<https://en.horizonnb.ca/home/facilities-and-services/facilities/saint-john-regional-hospital.aspx>

Important Safety Information for THERAKOS™ Photopheresis Procedure

INDICATION

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) and systemic sclerosis (SSc).

CONTRAINDICATIONS

Certain underlying medical conditions contraindicate THERAKOS Photopheresis, including:

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

WARNINGS & 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.
- **MR-Unsafe:** Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projective injury, and thermal injury and burns may occur. The device may generate artifacts in the MR image, or may not function properly.
- **Thromboembolic Events:** Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported in the treatment of Graft versus Host Disease (GvHD), an indication not approved in Canada. Special attention to adequate anticoagulation is advised when treating patients with GvHD.
- **Concomitant Therapy:** When prescribing and administering THERAKOS Photopheresis for patients receiving concomitant therapy, exercise caution when changing treatment schedules to avoid increased disease activity that may be caused by abrupt withdrawal of previous therapy.

ADVERSE REACTIONS

Hypotension may occur during any treatment involving extracorporeal circulation. Monitor the patient closely during the entire treatment.

Transient pyretic reactions, 37.7-38.9o C (100-102o F), have been observed in some patients within 6-8 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.

Important Safety Information for Methoxsalen Sterile Solution Used in Conjunction with THERAKOS™ CELLEX Photopheresis System

CONTRAINDICATIONS

Methoxsalen Sterile Solution is contraindicated in:

- Patients exhibiting idiosyncratic reactions to psoralen compounds
- Patients with aphakia
- Patients possessing a specific history of a light-sensitive disease state

SERIOUS WARNINGS & PRECAUTIONS

- **Concomitant Therapy:** Exercise care in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents.
- **Carcinogenicity:** Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. Patients exhibiting multiple basal cell carcinomas or having a history of basal cell carcinoma should be diligently observed and treated.
- **Teratogenicity:** Methoxsalen may cause fetal harm when given to a pregnant woman. Women undergoing photopheresis should be advised to avoid becoming pregnant.
- **Cataractogenicity:** Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after methoxsalen treatment, any time they are exposed to direct or indirect sunlight and whether they are outdoors or exposed through a window.
- Safety in children has not been established.

FOR MORE INFORMATION

Please consult the full product monograph for methoxsalen sterile solution (if used in conjunction with the THERAKOS™ CELLEX™ Photopheresis System) and the Operator's Manual for the CELLEX system at <https://www.mallinckrodt.ca/products/therakos/>, or by calling us at 1-877-566-9466.

