

EVIDENCE-BASED TREATMENT RECOMMENDATIONS



Extracorporeal photopheresis (ECP) is recommended by multiple International Guidelines.

Cutaneous T-cell lymphoma (CTCL)

Recommended option in Stage:	IIIA	IIIB	IVA1 (B2)	IVA2 (B2)
	Mycosis Fungoides		Sézary Syndrome	
National Comprehensive Cancer Network (NCCN) ¹ 2025	✓	✓	✓	✓
National Cancer Institute (NCI) ² 2025	✓	✓	✓	✓
European Dermatology Forum (EDF) ³ 2020	✓	✓	✓	✓
American Society for Apheresis (ASFA) ⁴ 2023	✓	✓	✓	
European Society for Medical Oncology (ESMO) ⁵ 2018	✓	✓	✓	✓
United Kingdom Photopheresis Society (UKPS) ⁶ 2017	✓	✓	✓	✓
European Organization for Research and Treatment of Cancer (EORTC) ⁷ 2023	✓	✓	✓	✓
British Association of Dermatologists and UK Cutaneous Lymphoma Group ⁸ 2018	✓	✓	✓	

Systemic sclerosis (SSc)

National German Guidelines (S2k) ⁹ 2022	• Second-line or adjuvant therapy in early progressive disease • For skin involvement in cases of aggressive progression, but not organ involvement
European Dermatology Forum (EDF) ¹⁰ 2020	• Second-line or adjuvant therapy in early progressive disease • For skin involvement in cases of aggressive advancement, but not organ involvement
American Society for Apheresis (ASFA) ⁴ 2023	Recommendation Category III • Optimum role of therapy is not established • Decision making should be individualized Recommendation Grade 2A • High-quality evidence, weak recommendation • Best action may differ depending on circumstances

Important Safety Information for THERAKOS® CELLEX® 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 CELLEX 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 CELLEX 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 CELLEX 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, 37.7-38.9 °C (100-102 °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

See 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 health-products.canada.ca/dpd-bdpp/ or by calling 1-833-223-4ECP (1-833-223-4327)

References: 1. NCCN Clinical Practice Guidelines in Oncology. Primary Cutaneous Lymphoma Version 1.2025, November 11, 2024. 2. National Cancer Institute PDQ Guidelines. Mycosis Fungoides and Other Cutaneous T-cell Lymphomas Treatment (PDQ®)-Health Professional Version. Updated February 19, 2025. 3. Knobler R, et al. *J Eur Acad Dermatol Venereol.* 2020;34(12):2693-2716. 4. Connelly-Smith L, et al. *J Clin Apher.* 2023;38(2):77-278. 5. Willemze R, et al. *Ann Oncol.* 2018;29(S4):iv30-iv40. 6. Alfred A, et al. *Br J Haematol.* 2017;177(2):287-310. 7. Latzka J, et al. *Eur J Cancer.* 2023;195:113343. 8. Gilson D, et al. *Br J Dermatol.* 2019;180(3):496-526. 9. AWMF-S2k Guideline (013-072): Extracorporeal Photopheresis. 10. Knobler R, et al. *J Eur Acad Dermatol Venereol.* 2021;35(1):27-49.

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