

# Understanding THERAKOS™ Extracorporeal Photopheresis (ECP)



## What is photopheresis?

Photopheresis is also known as Extracorporeal Photopheresis, or ECP:

- “Extracorporeal” means outside the body.
- “Photopheresis” is the combination of two words. “Photo” which means light and “apheresis” which means separation.

So ECP involves collecting and separating a small fraction of your blood cells which then undergo light activated therapy outside the body before being returned.

## What is ECP used for?

ECP was first used to treat skin symptoms associated with a type of blood cancer called Cutaneous T Cell Lymphoma (CTCL) but it is also used to treat a range of diseases caused by overreactions of the immune system. Examples include a condition called Graft-versus-Host Disease (GvHD) that can occur after stem cell or bone marrow transplantation and heart and lung transplant related rejection (SOT).

## How does ECP work?

In conditions such as GvHD or autoimmune disorders, certain types of white blood cell can become overactive and start attacking your body. During ECP, a small amount of white blood cells are collected and treated with a photosensitizer, which is activated by exposure to ultraviolet-A (UVA) light. The treated cells then help to modify your immune response in a process called immunomodulation.

ECP is ‘immunomodulatory’ which means it changes the response of your immune system.

This can help defend against infections caused by microorganisms that take advantage of weakened immune systems (opportunistic infections). Your immune system can also remember how to defend against toxins or foreign proteins (called antigens). Using ECP may allow the reduction of immunosuppressive drugs, which may be preferable when treating immune conditions.

## How can I prepare for my ECP treatment?

There are several things you can do to help your ECP treatment session be as comfortable as possible. Your doctor or nurse will tell you the best way for you to prepare based on your individual health and medical condition.

The plan below has some useful tips that can help you get ready for treatment:

	2 days before	The evening before	On the day
TIP	<ul style="list-style-type: none"><li>• Drink plenty of fluids</li><li>• Avoid caffeine</li><li>• Avoid alcohol</li></ul>	<ul style="list-style-type: none"><li>• Eat a low-fat meal</li><li>• Avoid food such as high-fat meat, cream, fried food, cheese, eggs, butter, and deserts</li></ul>	<ul style="list-style-type: none"><li>• Eat a low-fat breakfast and lunch</li><li>• Don't skip any meals</li><li>• Visit the bathroom right before the treatment</li></ul>
WHY?	Having lots of fluid in your body helps your blood flow better during treatment. Both caffeine and alcohol can cause a reduction in your body fluids.	High levels of fat in the blood may make the cell-separation process more difficult and could result in the treatment being stopped before it's finished.	You will need to remain seated throughout the procedure. These tips can help you to stay comfortable during treatment.

Remember to tell your doctor or nurse about any other conditions (such as heart problems, or low blood volume/pressure) as well as any medications you may be taking before starting treatment.

## What can I expect during my ECP treatment?

- 1 At the start of your treatment, you will be connected to the ECP instrument by a thin flexible tube (called a catheter), which will be inserted into a vein, usually in your arm. A small amount of blood will then start to be collected through this tube and into the ECP instrument.
- 2 During the collection, as your blood flows through the instrument, the different parts that make up your blood will be separated by centrifugation, in a process called apheresis. Your red blood cells and plasma are returned to you straight away, while your white blood cells remain in the ECP instrument for treatment.
- 3 Inside the ECP instrument, your white blood cells will be treated with the photosensitizer, which will then be exposed to UVA light to 'activate' it.
- 4 The treated white blood cells are then returned to your bloodstream.

You will be connected to the ECP instrument for the entire process.

Treatment duration varies from patient to patient. Usually, it takes between 1 to 3 hours to complete.

The tubing is replaced for every patient and the ECP system is completely closed so there is no chance that your blood will come into contact with anybody else's.

## Will it be painful?

Most people report little or no discomfort during treatment. However, as with any needle puncture procedure, there may be some minor discomfort when the catheter is inserted into your vein.

During ECP you may sometimes feel different sensations that are not painful. These may include a slight pulsing from the ECP instrument's pump and a slight chill or cold sensation as blood is returned to your body.

You may feel weak or dizzy during, or immediately after your treatment. This sometimes occurs because of a slight drop in blood pressure. Tell your doctor or nurse if this happens.

Scan to view the procedural video at [www.therakos.eu](http://www.therakos.eu)



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Scan to view your video guide to ECP at [www.therakos.eu](http://www.therakos.eu)



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## What should I do after my ECP treatment?

The photosensitizer used in ECP, can make you more sensitive to sunlight for about 24 hours after treatment. You should protect your eyes and skin by taking the following simple, but very important, precautions for 24 hours after every treatment:

- Avoid sunlight as much as possible, even indirect sunlight coming through a window
- Wear sunscreen SPF 15 or higher when exposed to sunlight (both outdoors and indoors)
- Wear UVA-protective, full-coverage sunglasses when exposed to direct or indirect sunlight

## What are the risks involved for ECP?

Side effects of ECP are most often related to a temporary drop in blood pressure due to changes in your blood volume during the treatment.

Your doctor or nurse will monitor you during treatment for low blood pressure. Other possible side effects such as fever or skin redness usually go away within a day. Venous access carries a small risk of infection and pain.

The THERAKOS™ Photopheresis System is the only approved “closed” system for ECP. This means that the blood that is collected and treated is never separated from you and the instrument so minimizing the risk of infusion errors when it is returned to the body.

Ask your doctor or nurse if you have any other concerns about ECP.

## How many treatments will I need?

Your treatment sessions will be repeated over time. The number of sessions will depend on the disease being treated, your symptoms and response to ECP. Your doctor will decide the number of treatments suited to your individual needs.

## When will I know it is working?

THERAKOS™ ECP has demonstrated positive effects in many people but it is difficult to predict the type and extent of response you will have.

The length of time it takes to respond to treatment will be different for every patient and will depend on the state of your immune system, the severity of your disease and how often you receive treatment.

Improvement may happen gradually and it is important that you don't give up or feel discouraged if you don't see results straight away.

## IMPORTANT SAFETY INFORMATION FOR THE THERAKOS™ PHOTOPHERESIS PROCEDURE

### Indications

The THERAKOS™ CELLEX™ Photopheresis System is indicated for patients older than 18 years of age for the administration of photopheresis in the following:

- Cutaneous T Cell Lymphoma (CTCL)
- Solid Organ Transplant Rejection (SOT) (heart, lung)

The THERAKOS™ CELLEX™ Photopheresis System is indicated in patients older than 3 years of age for the management of:

- Acute and Chronic Graft versus Host Disease (aGvHD, cGvHD)

### Contraindications

THERAKOS™ Photopheresis is contraindicated in:

- Patients possessing a specific history of a light sensitive disease
- Patients who cannot tolerate extracorporeal volume loss or who have white blood cell counts greater than 25,000 / mm<sup>3</sup>
- Patients who have coagulation disorders or who have previously had a 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.

- Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury, and thermal injury and burns may occur. The device may generate artifacts in the MR image, or may not function properly.
- Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported in the treatment of Graft versus Host Disease (GvHD). Special attention to adequate anticoagulation is advised when treating patients with GvHD.
- 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 Events

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

Please refer to the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual for a complete list of warnings and precautions.

## IMPORTANT SAFETY INFORMATION FOR METHOXSALEN USED IN CONJUNCTION WITH THERAKOS™ PHOTOPHERESIS

Consult the 8-methoxypsoralen (Methoxsalen (20 micrograms / mL)) professional leaflet or the oral 8-methoxypsoralen formulation package insert before prescribing or dispensing any medication.

### Warnings and Precautions

- Patients exhibiting multiple basal cell carcinomas or having a history of basal cell carcinoma should be diligently observed and treated.
- Methoxsalen may cause fetal harm when given to a pregnant woman. Women undergoing photopheresis should be advised to avoid becoming pregnant.
- Special care should be exercised in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents.
- Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic.
- Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after methoxsalen 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.

Refer to the package insert for methoxsalen sterile solution (20 micrograms / mL) or the oral 8-methoxypsoralen dosage formulation for a list of all warnings and precautions.

For more information about THERAKOS™ ECP please visit: [www.therakos.eu](http://www.therakos.eu)  
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