Therakos
ECP Immunomodulation

Understanding THERAKOS® Extracorporeal Photopheresis (ECP)

Harnessing the power of your immune system to fight disease

Information for patients

Mallinckrodt Pharmaceuticals

Your doctor has recommended that you have photopheresis (pronounced *foh-toh-fuh-ree-sis*) to treat your condition. Here we explain what this is, how it works and what you might expect from this treatment.

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 a type of blood cancer but it is now 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.

ECP is also used for transplant-related rejection (such as heart or lung transplants) and to treat other autoimmune disorders, such as systemic sclerosis and atopic dermatitis.

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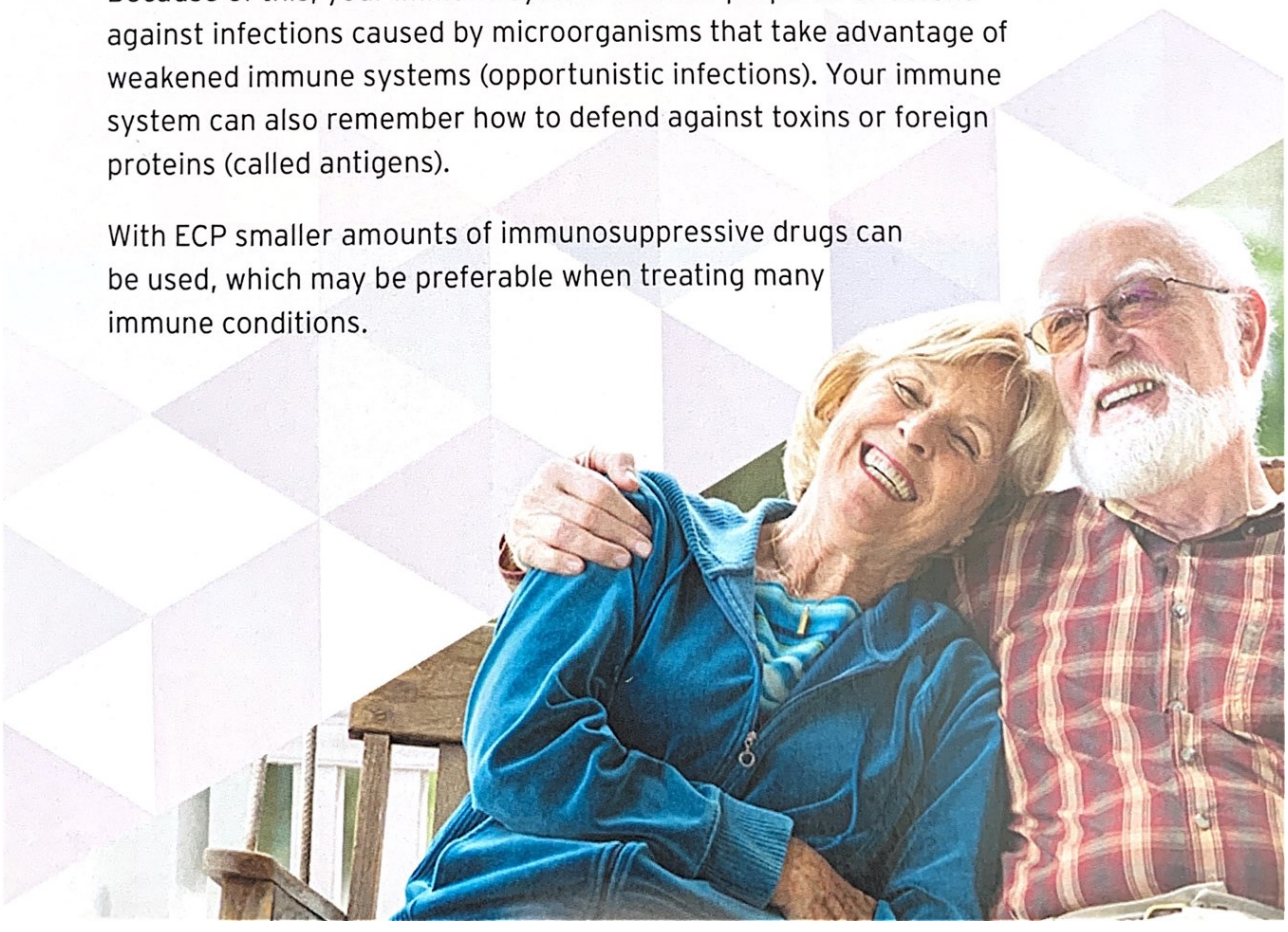
How does ECP work?

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 drug called methoxsalen (pronounced *meth-ox-a-len*), 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.

Many treatments for GvHD and autoimmune disorders are immunosuppressive. This means they temporarily weaken your immune system. In contrast, ECP is 'immunomodulatory' which means it changes the response of your immune system without suppressing it.

Because of this, your immune system is better prepared to 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).

With ECP smaller amounts of immunosuppressive drugs can be used, which may be preferable when treating many immune conditions.



Is ECP Safe?

Doctors have been administering THERAKOS® ECP to patients since 1987. Over one million treatments have been performed since then. ECP is generally considered to have a good safety profile and serious side effects are rare.

Side effects of ECP are most often related to a temporary drop in blood pressure due to minor 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.

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 there are no risk of reinfusion errors when it is returned to the body.

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

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, the different parts that make up your blood will be separated by a process called centrifugation. 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 methoxsalen, which will then be exposed to UVA light to 'activate' it (turn it on).
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.

Watch the THERAKOS® CELLEX® Photopheresis System Video at www.therakos.co.uk

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.

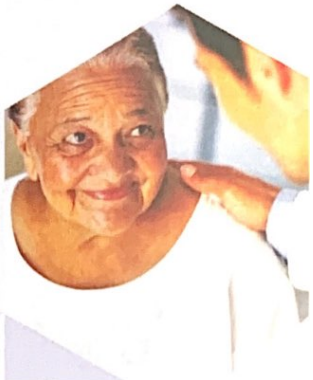
Improvement may happen gradually and it is important that you don't give up or feel discouraged if you don't see results straight away.

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.



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	■ Drink plenty of fluids ■ Avoid caffeine ■ Avoid alcohol	■ Eat a low-fat meal ■ Avoid food such as high-fat meat, cream, fried food, cheese, eggs, butter, and deserts	■ Eat a low-fat breakfast and lunch ■ Don't skip any meals ■ Visit the bathroom right before the treatment
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 should I do after my ECP treatment?

Methoxsalen, the drug 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