▼ **This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.**

UVADEX®

Methoxsalen 200 microgram/10 mL Concentrated Injection for Extracorporeal Circulation – via Photopheresis

Consumer Medicine Information

What is in this leaflet?

Read all of this leaflet carefully before you start using this medicine.

This leaflet answers some common questions about UVADEX. It does not contain all of the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you having UVADEX against the risks this medicine could have for you.

If you have any questions or concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.
You may need to read it again.

What is UVADEX used for?

The active ingredient in UVADEX is methoxsalen. This is a product that alters the response of the body to light which becomes active when it is exposed to UV radiation.This medicine is used to treat:

1. **Chronic Graft versus Host Disease (cGVHD)** is a common and sometimes serious side effect of a blood stem cell transplant. GVHD happens when the cells from your donor (the graft) see your body's cells (the host) as different and attack them, leading to complications involving the skin and other organs of the body.

   UVADEX is used in combination with the THERAKOS® CELLEX® Photopheresis System to treat chronic GVHD that is no longer responding to steroid treatment.
2. **Cutaneous T-cell lymphoma (CTCL)** is a blood disorder causing abnormal growths affecting the skin. UVADEX is used in combination with the THERAKOS® CELLEX® Photopheresis System to alleviate the skin symptoms of CTCL, when other treatments have not been effective.

   The THERAKOS CELLEX Photopheresis System provides the UV light necessary to activate methoxsalen which then destroys diseased white blood cells.

UVADEX is only available with a doctor's prescription.

Before you are treated with UVADEX

Make sure this medicine is suitable for you.

UVADEX should not be given to certain people.

You should not be given UVADEX if:

- You have had an allergic reaction to methoxsalen, another psoralen compound, or any of the other ingredients.
- You have skin cancer (melanoma, basal cell or squamous cell cancer).
- You have any disease which involves sensitivity to light such as porphyria, systemic lupus erythematosus or albinism (a condition where the pigment in your skin is reduced).
- Your spleen has been removed.
- You have a blood clotting disorder or an increased white blood cell count (greater than 25,000 mm^3).
- You are breast feeding.
- You have a condition which makes you unable to tolerate removal of large quantities of blood, such as heart disease or severe anaemia.
- You have had the lens removed from either of your eyes.

UVADEX should be given with special care to certain people

Your doctor will advise you whether you can receive treatment with UVADEX if:

- You have EPILEPSY and are being treated with phenytoin (this may cause UVADEX treatment to be ineffective).
- You have LIVER or KIDNEY problems.
- You are taking tolbutamide for DIABETES (this may cause increased photosensitivity).

- You have sunbathed recently before treatment.
- You are taking any other medicine which causes sensitivity to light, including some antibiotics (e.g. ciprofloxacin, doxycline and nalidixic acid), some diuretics (water tablets), some medicines used for treating diabetes (e.g. chlorpropamide), some medicines used to treat mental health problems (e.g. trifluoperazine and haloperidol) and some medicines used to treat skin conditions (e.g. isotretinoin).
- There is any possibility of you becoming PREGNANT.

Warning

This product contains 4.1% w/v ethanol. Each 1 mL of UVADEX contains 0.41 g of ethanol. This may be harmful for those suffering from liver disease, alcoholism, epilepsy, brain injury or disease as well as for pregnant women and children and may modify or increase the effect of other medicines.

Use in pregnancy and breast feeding

You should not be treated with UVADEX if you are breast feeding. You should let your doctor know if there is a chance you are or may become pregnant.

Use in children

UVADEX is not recommended for use in children.

Driving and using machines

You should not drive or operate machinery immediately following treatment.

If you are not sure whether you should be treated with UVADEX, talk to your doctor, nurse or pharmacist.

UVADEX and other medicines

Make sure that the doctor treating you knows about any other medicines you are taking, including any such as paracetamol which you may have bought for yourself.

Taking UVADEX with food and drink

No studies have been done evaluating the effect of food and drink. Since UVADEX is administered as part of a hospital procedure, your specialist doctor will decide whether you may eat or drink during a procedure.

How UVADEX is used

This medicine is always administered by a specialist doctor who can explain exactly what is happening. The doctor will decide how many treatment sessions you need.

cGVHD

Most patients with chronic GVHD may have 3 treatments in the first week, then 2 treatments per week for at least 12 weeks.

CTCL

Most patients with CTCL have treatment on two successive days once a month for six months. After four months this may be increased to two successive days twice a month if the doctor thinks it is necessary.

You should not have more than 20 photopheresis sessions in 6 months.

The medicine is administered as follows:

A professional specifically trained in the use of photopheresis will place a needle in your arm so that blood can flow into a specially designed instrument (the THERAKOS CELLEX Photopheresis System) and be separated into red blood cells, white blood cells and plasma. The red blood cells and most of the plasma are simply transfused back into your circulation during the procedure. The white blood cells and the rest of the plasma are mixed with a calculated dose of UVADEX, exposed to UV light in the instrument, and then returned to you.

The procedure takes up to three hours from the time the needle is inserted until all the components of your blood have been returned to you.

During administration of your treatment, and for 24 hours afterwards, you must wear special wraparound UVA-blocking sunglasses all of the time to avoid the light damaging your eyes by causing cataracts to form.

After receiving your treatment

After receiving your treatment you should avoid sunlight for at least 24 hours because it may damage your skin by causing burning or, in the long term, premature aging or skin cancer. If you must go outside you should cover your skin, use a strong sunblocking agent and wear sunglasses (see above).

If you are given too much UVADEX (overdose)

This is very unlikely. However, were you to be given too much you may need to remain in a darkened room for 24 hours or longer as part of your treatment.

What are the side effects?

Tell your doctor or nurse as soon as possible if you experience any problems after being given UVADEX, even if the problems are not listed in this leaflet.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Don't be alarmed by the following list of side effects. You may not experience any of them.

Like all medicines UVADEX can cause some unwanted effects but these have usually been mild and pass off quickly. Patients treated for cGVHD have experienced diarrhoea, low platelet count, nausea, headache, and high blood pressure have been reported.

Additional side effects include sinus and upper respiratory infections, tiredness, pain in feet and hands, fever, cough, and difficulty breathing.

Nausea and vomiting have been reported in up to 1 in 10 people treated for CTCL. Additional side effects include rash, allergic reactions, altered taste, fainting, anaemia, worsening of congestive heart failure, severe infection (sepsis), and heart valve infection or inflammation.

Blood clots in a vein and allergic reactions have been reported in association with the use of THERAKOS CELLEX.

Blood tests have shown that UVADEX may occasionally cause some small changes in the blood. The changes include decreases in albumin, calcium, haemoglobin, potassium, red and white blood cell count, and proportion of red cells in the blood. Your physician will check your blood through regular testing.

The photopheresis procedure may result in mild or moderate lowering of blood pressure, fever or local infection or damage to veins as a result of insertion of the needle. These effects have been reported at an incidence of up to 1 in 10 people.

If any of these symptoms become troublesome, or you notice anything else which you don't understand, discuss this with the doctor or nurse looking after you.

Storing UVADEX

UVADEX will be stored in the hospital pharmacy in a safe place out of the reach of children.

It should be stored below 25°C.

UVADEX should not be used after the expiry date on the box.

Product description

What UVADEX looks like

UVADEX comes in an amber glass vial with a rubber stopper containing 10 mL of solution.

Ingredients

UVADEX contains 20 micrograms/mL of the active ingredient, methoxsalen.

UVADEX also contains propylene glycol, ethanol, glacial acetic acid, sodium acetate trihydrate, sodium hydroxide, sodium chloride and water for injections.

Sponsor

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