**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

**B. PACKAGE LEAFLET**

**Package leaflet: Information for the user**

**UVADEX**
**20 MICROGRAMS/ML**
**SOLUTION FOR BLOOD FRACTION MODIFICATION**
(methoxsalen)

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**:


## 1. What UVADEX is and what it is used for

The name of this medicine is UVADEX 20 micrograms/ml Solution for Blood Fraction Modification

Methoxsalen is a product that alters the response of the body to light which becomes active when it is exposed to UV radiation.

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.

## 2. What you need to know before you are given UVADEX

**Do not use UVADEX:**

- If you have had an allergic reaction to methoxsalen, another psoralen compound, or any of the other ingredients.
- If you have skin cancer (melanoma, basal cell or squamous cell cancer).
- If 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).
- If your spleen has been removed.
- If you have a blood clotting disorder or an increased white blood cell count (greater than 25,000 per $mm^3$).

- If you are pregnant or breast feeding.
- If you are sexually active and do not use contraceptive precautions. If you are a sexually active man or woman, you must use contraceptive precautions both during and after treatment as methoxsalen may harm a baby which is conceived during or after treatment.
- If you have a condition which makes you unable to tolerate removal of large quantities of blood, such as heart disease or severe anaemia.
- If you have had the lens removed from either of your eyes.

**Warnings and precautions**

Talk to your doctor before you are treated with UVADEX:

- If you have EPILEPSY and are being treated with phenytoin (this may cause UVADEX treatment to be ineffective)
- If you have LIVER or KIDNEY problems
- If you are taking tolbutamide for DIABETES (this may cause increased photosensitivity)
- If you have sunbathed recently before treatment
- If you are taking any other medicine which causes sensitivity to light, including some antibiotics (e.g. ciprofloxacin, doxycycline 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 (See previous section).

**Children**
UVADEX is not for use in children as there is no sufficient experience available for this age group.

**Other medicines and UVADEX**

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.

**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.

**Pregnancy, Breast Feeding and Fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not be given UVADEX if you are pregnant or breast feeding.

If you are sexually active and of childbearing age, you must use appropriate methods of contraception during UVADEX treatment because the active substance, methoxsalen, may harm a child conceived during treatment with UVADEX.

**Driving and using machines**

You should not drive or operate machinery immediately following treatment.

**UVADEX contains small amounts of ethanol.**
This medicine contains 217 mg of alcohol (ethanol) in each 5.6 ml dose which is equivalent to 3.1 mg/kg per 5.6 ml dose. The amount in one 5.6 ml dose of this medicine is equivalent to less than 6 ml beer or 3 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

**UVADEX contains small amounts of sodium.**
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

## 3. How to use UVADEX

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. Most patients 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.

**Method of administration**
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.

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

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

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

**After 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 ageing. If you must go outside you should cover your skin, use a strong sun-blocking agent and wear sunglasses (see above).

**If you are given more UVADEX than you should**

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.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

Common (may affect up to 1 in 10 people):
- low blood pressure,
- nausea (feeling sick) and vomiting (being sick),
- infections
- transient fever (may occur 6 to 8 hours after treatment),
- damage to veins (as a result of repeated insertion of needle to the veins).
- Altered taste

Uncommon
- Sensitivity to sunlight

Not known (frequency cannot be estimated from the available data)
- Allergic reaction

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store UVADEX?

UVADEX will be stored in the hospital pharmacy. It should not be stored above 25ºC.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month

## 6. Contents of the pack and other information

**What UVADEX contains?**

- The active substance is methoxsalen.
- One vial of 10 ml contains 200 micrograms (µg) methoxalen. One millilitre contains 20 micrograms of methoxsalen.
  The other ingredients are Propylene Glycol, Ethanol 95%, Glacial Acetic Acid, Sodium Acetate Trihydrate, Sodium Hydroxide, Sodium Chloride And Water For Injections.

**What UVADEX looks like and contents of the pack**

Clear colourless solution.
10 ml amber glass vial with a rubber stopper.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: THERAKOS (UK) Limited, 3 Lotus Park, The Causeway, Staines-upon-Thames, Surrey TW18 3AG, United Kingdom.

Manufacturer: Penn Pharmaceutical Services Limited, Units 23 & 24 Tafarnaubach Industrial Estate Tredegar, Gwent, Wales, NP22 3AA, United Kingdom.

or

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