

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using UVADEX?

UVADEX contains the active ingredient methoxsalen. UVADEX is used to treat chronic graft versus host disease (cGVHD) and cutaneous T-cell lymphoma (CTCL).

For more information, see Section [1. Why am I using UVADEX?](#) in the full CMI.

2. What should I know before I use UVADEX?

Do not use if you have ever had an allergic reaction to UVADEX or any of the ingredients listed at the end of the CMI.

You have a condition which makes you unable to tolerate removal of large quantities of blood, such as heart disease or severe anaemia.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use UVADEX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with UVADEX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use UVADEX?

- UVADEX is administered by a specialist doctor in a hospital in a procedure known as photopheresis.
- Your doctor will administer UVADEX at the dose and duration of treatment required for your condition.

More instructions can be found in Section [4. How do I use UVADEX?](#) in the full CMI.

5. What should I know while using UVADEX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using UVADEX.• Contact your doctor if you become pregnant or experience an allergic reaction.
Things you should not do	<ul style="list-style-type: none">• Do not expose yourself to strong sunlight for 24 hours after receiving UVADEX treatment.
Driving or using machines	<ul style="list-style-type: none">• You should not drive or operate machinery immediately following treatment.
Drinking alcohol	<ul style="list-style-type: none">• You should not drink alcohol while using UVADEX particularly if you have some other diseases.• Discuss further with your doctor or pharmacist.
Looking after your medicine	<ul style="list-style-type: none">• UVADEX is administered in a hospital and will be stored in the hospital pharmacy.

For more information, see Section [5. What should I know while using UVADEX?](#) in the full CMI.

6. Are there any side effects?

Patients treated for cGVHD have experienced diarrhoea, low platelet count, nausea, headache, and high blood pressure. Other side effects that were reported from patients treated with UVADEX include anaemia, worsening of congestive heart failure, severe infection (sepsis), heart valve infection or inflammation, allergic reactions and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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[®]

Active ingredient(s): methoxsalen

Consumer Medicine Information (CMI)

This leaflet provides important information about using UVADEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using UVADEX.**

Where to find information in this leaflet:

- [1. Why am I using UVADEX?](#)
- [2. What should I know before I use UVADEX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use UVADEX?](#)
- [5. What should I know while using UVADEX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using UVADEX?

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.

UVADEX 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.

2. What should I know before I use UVADEX?

Warnings

Do not use 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 per mm³).
- 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.

Check with your doctor if you:

- 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.
- There is any possibility of you becoming pregnant.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

You should let your doctor know if there is a chance you are or may be pregnant or intend to become pregnant.

You should not be treated with UVADEX if you are breast feeding.

Use in children

UVADEX is not recommended for use in children.

Use in the elderly

There is no evidence of a requirement for reduction in frequency or duration of treatment with UVADEX in elderly patients.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with UVADEX and affect how it works.

Effects of UVADEX on other medicines

Some medications may interfere with UVADEX, because they are inactivated by the same mechanism as UVADEX, or because they bind to the same body structures as UVADEX.

Caffeine may not be eliminated from the body as quickly as normal while UVADEX is used. The pain reduction of paracetamol may be reduced while UVADEX is given. The concentration of other medicines may be increased and may lead to side effects from these medicines (e.g. dicoumarol, promethazine, tolbutamide and warfarin).

Medicines that may reduce the effect of UVADEX include:

- phenytoin used to treat epilepsy

Medicines that may increase your sensitivity to light after using UVADEX

- Special care should be exercised if you are receiving concomitant therapy (either topically or systemically) with known photosensitising agents.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect UVADEX.

4. How do I use UVADEX?

How much to use

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.

When to use UVADEX

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.

How UVADEX is used

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 reinfused to your body.

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

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 sunscreen and wear sunglasses (see above).

If you are given too much UVADEX

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.

If you think that you have been given too much UVADEX, you may need urgent medical attention.

You should immediately:

phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using UVADEX

Things you should do

- For 24 hours after a treatment, wear wrap-around UVA-blocking sunglasses all the time. If you must go outside, use a strong sunscreen and wear protective clothing that covers your skin when exposed to strong sunlight. Your skin may be more sensitive to sunlight after using UVADEX.
- Both men and women who are being treated with UVADEX should take adequate contraceptive precautions both during and after completion of photopheresis treatment.
- Call your doctor straight away if you:
 - Become pregnant
 - Experience an allergic reaction
 - Experience visual disturbances
 - Experience skin changes (e.g. skin burns)

Remind any doctor, dentist or pharmacist you visit that you are using UVADEX.

Things you should not do

- After receiving your treatment, avoid sunlight for at least 24 hours as your skin may be more sensitive to sunlight and UV light after using UVADEX. Do not go out in strong sunlight or use sunlamps, or other sources of ultraviolet (UV) light.

Driving or using machines

You should not drive or operate machinery immediately following treatment.

Drinking alcohol

Tell your doctor if you drink alcohol.

This product contains 4.1% w/v ethanol. Each 10 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.

Looking after your medicine

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Blood related:</p> <ul style="list-style-type: none"> • decreases in albumin, calcium, haemoglobin, potassium, red and white blood cell count and proportion of red blood cells • low platelet count <p>General body related:</p> <ul style="list-style-type: none"> • fever • headache <p>Heart related:</p> <ul style="list-style-type: none"> • fainting • high blood pressure <p>Muscle or pain related:</p> <ul style="list-style-type: none"> • pain in feet and hands • tiredness <p>Respiratory related:</p> <ul style="list-style-type: none"> • cough • difficulty breathing • respiratory infections • sinus infections <p>Skin related:</p> <ul style="list-style-type: none"> • rash • sensitivity to light <p>Stomach and digestive system related:</p> <ul style="list-style-type: none"> • altered taste • diarrhea • nausea • vomiting 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Your doctor will check your blood through regular testing</p>

Serious side effects

The side effects in the following table may have potentially serious outcomes.

Serious side effects	What to do
<p>Blood related:</p> <ul style="list-style-type: none"> • Anaemia (low red blood cells which may make you feel tired or short of breath) <p>Broad or affecting different parts of the body:</p> <ul style="list-style-type: none"> • allergic reactions • blood clots in a vein • heart valve infection or inflammation • severe infection (sepsis) • worsening of congestive heart failure 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What UVADEX contains

Active ingredient (main ingredient)	methoxsalen
Other ingredients (inactive ingredients)	propylene glycol, ethanol, glacial acetic acid, sodium acetate trihydrate, sodium hydroxide, sodium chloride and water for injections.
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What UVADEX looks like

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

(Aust R 308832)

Who distributes UVADEX

Ikaria Australia Pty Ltd
Ground Floor, 17 Cotham Road,
Kew, Victoria 3101
Phone: (03) 9851 9100
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