Package leaflet: Information for the patient

Methoxsalen G.L. Pharma 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 or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Methoxsalen G.L. Pharma is and what it is used for

The active substance in Methoxsalen G.L. Pharma is methoxsalen, a medicine which becomes active through UV radiation.
Methoxsalen is added to your white blood cells outside the body and activated by ultraviolet light (long-wave UV light). The white blood cells are then returned into your body. This process is called photopheresis. As a result of this process, diseased white blood cells can be destroyed.

Methoxsalen G.L. Pharma is used to alleviate the skin symptoms of the advanced stage of cutaneous T-cell lymphoma (a tumour occurring in the skin and caused by specific white blood cells known as T-lymphocytes) when other treatments have not been effective.

2. What you need to know before you are given Methoxsalen G.L. Pharma

Do not use Methoxsalen G.L. Pharma:
- if you are allergic to methoxsalen, related substances (psoralens) or any of the other ingredients of this medicine (listed in section 6)
- if you have skin cancer (for example melanoma or basalioma)
- if you have a disease associated with increased sensitivity to light, such as porphyria, systemic lupus erythematosus or albinism
- if you are sexually active and of childbearing age and have not yet taken any contraceptive measures
- if you have had an eye lens removed
- if you are pregnant or breast-feeding.

The photopheresis procedure must not be used:
- if your body cannot tolerate the temporary loss of blood caused by the treatment, for example due to heart disease or severe anaemia
- if your spleen has been removed
- if you have a blood clotting disorder
- if you have a high number of white blood cells (over 25,000/mm^3).

Warnings and precautions
Talk to your doctor before you are treated with Methoxsalen G.L. Pharma.

- If you normally take medicines that lower high blood pressure, you should wait until the end of photopheresis treatment before taking them.
- To ensure that the photopheresis procedure can be carried out effectively, the triglyceride level (a certain fat component) in your blood should be as low as possible. Your doctor will therefore instruct you to fast before each treatment.
- During Methoxsalen G.L. Pharma treatment sexually active men and women of childbearing age must use a suitable method of contraception.
- If you have liver problems, your doctor may arrange for monitoring of your liver values.

Important notes to prevent skin and eye damage
Methoxsalen G.L. Pharma will make your skin more sensitive to sunlight and sun-like artificial light. As the amount of medicine used in photopheresis treatment is very low, this side effect is rather unlikely to occur. Nevertheless, in order to minimise the risk of side effects, especially to the eyes and skin, you should not expose yourself to sunlight during the first 24 hours after photopheresis treatment.
During treatment with Methoxsalen G.L. Pharma and for 24 hours afterwards, you should wear special wrap-around, UVA-blocking sunglasses to protect your eyes from damage.

Tell your doctor if you have problems with your liver function, because you may need to continue these precautions against sunlight exposure for a longer period.

Children and adolescents (under 18 years)
Methoxsalen G.L. Pharma is not for use in children and adolescents as there is no sufficient experience available for this age group.

Other medicines and Methoxsalen G.L. Pharma
Tell your doctor if you are taking/using, have recently taken/used or might take/use any other medicines.

Phenytoin (a medicine used to treat seizures) may lead to a more rapid elimination of Methoxsalen G.L. Pharma from the body and thus reduce the effectiveness of photopheresis treatment.

The effect of Methoxsalen G.L. Pharma is influenced by substances which can also destroy cells or increase sensitivity to light. These include:
- other medicines used to treat skin diseases (for example anthralin, coal tar, griseofulvin, retinoids)
- various antibiotics (for example tetracyclines, fluoroquinolones) and chemotherapeutic agents (for example nalidixic acid, sulphonamides)
- medicines used to treat diabetes (sulphonylureas, particularly tolbutamide)
- diuretics (‘water tablets’, for example thiazides, furosemide)
- medicines with a calming and/or sedative effect (phenothiazines)
- certain medicines that affect blood clotting (oral anticoagulants derived from coumarin, halogenated salicylanilide derivatives)
- dyes (for example methylene/toluidine blue, rose bengal, methyl orange)
- medicines containing caffeine.

Methoxsalen G.L. Pharma with drink and alcohol
You should avoid drinking coffee or tea during Methoxsalen G.L. Pharma treatment. The substances which they contain (caffeine, theophylline) may prolong the duration of sensitivity to light.

You should avoid alcohol during Methoxsalen G.L. Pharma treatment because the effects of the ethanol (alcohol) contained in Methoxsalen G.L. Pharma may be increased by other medicines taken at the same time.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Methoxsalen G.L. Pharma must not be used during pregnancy and breast-feeding.

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

Driving and using machines

 Warning: This medicine may affect reactivity and the ability to drive.

You should not drive or use machines immediately after treatment.

Methoxsalen G.L. Pharma contains small amounts of ethanol (alcohol), less than 100 mg per millilitre. In extracorporeal therapy it can be expected that general effects on your body are limited. However, the prescribing doctor will monitor you for possible interactions with other medicines. Particular caution is required in patients with liver disorder, alcoholism, epilepsy, brain injury or brain disorder.

Methoxsalen G.L. Pharma contains less than 1 mmol **sodium** (23 mg) per millilitre, that is to say essentially ‘sodium-free’.

3. How to use Methoxsalen G.L. Pharma

This medicine is always administered by a specialist physician who is thoroughly familiar with handling Methoxsalen G.L. Pharma. Your doctor will decide how many treatment sessions you need.

Method of administration
Extracorporeal use (meaning: outside the patient’s body).

The content of the ampoule is never injected directly into the patient.

A professional specially trained in the administration of photopheresis will use a needle to draw a small amount of blood from one of your veins. This blood is separated into red blood cells, white blood cells and plasma. The red blood cells and most of the plasma are returned to your blood circulation during the procedure. The white blood cells and the remainder of the plasma will be mixed with an Methoxsalen G.L. Pharma dose individually calculated for you, exposed to radiation with UV light and then also returned to your body.

During administration of your treatment and for the next 24 hours, you must wear special wrap-around UVA-blocking sunglasses all the time to avoid damage to your eyes, which can lead to formation of cataracts.

Duration of treatment
During the first 3 months it is recommended to treat patients on 2 successive days every 2 to 4 weeks. Afterwards, the 2-day treatment cycles usually take place once every 3 to 4 weeks.

At the time of best treatment response, the intervals will slowly be extended to 4 to 8 weeks and treatment should then be continued every 8 weeks.

Photopheresis should be carried out for at least 6 months.
If you respond well to the treatment or if your illness does not worsen, photopheresis should be continued for 2 years or more.
If you do not respond to photopheresis treatment alone, your doctor may recommend another medicine additionally (for example interferon and/or bexarotene).

This is a general guideline. The treatment cycle may be adapted by your physician according to the individual symptoms and response.

The procedure takes about three to four hours in total, from the time your doctor places the needle until the time when all of your blood components have been returned to you.

Patients with impaired liver or kidney function
If you have liver or kidney problems, your doctor will probably check your blood count regularly; Methoxsalen G.L. Pharma has not been clinically tested in patients with impaired kidney or liver function.

After treatment
After receiving your treatment, you should avoid direct sunlight for at least 24 hours, as damage to the skin resulting from sunburn or, in the long term, premature aging of the skin are possible. If you must go outdoors, cover your skin, use a sun-blocking agent with a high sun protection factor and wear special sunglasses (see above).

If you are given more Methoxsalen G.L. Pharma than you should
An overdose is unlikely. However, if you have been given an overdose, you will have to stay in a darkened room for 24 hours or longer.

If you have any further questions on the use of this medicine, ask your doctor.

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)
- Infections
- Low blood pressure, dizziness
- Nausea, vomiting
- Venous access complications after repeated access to the veins (venipuncture)

Not known (frequency cannot be estimated from the available data)
- Changes in the eye as a result of exposure to light (phototoxic reactions) such as clouding of the eye lens (cataract formation) and inflammation of the middle layer of the eye (choroid) with subsequent inflammation of the retina (chorioretinitis)
- Changes in the skin due to exposure to light (phototoxic reactions) such as itching or skin redness
- Fever (mild fever may occur 2 to 12 hours after treatment)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Methoxsalen G.L. Pharma

Store in the original package in order to protect from light.

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 Methoxsalen G.L. Pharma contains
- The active substance is: methoxsalen. One ampoule of 5 ml contains 100 micrograms (µg) methoxsalen. One ml solution contains 20 micrograms methoxsalen.
- The other ingredients are: sodium chloride, ethanol 96%, water for injections.

What Methoxsalen G.L. Pharma looks like and contents of the pack
Clear, colourless solution.
The solution has a pH value of 5.0 to 7.0.

5 ml amber glass ampoules.
Pack sizes: packs of 5, 25, 50 and 5 x 25 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

G.L. Pharma GmbH
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