PATIENT INFORMATION LEAFLET

PUVA TREATMENT

using

Puvasoraleen 10mg Tablets (8-methoxypsoralen)

If you have any questions or are not sure about any aspect of your treatment please ask your dermatologist, nurse or staff of your phototherapy department for advice.

Date of preparation: June 2011
PATIENT INFORMATION

Puvasoralen 10mg Tablets
(8-methoxypsoralen)

Read all of this information carefully before using this medicine.

- Keep this information. You may need to read it again.
- If you have any further questions ask your dermatologist, doctor, nurse, pharmacist or phototherapy department.
- This medicine is prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this information please tell your dermatologist, doctor, nurse, pharmacist or phototherapy department.

Information includes:

1. What PUVA treatment is and what it is used for
2. Before you take Puvasoralen Tablets and start PUVA treatment
3. How PUVA treatment is conducted
4. Possible side effects
5. How to store Puvasoralen Tablets
6. Further Information

1. WHAT PUVA TREATMENT IS AND WHAT IT IS USED FOR

PUVA treatment is the combination of taking Puvasoralen Tablets (Psoralen) and then exposure to Ultra Violet (UV) A light, hence the name PUVA treatment.

Psoralens increase skin sensitivity to long wave UV A light.

Your dermatologist will decide if your skin condition is suitable for PUVA treatment using Puvasoralen Tablets.

2. BEFORE YOU TAKE PUVASORALEN TABLETS AND START PUVA TREATMENT

Do not take Puvasoralen Tablets and start PUVA treatment if the following applies to you:

- you are allergic (hypersensitive) to the active substance (8-methoxypsoralen) or any of the other ingredients
- you have or ever had skin cancer
- you have liver problems
- you are taking an anticoagulant (e.g. warfarin) to thin your blood
- you have or ever had porphyria (an enzyme deficiency), which can cause skin damage

Do not use Puvasoralen Tablets for children under 12 years of age.
Take special care and consult with your dermatologist before taking Puvasoralen Tablets and starting PUVA treatment if the following applies to you:

- If you are sensitive to sunlight and you have or ever had a severe rash/eruption on your skin when exposed to sunlight.
- Do not sunbathe and you must protect yourself against the sun with suitable clothes and sunscreens before, during and after your PUVA treatment.
- Unless you are advised it is safe to do so by the phototherapy department on the day of your treatment do not use any creams, ointments or toiletries as they may contain chemicals that may lead to a “sunburn effect” following PUVA treatment.

Taking other medicines

If you are taking an anticoagulant (a medicine to thin the blood) such as warfarin, or any other drug that has a photosensitising ability talk to your dermatologist or staff in the phototherapy department before starting PUVA treatment.

Puvasoralen Tablets will slow down the metabolism of caffeine and paracetamol.

Please tell your dermatologist or phototherapy staff if you are taking or have recently taken any other medicines including medicines you have bought without a prescription as some medicines can affect your sensitivity to UV A light.

Pregnancy and Breastfeeding

Ask your dermatologist for advice before using Puvasoralen Tablets or starting PUVA treatment.

Puvasoralen Tablets must not be used by pregnant women. Tell your doctor if you are pregnant, think you might be pregnant or trying to become pregnant before using Puvasoralen Tablets or starting PUVA treatment.

It is not known if Psoralen can pass into breast milk, so you must not breast feed while undergoing PUVA treatment.

Both men and women receiving PUVA treatment should use a reliable method of contraception during treatment and for 3 months after treatment has stopped unless you are advised otherwise by your dermatologist or staff in the phototherapy department.

3. HOW PUVA TREATMENT IS CONDUCTED

Your dermatologist will advise you on your treatment. Your treatment will be undertaken in a hospital or a suitable clinic.

Before starting PUVA treatment your dermatologist will perform some routine blood tests.

The number of Puvasoralen Tablets prescribed for your PUVA treatment will be based on your height and weight.

Puvasoralen Tablets must be taken 2 hours before your PUVA treatment. It is important you take your tablets on time as this is when your skin is most sensitive to UV A light.
The number of treatments required to treat your skin condition is dependent on your response to the PUVA treatment.

Puvasoralen Tablets must not be used more than once every five days because the full extent of phototoxic reactions may not be evident until 96 hours after exposure.

If you use more Puvasoralen Tablets than you should
Never use more Puvasoralen Tablets or undertake additional PUVA treatment than prescribed for you as it may result in burning or blistering of your skin after exposure to the UV A light.

If you miss a PUVA treatment
If a treatment is missed, the UV A light exposure time at the next treatment should not be increased. If more than one treatment is missed, the UV A light exposure will be reduced so it is important you attend regularly.

Take special care during PUVA treatment
The following precautions must be taken during your PUVA treatment:

- Eye protection
  Wear suitable UV protective glasses. Phototherapy department staff can advise on suitable glasses to be worn. The glasses should be large and fit close to your face.

- Lip protection
  The lips should be covered with a sun block prior to PUVA treatment.

- Male Patients
  Wear suitable protective (dark, closely woven) underpants (unless this is the treatment area).

Take special care after PUVA treatment
The following precautions must be taken after your PUVA treatment:

- Eye protection
  Wear the glasses immediately after Psoralen treatment (prior to UV A light) and for 12 - 24 hours after each treatment both inside and outside during daylight hours or under fluorescent lighting.

- Skin and Lip protection
  Do not expose the skin or lips to sunlight or sun lamps for at
least 24 hours after PUVA treatment. You may be more sensitive to sunlight for up to 3 days following PUVA treatment.

Cover as much of your skin with clothing (dark, closely woven) as possible.

The skin that is not covered and your lips should be treated with a sun block or high SPF sunscreen.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PUVA treatment can cause side effects although not everybody gets them.

Very common side effects include:
- Redness of the skin
- Itching of the skin
- Sickness or vomiting

Common side effects include:
- Headache
- Blistering/sunburn

Occasionally with Puvasoralen Tablets, nervousness, insomnia, dizziness and depression may be experienced.

If using proper eye protection, there is no evidence of an increase in the incidence of cataracts.

As with long term sun exposure, with prolonged use of PUVA treatment there is a risk of developing skin cancer. Therefore, the number of PUVA treatments you can have is limited in order to minimise your risk of developing skin cancer.

If any of the side effects gets serious, or if you notice any side effects not listed in this information, please tell your dermatologist, nurse or phototherapy department staff.

5. HOW TO STORE PUVASORALEN TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C. Store in original package. Keep blister in outer carton.

6. FURTHER INFORMATION

What Puvasoralen Tablets contains and looks like

Puvasoralen Tablets contains 10mg of the active ingredient 8-methoxypsoralen. Puvasoralen Tablets also contains lactose, maize starch, pregelatinised maize starch, stearic acid and magnesium stearate.

Puvasoralen Tablets are white round flat bevelled edge tablets with a break line on one side and can only be obtained from a hospital pharmacy.