Package Leaflet:
Information for the User

Acitretin 10 mg capsules

Acitretin 25 mg capsules

WARNING
CAN SERIOUSLY HARM AN UNBORN BABY
Women must use effective contraception
Do not use if you are pregnant or you think you may be pregnant

You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been 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 leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1 What Acitretin is and what it is used for

The name of your medicine is "Acitretin 10 mg Capsules" or "Acitretin 25 mg Capsules" but will be referred to as "Acitretin" throughout the leaflet.
Acitretin belongs to a group of medicines known as retinoids. Retinoids are derived from vitamin A.

The medicine is used to treat severe skin problems where the skin has become thick and may be scaly and which does not respond to other conventional treatments satisfactorily.

Acitretin is used to treat
- **extensive and serious forms of various skin disorders** resulting from disturbances of the outer layer of skin (the epidermis), such as psoriasis, together with a dry, scaling, waxy rash
- **specific skin disorders characterized by dry scales** as a result of marked keratinization (ichthyosis, an organic process by which keratin is deposited in cells and the cells become horny like nails and hair) and similar disorders in which a skin rash (pityriasis) or small elevations of skin and mucosa (lichen ruber) occur.

2 What you need to know before you take Acitretin

Do not take Acitretin
- **if you are pregnant** or **breast-feeding.**
- if there is a chance you could become pregnant, you must follow the precautions under "Pregnancy and prevention programme". See section on "Warnings and precautions"
- if your **liver** is not working properly.
- if your **kidneys** are not working properly.
- if you have very high levels of **fat or cholesterol** in your blood (also known as "hyperlipidaemia").
- if you use **other retinoid medicines** or medicines, vitamin supplements or foods that contain high levels of vitamin A (more than 5000 IU per day) (See "Other medicines and Acitretin").
- if you use an **antibiotic tetracycline**.
- if you use a medicine called **methotrexate** (a medicine that is used in the treatment of cancer, psoriasis and rheumatic diseases).
- if you use the so-called **mini-pill** (a contraceptive pill with only a low progesterone content).
- if you are **allergic** (hypersensitive) to acitretin or any of the other ingredients of this medicine (listed in section 6) or to other "retinoid" medicines. Hypersensitivity usually shows itself in the form of skin reactions, such as a rash, hives and/or itching.
- if you are a child.

If one or more of these warnings are applicable for you, talk to your doctor before taking Acitretin.

Warnings and precautions
- if you are a **blood donor**. You must not give blood while you are taking Acitretin or for 3 years after you stop taking it.
- if you receive **donor blood**. You must not receive donor blood from patients treated with acitretin if you are a woman of childbearing age.
- if you suffer from high levels of **sugar in the blood (diabetes)**. You will need to check your blood sugar levels more often when you start taking this medicine.
- if you drink **alcohol** (see "Pregnancy" and "Possible side effects"). Talk to your doctor about your alcohol use.
- if you notice that you have problems with your **vision**, especially in the dark (see "Driving and using machines").
- if you wear **contact lenses**. Acitretin causes dry eyes, therefore you have to wear glasses throughout the period of treatment.
- if Acitretin is to be used in **children**. Growth and bone development must be checked at regular intervals. In long-term treatment of children, the doctor must carefully weigh the possible severe side effects against the benefit of therapy with this medicine.
- if you are going out into **strong sunlight** or you are going to use a **sun bed**, Acitretin can make the effects of UV light on the skin stronger. In this case avoid too much sun and do not use a sun bed. Before going out in the sun, you must make sure you have adequate sun protection.
- if you have ever had **mental health problems** including depression, aggressive tendencies, mood changes or signs of psychosis (altered sense of reality, such as hearing voices or seeing things that are not there). This is because taking acitretin may affect your mood and mental health.

Talk to your doctor if any of the above warnings apply to you or have applied to you in the past.

Women who are pregnant must not take this medicine.
This medicine can seriously harm an unborn baby (the medicine is said to be 'teratogenic')
- it can cause serious abnormalities of the unborn baby's brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid gland). It also makes a miscarriage more likely. This may happen even if this medicine is taken only for a short time during pregnancy.
- You must not take this medicine if you are pregnant or if you think you might be pregnant.
- You must not take this medicine if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.
- You must not take this medicine if you could get pregnant during treatment.
- You must not get pregnant for 3 years after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed this medicine under strict rules. This is because of the risk of serious harm to the unborn baby
These are the rules:
- Your doctor must explain the risk of harm to the unborn baby - you must understand why you must not get pregnant and what you need to do to prevent getting pregnant.
- You must have talked about contraception (birth control) with your doctor. The doctor will give you information on how not to get pregnant. The doctor may send you to a specialist for contraception advice.
- Before you start treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with this medicine.

Women must use effective contraception before, during and after taking this medicine
- You must agree to use at least one very reliable method of contraception (for example an intra uterine device or contraceptive implant) or, two effective methods that work in different ways (for example a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.
- You must use contraception for a month before taking this medicine, during treatment and for 3 years afterwards.
- You must use contraception even if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).

Women must agree to pregnancy testing before, during and after taking this medicine
- You must agree to regular follow-up visits, ideally every month
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, every 1 to 3 months for 3 years after stopping treatment (unless your doctor decides that this is not necessary in your case).
- You must agree to extra pregnancy tests if your doctor asks you.
- You must not get pregnant during treatment or for 3 years afterwards because some medicine may still be left in your body.
- Your doctor will discuss all these points with you, using a checklist and will ask you (or a parent/guardian) to sign it. This form confirms that you have been told about the risks and that you will follow the rules above.

If you get pregnant while taking this medicine, **stop taking the medicine straight away**, and contact your doctor. Your doctor may send you to a specialist for advice.
Also if you become pregnant within 3 years after you stop taking this medicine, you should contact your doctor. Your doctor may send you to a specialist for advice.
Advice for men
The levels of oral retinoid in the semen of men taking this medicine are too low to harm their partners' unborn baby. However, you must never share your medication with anyone.
Additional precautions
You should never give this medicinal product to another person. Please take any unused capsules to your pharmacist at the end of treatment.
You should not donate blood during treatment with this medicine and for 3 years after stopping this medicine because an unborn baby could be harmed if a pregnant patient receives your blood.

Mental health problems
You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that this medicine could affect your mood and behaviour. They may notice these changes and help you to identify any problems that you need to talk to your doctor about.

Advice for all patients:

- Your doctor should have your blood tested to **check your liver function** before the start of treatment. Your blood must also be tested every week or every other week during the first 1 to 2 months after the start of treatment. After this, it should be tested at least every 3 months. If your liver seems to be working abnormally, this must be monitored every week. If this abnormal liver function results in early discontinuation of treatment, the liver function must be monitored for at least 3 months after stopping Acitretin therapy.
- If you suffer from **high levels of sugar in your blood (diabetes)**, if you have high levels of **fats** in your blood, if you are **overweight** or if you drink a lot of **alcohol** and are in long-term treatment, your blood must be checked for the amount of fats.
- Before treatment with Acitretin and during long-term therapy, your doctor will take **xrays of certain bones** at regular intervals (e.g. once a year) because this medicine may cause changes in your bones. If this applies to you, the doctor will discuss with you the advantages and disadvantages of continuation of therapy.

Please inform your doctor if you notice the following possible signs of bone changes: pain in bones, joints or muscles, restricted mobility.
- A serious condition which causes the small blood vessels (capillaries) to leak has been reported very rarely (Capillary Leak Syndrome/Retinoic Acid Syndrome). This can lead to severe hypotension (low blood pressure), oedema (build up of fluid leading to swelling) and shock (collapse).

- A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis) has been reported very rarely.

- Acitretin commonly increases blood fats, such as cholesterol or triglycerides which have been associated with pancreatitis. Tell your doctor if you experience severe pain in the abdomen and back (these can be signs of inflammation of the pancreas).

Other medicines and Acitretin
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription.
The effect of phenytoin (a medicine for epilepsy) may be increased by Acitretin. The dosage of phenytoin may need to be adjusted.

Do not take Acitretin together with:
- the **antibiotic tetracycline**, because increased pressure in the brain may occur.
- **methotrexate** (a medicine that is used in the treatment of cancer, psoriasis and rheumatic diseases), because this combination can cause inflammation of the liver.
- the so-called **mini-pill** (a contraceptive pill with only a low progesterone content). Acitretin may reduce the contraceptive effect, therefore you must not use these pills as a contraceptive together with Acitretin.

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- medicines or vitamin A supplements that contain **high levels of vitamin A** (more than 5000 IU per day).
- **other retinoid medicines** such as isotretinoin.

Acitretin with food and alcohol
You should not drink alcohol during treatment with Acitretin as the risk for side effects would be increased.
Girls and women of childbearing age **must not** drink alcohol at all during treatment with Acitretin and 2 months after stopping it (see **"Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby")**).

Pregnancy, breast-feeding and fertility
For more information on pregnancy and contraception, see section 2 "Pregnancy and prevention programme".

! Important information about some of the ingredients
This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially "sodium-free".

Driving and using machines
Your night vision may get worse during treatment. This can happen suddenly. In rare cases, this has continued after the treatment has stopped. Be careful if you are driving or using any tools or machines at night or in a tunnel (see "Warnings and precautions").

3 How to take Acitretin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Take Acitretin at a meal time, preferably with a drink of milk.
- Swallow each capsule whole. The dose varies from one patient to another. Your doctor will work out the right dose for you.

Adults and elderly people
- The usual starting dose for adults and elderly people is 25 mg or 30 mg once a day.
- After 2 to 4 weeks, your doctor may increase or decrease your dose. This will depend on how well it works and how it affects you.
- The maximum dose is 75 mg a day.
- Most people take Acitretin for up to 3 months. However, your doctor may decide that you need to take it for longer.

Use in children and adolescents
Acitretin is not normally given to children. If it is given to a child, the doctor will decide the correct dose. This is based on the child's weight. You can use additional local treatments of the skin, including skin care products, after consultation with your doctor.

If you take more Acitretin than you should
If you take more Acitretin than you should, you may suffer from headache, nausea and/or vomiting, drowsiness, irritability and itching.
Stop taking the medicine and consult your doctor immediately.

If you forget to take Acitretin
Do not take a double dose of Acitretin to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember and continue according to the dosing schedule. However, if it is nearly time for the next dose, skip the missed dose.

If you stop taking Acitretin
Your doctor can judge best if and how you must stop taking Acitretin. Always contact your doctor before you want to stop taking the medicine.

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

4 Possible side effects

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

- The side effects of Acitretin are dose related. The higher the daily dose, the greater the risk of side effects.
- Most side effects occur at the start of treatment when the dose still has to be adjusted. Most side effects are reversible after altering the dose or discontinuation of treatment.
- Occasionally the symptoms of your skin may get worse in the beginning of treatment.
- As Acitretin is a vitamin A derivative, most of its side effects are similar to the symptoms that occur if someone has used too much vitamin A.

Very common side effects
(affecting more than 1 of 10 patients treated)
- over 80% of patients experienced:

– dry skin and mucous membranes, dry lips and possibly inflamed lips.
- 40 – 80% of patients experienced:

– dry mucous membranes of the skin and nose
– peeling of the skin, especially the palms of the hands and soles of the feet
– inflammation of the nasal mucosa.
- 10 – 40% of patients experienced:

– nose bleed
– scaling and thinning of healthy skin with increased sensitivity
– reddening of the skin
– itching
– sensation of "burning skin"
– sensation of "sticky skin"
– inflammatory skin changes
– hair loss
– swelling and pain in the area around your nails
– fragile nails
– inflammation of the eye (conjunctivitis)
– feeling more thirsty than usual
– feeling cold.

Using moisturisers or "emollients" from the start of treatment can help you to deal with dry skin problems.

Side effects of the skin and mucous membranes occur rather soon (a few days) after start of treatment, hair loss cannot be expected until several weeks into the treatment.

These side effects are reversible after altering the dose or discontinuation of treatment. However, new growth of hair will take some months, due to the hair growth cycle.

Common side effects
(affecting 1 to 10 of 100 patients treated)
- chapping
- inflammation of oral mucosa and gums
- blisters on skin
- changes in skin and hair colour
- change in the growth rate and texture of hair
- visual disturbances such as dry eye, blurred vision, impaired night vision. Wearing of contact lenses might become impossible.

For this reason you should wear glasses before treatment with Acitretin (see "Warnings and precautions").

Uncommon side effects
(affecting 1 to 10 of 1,000 patients treated)
- muscle, joint and bone pain After long-term treatment with Acitretin, bone changes may occur (extra growth on the surface of your bones, thinning of bones, reduced bone density [osteoporosis], premature stop of bone growth) and calcifications in soft tissues (ligaments and tendons) (see "Warnings and precautions").
- increased retention of water in the body (oedema)
- sensation of heat
- changed sense of taste
- headache.

Rare side effects
(affecting 1 to 10 of 10,000 patients treated)
- increased sensitivity of the skin to sunlight, as a result of which sunburn can occur after only a brief exposure to the sun
- inflammations or ulcers of the cornea
- gastro-intestinal troubles (e.g. nausea, vomiting, abdominal pain, diarrhoea, digestive disorders)
- inflammation of the liver (hepatitis) and jaundice
- increased pressure in the brain (pseudotumor cerebri).

Symptoms can include severe headache, nausea, vomiting and blurred vision. **If you experience these symptoms immediately stop taking the medicine and contact your doctor.**

Not known
(frequency cannot be estimated from the available data)
- A serious condition which causes the small blood vessels (capillaries) to leak (Capillary Leak Syndrome/Retinoic Acid Syndrome). This can lead to severe hypotension (low blood pressure), oedema (build up of fluid leading to swelling) and shock (collapse).
- Changes in the sound of the voice (dysphonia).
- A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis).
- Altered mood.
- Signs of psychosis: altered sense of reality, such as hearing voices or seeing things that are not there.
- Loss of eyelashes or eyebrows (madarosis).
- Immediate allergic reaction with symptoms such as skin rash, swelling or itching of the skin, red and swollen eyes, severe nasal congestion, asthma or wheezing. The reaction can be minor to life-threatening.

Other side effects observed during treatment with Acitretin

- increased occurrence of vaginal infection (also known as Candida or thrush)
- increased levels of liver enzymes
- increased levels of fats and cholesterol in the blood.

These changes are particularly seen in patients with a disposition to increased fatty acid levels, (diabetes, obesity, alcohol misuse or disturbance of fat metabolism), but they are not of a lasting nature and may be treated by dietary means. However, potential arterial stenosis (when the carotid arteries become narrow or blocked) due to the increased fatty acid and cholesterol levels cannot be excluded.

Reporting of side effects
If you get any side effects, talk to your doctor, 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 at: 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 Acitretin

Keep out of the sight and reach of children. Do not use the medicine after the expiry date which is stated on the carton and blister label after EXP. The expiry date refers to the last day of that month.
Do not store above 30°C. Store in the original package, in order to protect from moisture. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Acitretin contains
The active substance is acitretin.
Acitretin 10 mg capsule: Each hard capsule, contains 10 mg acitretin.
Acitretin 25 mg capsule: Each hard capsule, contains 25 mg acitretin.

The other ingredients are:
Capsule filling:
– Maltodextrin
– Sodium ascorbate
– Microcrystalline cellulose
Capsule shell:
– Gelatin
– Propylene glycol (E1520)
– Sodium laurilsulfate
– Titanium dioxide (E171)
– Iron oxide yellow (E172)
– Iron oxide black (E172)
– Iron oxide red (E172)
– Purified water
– Shellac

What Acitretin looks like and contents of the pack
Acitretin 10 mg capsules consist of a white to off-white body and a brown cap printed in black with "A10" on the capsule body and filled with a yellow powder.

Acitretin 25 mg capsules consist of a yellow to light yellow body and a brown cap printed in black with "A25" on the capsule body and filled with a yellow powder.
The capsules are packaged in PVC/PVDC aluminium blister packs.

Pack sizes: 30 and 60 hard capsules.
Not all pack sizes may be marketed.

POM
PL 06831/0251 Acitretin 10 mg Capsules
PL 06831/0252 Acitretin 25 mg Capsules

Marketing Authorisation Holder and Manufacturer
Genus Pharmaceuticals Linthwaite, Huddersfield, HD7 5QH, UK.
Detailed and updated information is available on the following URL:
www.medicines.org.uk/emc/rmm/1430/Document

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