

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

▼ This medicinal product 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. 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
- 2 What you need to know before you take Acitretin
- 3 How to take Acitretin
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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 or mood changes. This is because taking this product may affect your mood.

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).

please turn over ►



