

Acitretin

10 mg and 25 mg Capsules

WARNING**CAN SERIOUSLY HARM AN UNBORN BABY**

Women must use effective contraception
Do not use if you are pregnant or think you may be pregnant

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 Acitretin is and what it is used for
2. What you need to know before you take Acitretin
3. Important information for women
4. 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 10mg Capsules or Acitretin 25mg Capsules but will be referred to as Acitretin throughout this leaflet.

Acitretin Capsules contains a medicine called acitretin. This belongs to a group of medicines called 'retinoids'. Acitretin is used to treat severe skin problems where the skin has become thick and maybe scaly. These skin problems include psoriasis, ichthyosis and keratosis follicularis (Darier's disease). It works by making your skin grow more normally.

Acitretin is normally used while under the care of a specialist dermatologist (skin doctor).

2. What you need to know before you take Acitretin**Do not take Acitretin:**

- If you are pregnant or breast-feeding.
- If there is any chance you could become pregnant, you must follow the precautions under "Pregnancy and prevention programme", see section on "Warnings and precautions".
- If you **might get pregnant while taking Acitretin or within 3 years of stopping it** (see Section 3: 'Important information for women'),
- If you are taking an antibiotic called tetracycline (for an infection) or a medicine called methotrexate (for skin problems, arthritises or cancer). See Section 2: 'Other medicines and Acitretin',
- If you are taking other retinoid medicines; or medicines, vitamin supplements or foods that contain Vitamin A (see Section 2: 'Other medicines and Acitretin'),
- If you have kidney or liver problems,
- If you have very high levels of fat in your blood (also known as 'hyperlipidaemia').

Do not take Acitretin Capsules if you are allergic to:

- Acitretin or any of the other ingredients of this medicine (listed in section 7).
- Other 'retinoid' medicines. These include isotretinoin and tazarotene.

Do not take Acitretin if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Acitretin.

PREGNANCY AND PREVENTION PROGRAMME:**Women who are pregnant must not take Acitretin:**

- 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 Acitretin is taken only for a short time during pregnancy.
- You must not take Acitretin if you are pregnant or if you think you might be pregnant.
 - You must not take Acitretin if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.
 - You must not take Acitretin 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 Acitretin 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 Acitretin.

Women must use effective contraception before, during and after taking Acitretin:

- 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 Acitretin, 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 Acitretin:

- 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 Acitretin (unless your doctor decides 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 Acitretin, **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 Acitretin, 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 Acitretin 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 Acitretin capsules to your pharmacist at the end of treatment.

Warnings and precautions

Talk to your doctor or pharmacist before taking Acitretin 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 Acitretin.
- You have high levels of fat in your blood, you are obese, drink a lot of alcohol or at risk of heart problems. Your doctor may need to do blood tests while you are taking Acitretin to check the amount of fat and/or sugar in your blood and check your blood pressure.
- 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. Before going out into strong sunlight apply a sunblock to exposed skin.
- You have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking Acitretin may affect your mood.

Advice for all patients:

Acitretin commonly increase 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).

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 may affect your liver function. Your doctor may need to do blood tests whilst you are taking this medicine to check your liver function.

Acitretin may cause increased pressure in the head. You should tell your doctor if you experience severe headaches, feeling or being sick or changes in sight. Your doctor may carry out further checks.

Acitretin may cause changes in bone growth. You should tell your doctor if you feel pain in your muscles or bones. Your doctor may carry out further checks.

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 identify any problems that you need to talk to your doctor about.

High doses of Acitretin can cause mood changes such as irritability, aggression, depression.

Hair loss is a very common side effect of Acitretin.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Acitretin.

Children

Acitretin should not be given to children. Acitretin may cause changes in bone growth in children.

Other medicines and Acitretin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Acitretin can affect the way some other medicines work. Also, some other medicines can affect the way Acitretin works.

Do not take Acitretin, and tell your doctor or pharmacist, if you are taking any of the following medicines:

- An antibiotic called tetracycline (for an infection).
- A medicine called methotrexate (for skin problems, arthritis or cancer).
- Medicines or vitamin supplements that contain Vitamin A.
- Other retinoid medicines, such as isotretinoin or tazarotene.

Tell your doctor or pharmacist if you are taking the following medicine:

- Phenytoin (used to treat epilepsy).
- Low dose progesterone only contraceptives ('minipills').

Acitretin with food, drink and alcohol

Women of childbearing potential should not consume alcohol (in drinks, food or medicines) during treatment with Acitretin and for 2 months after cessation of therapy. Concurrent ingestion of Acitretin and alcohol may result in formation of a compound (etretinate), which may be harmful to an unborn child, and if formed takes some time for it to be totally removed from the body.

Driving and using machines

Your vision may be affected, particularly at night time, while you are taking Acitretin. Be careful if you are driving or using any tools or machines.

Important information for blood donors

You should not donate blood during treatment with this medicine and for 3 years after stopping Acitretin because an unborn baby could be harmed if a pregnant patient receives your blood.

Important information about Acitretin Capsules

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. Important information for women

Acitretin will damage an unborn baby. The following instructions must be strictly followed, even if you have fertility problems:

Pregnancy, breast-feeding and fertility

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

Birth control (contraception) and pregnancy tests

If you are a female patient at an age where you could get pregnant:

- **You must use an effective method of birth control** (contraception) for at least 1 month before you start taking Acitretin, while you are taking it, and for 3 years after you stop taking it.
- Your doctor will want you to **have a pregnancy test** about 2 weeks before starting treatment, which must be negative. You may also be asked to have regular pregnancy tests while you are taking Acitretin.
- Start taking Acitretin **after the negative pregnancy test**, on the second or third day of your next period.
- While you are taking Acitretin, and for 3 years after stopping it, **contact your doctor straight away if you get pregnant or think you may be pregnant**.

If you have any questions about these instructions, talk to your doctor or pharmacist before taking Acitretin.

4. 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, or with a glass 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 recommended 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. You must not take Acitretin for more than 6 months at a time.

Use in children

Acitretin should not be 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.

If you take more Acitretin than you should

If you take more Acitretin than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: a bad headache, dizziness, feeling or being sick, being sleepy or irritable or having itchy skin.

If you forget to take Acitretin

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Acitretin

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

If someone else takes your Acitretin Capsules by mistake, they should talk to a doctor or go to a hospital straight away.

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

5. Possible side effects

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

You will probably have some side effects during treatment with Acitretin, even before you see your skin starting to get better. These effects often wear off as your treatment continues. Your doctor can help you to deal with them.

Stop taking Acitretin and see a doctor straight away if you experience the following side effects:

- Immediate allergic reaction with symptoms such as skin rash, swelling or itching of the skin, swelling of the face, lips, throat or tongue, red and swollen eyes, severe nasal congestion, asthma or wheezing. The reaction can be minor to life-threatening.
- A severe headache.
- Feeling or being sick.
- Problems with your eye sight.
- You feel any aches and pains in your muscles, bones or joints. This may mean you have extra growth on the surface of your bones. This can happen if you take Acitretin for a long time.

Your doctor may want to check you regularly to find out if this is happening. These checks are particularly important if a child is taking Acitretin.

Other possible side effects:

Very common (may affect more than 1 in 10 people):

- dry, irritated or swollen eyes, which may lead to intolerance of contact lenses,
- dry, irritated or runny nose, nose bleeding,
- dry mouth, thirst,
- dryness or inflammation of the lips, which may be alleviated by application of a fatty ointment. Itching, hair loss, peeling of the skin from the palms of hands or the soles of the feet or even rest of the body,
- changes in how the liver is working (shown by blood test),
- increased levels of fats in your blood (shown by blood test).

Common (may affect up to 1 in 10 people):

- headache,
- inflammation of the mucous tissue of the mouth, abdominal pain, diarrhoea, feeling sick, being sick,
- fragile skin, sticky feeling on the skin or a rash, skin inflammation, changes to the texture of the hair, brittle nails, skin infection around a nail, redness of the skin,
- joint pain, muscle pain,
- swelling of hands, ankles and feet.

Uncommon (may affect up to 1 in 100 people):

- dizziness,
- blurred vision,
- inflammation of the gums,
- inflammation of the liver,
- fissures, cracks or fine linear scars in the skin e.g. around the mouth (rhagades), blisters and inflammation of the skin (dermatitis bullous), skin being more sensitive to the sun (photosensitivity reaction).

Rare (may affect up to 1 in 1,000 people):

- damage to the peripheral nervous system, which may include symptoms like muscle weakness, numbness and tingling in the feet and hands or burning, stabbing or shooting pain.

Very rare (may affect up to 1 in 10,000 people):

- increased blood pressure in the skull,
- night blindness, inflammation of the cornea in the eye (ulcerative keratitis),
- yellowing of the skin or the whites of the eyes (jaundice),
- bone pain, changes in bone growth.

Side effects with unknown frequency:

- infection of the vagina (also known as candida or thrush),
- impaired hearing, ringing in the ear (tinnitus),
- 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),
- flushing; sweating, skin redness on the face,
- changes in the way things taste; bleeding in the rectum,
- a serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis),
- small, reddish bumps or nodules on the skin that may bleed easily (pyogenic granuloma), scaling or thinning of the skin,
- cracks or scaring at the corners of the mouth,
- loss of eyelashes or eyebrows (madarosis),
- improved or worsened glucose tolerance in diabetic patients,
- general unwell feeling, drowsiness,
- swelling of the face, lips, throat or tongue (angioedema),
- severe itchy skin rash with pale or red irregular raised patches (hives),
- changes in the sound of the voice (dysphonia).

An initial worsening of psoriasis symptoms is sometimes seen at the beginning of the treatment period.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

6. How to store Acitretin

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 and blister after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

7. Contents of the pack and other information

What Acitretin Capsules contain

The active substance is acitretin.

Acitretin 10mg Capsule: Each capsule contains 10mg acitretin.

Acitretin 25mg Capsule: Each capsule contains 25mg acitretin.

The other ingredients are:

- Capsule filling containing disodium edetate, maltodextrin, cellulose microcrystalline, poloxamer 407, purified water and sodium ascorbate.
- Capsule shell containing gelatin, titanium dioxide (E171), iron oxide yellow (E172), iron oxide black (E172) and iron oxide red (E172).
- Printing Ink - White containing shellac, titanium dioxide (E171), isopropyl alcohol, N-butyl alcohol and propylene glycol (E1520).

What Acitretin Capsules look like and contents of the pack

Acitretin 10mg Capsules are brown opaque/white opaque size '4' hard gelatin capsules imprinted with 'U68' in white ink on cap containing yellow granular powder.

Acitretin 25mg Capsules are brown opaque/yellow opaque size '1' hard gelatin capsules imprinted with 'U69' in white ink on cap containing yellow granular powder.

The capsules are packaged in aluminium blister packs. Pack sizes: 10, 20, 28, 30, 56, 60, 100 and 120 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Detailed and updated information on this product is available by scanning the QR code included in the PL with a smartphone. The same information is also available on the following URL: www.morningsidehealthcare.com/acitretin and www.mhra.gov.uk.

QR code:

