
SCHEDULING STATUS

S5

ACITRETIN 10 PHARMC capsules

ACITRETIN 25 PHARMC capsules

Acitretin

Sugar free

Read all of this leaflet carefully before you start taking ACITRETIN PHARMC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ACITRETIN PHARMC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ACITRETIN PHARMC is and what it is used for
2. What you need to know before you take ACITRETIN PHARMC
3. How to take ACITRETIN PHARMC
4. Possible side effects
5. How to store ACITRETIN PHARMC
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1. What ACITRETIN PHARMC is and what it is used for

ACITRETIN PHARMC contains a medicine called acitretin. It belongs to a group of medicines called retinoids.

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

2. What you need to know before you take ACITRETIN PHARMC

Do not take ACITRETIN PHARMC:

- If you are pregnant or breastfeeding your baby. ACITRETIN PHARMC can seriously harm an unborn baby (see below *Important information for women* under "Warnings and precautions").
- If you might get pregnant while taking ACITRETIN PHARMC or within 3 years of stopping it (see below: *Important information for women* under "Warnings and precautions").
- If you are hypersensitive (allergic) to acitretin or any of the other ingredients of ACITRETIN PHARMC (listed in section 6).
- If you are allergic to other 'retinoid' medicines. These include isotretinoin and tazarotene.
- If you have liver or kidney problems.
- If you have very high levels of fat in your blood (also known as hyperlipidaemia).
- If you are taking microdosed progesterone preparations or "minipills".
- If you have hypervitaminosis A, a disorder where there is too much vitamin A in your body.
- If you are younger than 18 years old.
- If you are taking an antibiotic called tetracycline (for an infection) or a medicine called methotrexate (for skin problems, arthritis or cancer).

Warnings and precautions

Important information for women

- This medicine can seriously harm an unborn baby (the medicine is teratogenic). It can cause serious abnormalities in an unborn baby.
- ACITRETIN PHARMC is contraindicated in pregnant women and women who might potentially become pregnant.
- Women have to start using a very effective form of contraception at least month before they start taking the medicine and they must continue with the contraceptive for at least 3 years after the medicine has been stopped.
- Ideally you should only take this medicine for 30 days before going back to the doctor for a check-up. The doctor will perform a pregnancy test and rule out any possibility of a pregnancy before the next cycle of medicine can be started.

Take special care with ACITRETIN PHARMC. Check with your doctor or pharmacist before taking ACITRETIN PHARMC:

- If you have diabetes. You will need to check your blood sugar levels more often when you start taking ACITRETIN PHARMC.
- If you have high levels of fat in your blood or you are obese or drink a lot of alcohol. Your doctor may need to do blood tests while you are taking ACITRETIN PHARMC to check the amount of fat in your blood.
- If you are going out in strong sunlight or you are going to use a sun bed. ACITRETIN PHARMC can make the effects of UV light on the skin stronger. Before going out into strong sunlight apply a sunblock to exposed skin.
- If you have ever had any mental health problems including depression, aggressive tendencies or mood changes.
- If you experience increased pressure in the head. You should tell your doctor if you experience severe headaches, feeling or being sick or changes in sight.
- A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (exfoliative dermatitis) has been reported very rarely.

- 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).
- ACITRETIN PHARMC 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 PHARMC may cause changes in bone growth. You should tell your doctor if you feel pain in your muscles or bones.
- Patients should not donate blood while taking ACITRETIN PHARMC or for at least 3 years after stopping treatment.
- Night vision might be affected and patients should be careful not to drive at night if they experience this.
- Hair loss (alopecia) is a very common side effect.

Children and adolescents

ACITRETIN PHARMC should not be given to children or adolescents under the age of 18 years or until their bone development is complete.

Other medicines and ACITRETIN PHARMC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are already taking any of the following as they may interact with ACITRETIN PHARMC:

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

- Phenytoin (used to treat epilepsy).

ACITRETIN PHARMC with food, drink and alcohol

The capsules should be taken preferably with a meal, or with some milk.

Women of childbearing potential should not consume alcohol (in drinks, food or medicines) during treatment with ACITRETIN PHARMC and for 2 months after cessation of therapy. Concurrent ingestion of ACITRETIN PHARMC 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.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

ACITRETIN PHARMC is contraindicated during pregnancy and breastfeeding. See “Do not take ACITRETIN PHARMC” and “Warnings and precautions”.

Driving and using machines

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

3. How to take ACITRETIN PHARMC

Do not share medicines prescribed for you with any other person.

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

Your doctor will tell you how long your treatment with ACITRETIN PHARMC will last.

If you have the impression that the effect of ACITRETIN PHARMC is too strong or too weak, tell your doctor or pharmacist.

Take ACITRETIN PHARMC at a meal time or 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 (1 capsule; 25 mg) or 30 mg (3 capsules; 10 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.

Children

ACITRETIN PHARMC therapy in children under 18 years of age is contraindicated (see Do not take ACITRETIN PHARMC).

If you take more ACITRETIN PHARMC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine pack with you.

If you forget to take ACITRETIN PHARMC

If you forget to take a dose of ACITRETIN PHARMC, take it as soon as you remember. Do not take a double dose to make up for forgotten doses.

If you stop taking ACITRETIN PHARMC

Do not stop taking ACITRETIN PHARMC unless your doctor tells you to.

4. Possible side effects

ACITRETIN PHARMC can have side effects.

Not all side effects reported for ACITRETIN PHARMC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACITRETIN PHARMC, please consult your health care provider for advice.

If any of the following happens, stop taking / using ACITRETIN PHARMC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, mouth, throat, face, lips or eyes,
- shortness of breath or wheezing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to ACITRETIN PHARMC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- a severe headache,
- feeling or being sick,
- problems with your eye sight,
- if 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 PHARMC for a long time.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- 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),
- 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.

Less frequent

- 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),
- 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,
- 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.

Frequency unknown

- 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),
- improve or worsen 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).

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Health care providers are asked to report any suspected adverse reactions to

SAHPRA via the “6.04 Adverse Drug Reactions & Quality Problem Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of ACITRETIN PHARMC.

5. How to store ACITRETIN PHARMC

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from moisture.
- Do not use after the expiry date stated on the blister / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACITRETIN PHARMC contains

- The active substance is acitretin. Each ACITRETIN PHARMC capsule contains either 10 mg acitretin or 25 mg acitretin. Sugar free.
- The other ingredients are maltodextrin, microcrystalline sodium and sodium ascorbate.
- The capsule shell is made up of gelatin, iron oxide red (E172), iron oxide yellow (E172 – in ACITRETIN PHARMC 25 mg only), purified water, sodium lauryl sulphate and titanium dioxide.
- The ink used for the printing is made up of Iron oxide black (E172), propylene glycol and shellac glaze.

What ACITRETIN PHARMC looks like and contents of the pack

ACITRETIN 10 PHARMC - Hard gelatin capsule containing a yellow powder with a white to off-white body and a brown cap printed in black with “A 10” on the capsule body.

Each carton contains 1, 2, 3, 5, 6 or 10 PVC/PVDC/aluminium blister strips containing 10 capsules/strip.

ACITRETIN 25 PHARMC - Hard gelatin capsule containing a yellow powder with a yellow to light yellow body and a brown cap printed in black with "A 25" on the capsule body.

Each carton contains 1, 2, 3, 5, 6 or 10 PVC/PVDC/aluminium blister strips containing 10 capsules/strip.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pharmacorp (Pty) Ltd.

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RSA

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Access to the corresponding Professional Information

Available on the SAHPRA website