

PATIENT INFORMATION LEAFLET

ACITRET CAPSULE 10mg (Acitretin Capsules BP 10mg)

ACITRET CAPSULE 25mg (Acitretin Capsules BP 25mg)

301xxxx

180 mm

XXXXXX PIL-Acitrein Booklet with Cov Pg_v4

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PATIENT INFORMATION LEAFLET

ACITRET CAPSULE 10mg (Acitretin Capsules BP 10mg)
ACITRET CAPSULE 25mg (Acitretin Capsules BP 25mg)

Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything, ask your dermatologist or alternatively your doctor or pharmacist.

What is ACITRET CAPSULE 10mg/25mg?

ACITRET CAPSULE 10mg/25mg contains the active ingredient acitretin. Two strengths are available:

- Acitretin Capsules BP 10mg:

Brown opaque/ white opaque size ‘4’hard gelatin capsules imprinted with ‘U68’ in white ink on cap containing yellow granular powder.

- Acitretin Capsules BP 25mg:

Brown opaque/ yellow opaque size ‘1’hard gelatin capsules imprinted with ‘U69’ in white ink on cap containing yellow granular powder.

Acitretin is one of a group of medicines known as retinoids which are usually used to treat skin problems.

What is ACITRET CAPSULE used for?

This medicine is used to treat skin problems characterized by the thickening and shedding of skin, such as psoriasis and severe disorders of keratinization which includes ichthyosis, pityriasis rubra pilaris and Darier’s disease.

To help you get the full benefits from this medicine you should read this leaflet carefully and ask your doctor to explain anything you do not understand.

PRE-MEDICATION ASSESSMENT

Your dermatologist will usually perform a full physical examination and request blood tests to ensure you are suitable to benefit from taking ACITRET CAPSULE.

When must ACITRET CAPSULE NOT be used?

- If you are pregnant or think you may be pregnant
- If you are breast-feeding
- If you are planning to get pregnant in the next 3 years
- If you have very high fat levels in your bloods (lipid disorder)
- If you are allergic to ACITRET CAPSULE or any of the ingredients it contains

Inform your doctor if you are taking any other drugs or medication.

ACITRET CAPSULE must **NOT** be taken during pregnancy

IMPORTANT

Female patients in the reproductive age group must strictly follow these instructions

- You must use an effective method of birth control for one month before treatment, during treatment and for three years after treatment ends. Before you start treatment, your doctor will determine that you are not pregnant. You should start taking ACITRET CAPSULE on the second or third day of your menstrual cycle.
- You must not become pregnant at any time during treatment and for three years after treatment ends.
- Contact your dermatologist immediately if you do become pregnant or think you may be pregnant during treatment or in the three years after treatment ends.

Inform your doctor if:

- there is a family history of high triglyceride levels in the blood.
- there is a family history of diabetes mellitus.
- you have or have had a liver disease. Inform your doctor of all your major medical events. The above information will enable your doctor to determine if you are suitable to receive ACITRET CAPSULE or if special advice is needed before taking ACITRET CAPSULE.
- Special note for blood donors. You should not donate blood either during or for at least three years after ACITRET CAPSULE treatment.

Talk to your doctor before taking ACITRET CAPSULE:

If you have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking ACITRET CAPSULE may affect your mood.

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.

How should ACITRET CAPSULE be taken?

- Acitret Capsules to be taken orally once daily with a meal, or with milk.
- Always take the capsules as your doctor tells you to. The duration and dose of the treatment will depend on your body weight, severity of your skin condition and response to the treatment.
- You will usually be on a dose of between 25mg and 50mg a day. The average treatment duration is 2-4

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weeks for initial daily dosage followed by further 6-8 weeks for maintenance dose.

- The capsules should be taken at mealtimes with a drink. Swallow the capsules whole, do not suck or chew them.
- If you miss a dose, take it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not double a dose.
- When your skin has improved, your doctor will probably lower the dose and stop giving you ACITRET CAPSULE. If your condition relapses after clearing, your doctor may prescribe a second course.

What are the possible unwanted effects of ACITRET CAPSULE?

You will probably have some unwanted reactions to your treatment, even before you see your skin getting better. These effects will stabilize as your treatment continues and your doctor can help you deal with them. The unwanted effects of ACITRET CAPSULE will disappear when you stop your treatment. If the side effects are troublesome, discuss with your doctor.

- **Dryness of the lips** will be experienced earliest. Can be prevented by using lip balm frequently.
- **Dryness of the skin** associated with itching and rash. Avoid soaps and hot showers. Use shower gel/ oil and emollient.
- **Drying of the inside** of the nose. Smearing a thin layer of petroleum jelly on the inside of the nose will help.
- **Skin fragility.** Your skin may also break more easily during therapy. Use emollients.
- **Dry eyes.** Your eyes may feel dry and slightly irritated. This may be a problem if you wear contact lenses. Ask your doctor to suggest some suitable eye drops to help.
- **Sensitivity to sunlight while taking ACITRET CAPSULE.** Avoid too much sun. Before going into strong sunlight, apply a sun block and use adequate protection (like hats, umbrellas).
- **Hair loss.** Some patients may notice changes in hair texture or hair loss after taking the medicine for a while. This is only temporary. Hair should return to normal after the treatment ends.
- **Muscle aches and pains.** Some people have muscle aches and pains when they are taking this medicine. These will normally be relieved by avoiding vigorous exercise. However, if the muscle aches or joint pains are troublesome inform your doctor.
- Other less common unwanted effects reported include headaches, tiredness, nausea, sweating,

peeling of skin of arms and legs, poor night vision, blurred vision, gum disease, nail fragility, infections round the base of the nail, thrush, jaundice and liver disease in patients while taking ACITRET CAPSULE.

- If you have any questions about these or any other unwanted effects, talk to your doctor.

What to do if you take more ACITRET CAPSULES than you should?

If you take more Acitret Capsules than you should, stop taking Acitret immediately and seek medical attention. 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.

What ACITRET CAPSULE look like and composition?

Acitretin Capsules BP 10mg:

Brown opaque/ white opaque size ‘4’hard gelatin capsules imprinted with ‘U68’ in white ink on cap containing yellow granular powder.

Acitretin Capsules BP 25mg:

Brown opaque/ yellow opaque size ‘1’hard gelatin capsules imprinted with ‘U69’ in white ink on cap containing yellow granular powder.

Composition

Each Capsule contains
Acitretin Ph.Eur. 10mg / 25mg

Excipients:

Maltodextrin, Cellulose Microcrystalline, Sodium Ascorbate, Disodium Edetate, Poloxamer 407, Capsule shell (contains Gelatin, Titanium dioxide, Red Iron Oxide, Yellow iron oxide and Black iron oxide), OPACODE Monogramming INK S-1-18086 White (contains Shellac Glaze-45%, Titanium Dioxide, Isopropyl Alcohol, N-Butyl Alcohol and Propylene Glycol)

How should ACITRET CAPSULE be stored?

The capsules should be stored in the original package.

Do not store above 30°C.

Keep this medicine out of reach of children, in a safe place.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours

Product Registrant:

Goldplus Universal Pte Ltd
103 Kallang Avenue #06-02
Singapore 339504

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