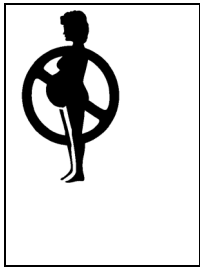


PATIENT INFORMATION LEAFLET

Roaccutane causes severe birth defects. Do not use in pregnancy.

It is a criminal act to give Roaccutane to any person who does not have a valid prescription.

Please read this leaflet carefully before you use Roaccutane Capsules. This leaflet does not tell you all the information known about Roaccutane Capsules. If you have any questions or are worried about any of this information, please speak to your doctor or pharmacist.

SCHEDULING STATUS

S5

Roaccutane® 10 mg and Roaccutane® 20 mg; soft gelatin capsules

Isotretinoin

Contains sugar (sorbitol and mannitol)

Read all of this leaflet carefully before you start taking Roaccutane

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Roaccutane 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 Roaccutane is and what it is used for
2. What you need to know before you are take Roaccutane
3. How to take Roaccutane
4. Possible side effects
5. How to store Roaccutane
6. Contents of the pack and other information

1. What Roaccutane is and what it is used for

Roaccutane is used to treat **severe, resistant, nodular acne after other anti-acne medicines have failed to help**. It works by decreasing the activity of the sebaceous glands in the skin and prevents the formation of active acne lesions. It takes about four weeks of treatment before the benefits of treatment can be noticed.

Roaccutane is given as a 4 - 8 month course of treatment, depending on the daily dose taken. A second course of treatment may be prescribed, if needed, 8 weeks after completing the first course.

NOTE: Roaccutane is only available on a doctor's prescription. It is a criminal act to give it to any person who does not have a valid prescription.

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

- Tell your doctor and pharmacist if you are allergic to Roaccutane or to any of the ingredients of Roaccutane, to any other medicines, or to soya.
- If you are pregnant or intend to become pregnant or breastfeeding your baby (see important warning for females below).
- Tell your doctor and pharmacist if you have any other medical problems, especially high blood lipid levels, diabetes (high blood sugar), depression, liver or kidney problems.

Warnings and precautions

- Tetracycline antibiotics, vitamin A and other anti-acne medicines should not be used whilst taking Roaccutane.
- Please consult your doctor, pharmacist or other healthcare professional for advice, if you are taking other medicines on a regular basis, including complementary or traditional medicines, prescription medicines and medicines bought without a prescription, especially tetracycline antibiotics, vitamin A and other anti-acne medicines. The use of Roaccutane with these medicines may cause undesirable interactions.
- Exfoliating anti-acne preparations should NOT be used while you are taking Roaccutane. Mild topical products may be used if recommended by your doctor.

NOTE: It is important that you do **not take vitamin A supplements while on Roaccutane.**

Make sure that any multivitamins you take do not contain vitamin A.

- Do not have any wax treatment to remove hair while you take Roaccutane Capsules and for 6 months after you stop treatment.
- Roaccutane makes your skin **sensitive to the sun and UV radiation**. Do NOT use a sunlamp. Avoid the sun as much as possible. Wear a good sunscreen, protective clothing and a hat when outdoors.
- Roaccutane has been associated with serious skin reactions. Any rash may become serious. Stop using Roaccutane and call your doctor right away if you develop conjunctivitis (red or inflamed eyes like “pink eye”), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- Roaccutane may cause dry eyes. If you wear contact lenses, you may need to use an eye-lubricating solution or wear your spectacles while you take Roaccutane.
- Roaccutane may cause dry lips. Apply a lip ointment to help relieve this problem.
- Roaccutane may change your night vision. If this happens, do not drive or do anything else that requires you to see well. Also, speak to your doctor. This will revert to normal after the treatment.
- **Do not donate blood** while you are taking Roaccutane or for 30 days after you stop taking it. This is to avoid the possibility of a pregnant woman receiving your blood that contains Roaccutane.

- Roaccutane has been prescribed particularly for you. **Never share medicines prescribed for you with others.**

Other medicines and Roaccutane

If you are taking medicines on a regular basis, using Roaccutane at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Always tell your healthcare professional if you are taking other medicine. (This includes complementary and traditional medicines).

Roaccutane with food and drink

Take Roaccutane with food or milk once or twice a day.

Pregnancy and breastfeeding

IMPORTANT WARNINGS FOR FEMALES

Do not use Roaccutane if you are pregnant, intend becoming pregnant or are breastfeeding.

- Roaccutane causes **severe birth defects**. If you have child-bearing potential you must use **two reliable methods of contraception** while on Roaccutane, starting one month before Roaccutane therapy is started and continuing for one month after stopping Roaccutane.
- Roaccutane therapy must start on the third day of menstruation. A pregnancy test is done 2 weeks before starting treatment and may be done during Roaccutane treatment.
- If you have child-bearing potential you must sign the Consent Form before starting Roaccutane therapy.

NOTE: If you do become pregnant while you are taking Roaccutane, there is a high risk of severe birth defects to your baby.

Please note that your doctor must give you the following information with your prescription:

- Patient Information Brochure
- Brochure on Birth Control
- Female Patient Information and Consent Form

Driving and using machines

Cases of decreased night vision have occurred during Roaccutane therapy and some have persisted after therapy. Because it can happen suddenly, you must be aware of the potential problem and be cautious when you drive or operate machinery.

Roaccutane contains sorbitol, mannitol and soya-bean oil

Roaccutane capsules contain sorbitol and mannitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take Roaccutane.

Roaccutane contains soya-bean oil. If you are allergic to peanut or soya, do not take Roaccutane.

3. How to take Roaccutane

- Do not share medicines prescribed for you with any other person.
- Follow your doctor's directions for taking Roaccutane. It is very important that you take Roaccutane only as directed. Do not take more or less of this medicine than your doctor told you.
- Take Roaccutane with food or milk once or twice a day.
- The dose of Roaccutane will be different for different patients. It is based on your bodyweight. Your doctor may later change your dosage depending on your response and if side effects occur.

NOTE: Acne may be worsened at first. Do not stop taking the medicine as it is essential that you continue treatment during this phase.

Usual dose of Roaccutane

Adults and teenagers: 0,5 to 1 mg/kg of body weight a day

- A treatment course is usually 4 - 8 months depending on the daily dose. After stopping treatment, many patients notice a further improvement and repeated courses are not usually needed. If a definite relapse does occur, a repeat course may then be given but should only be started at least 8 weeks after stopping the first course.

NOTE: Roaccutane is only available on a doctor's prescription. It is a criminal act to give it to any person who does not have a valid prescription.

If you take more Roaccutane than you should

Acute toxicity of Roaccutane is low. However, in case of overdose or accidental intake, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take Roaccutane

If you miss a dose of Roaccutane take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for the missed dose.

4. Possible side effects

Roaccutane can have side effects.

Not all side effects reported for Roaccutane are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Roaccutane, consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects and adverse events have been reported under Roaccutane therapy.

Most of the side effects of Roaccutane are dose-related. If these effects continue, are severe or bother you, speak to your doctor or pharmacist.

- Dry mouth, throat or nose
- Dry eyes and inflammation of the eye
- Dryness, itching or crusting of the skin
- Peeling of skin on palms of hands or soles of feet
- Headache or unusual tiredness
- Stomach upset
- Thinning of hair
- Burning, itching or redness of the eyes or lips
- Nose bleeds

- Skin infection, rash or scaling
- Bone or joint pain
- Raised liver enzymes
- Severe stomach pain, diarrhoea, nausea or vomiting
- Mood or mental changes
- Changes in vision or eye pain
- Severe headache or drowsiness
- Unusual bleeding
- Back pain, pain or stiffness of muscles
- Yellow eyes or skin
- Allergic reactions such as rash and itchiness
- A serious skin rash can occur in patients taking Roaccutane. Stop using Roaccutane and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like “pink eye”), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- A rapid breakdown of skeletal muscle due to injury to muscle tissue (rhabdomyolysis) causing muscle pain and kidney failure. To avoid making any bone or muscle problems worse, cut down on intensive physical activity while you’re on Roaccutane.

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 nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction 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 Roaccutane.

5. How to store Roaccutane

Store all medicines out of the reach of children.

Store aluminium and triplex blisters at or below 30 °C, protect from light.

Store duplex blisters at or below 25 °C, protect from light.

Keep in the original container until required for use.

Do not use after the expiry date stated on the pack.

Return unused or expired medicines to your pharmacist for safe disposal.

6. Contents of the pack and other information

What Roaccutane contains:

Each Roaccutane 10 mg capsule contains 10 mg isotretinoin.

Each Roaccutane 20 mg capsule contains 20 mg isotretinoin.

Inactive ingredients:

Capsule filling: beeswax yellow, soya-bean oil,

Capsule shell: gelatin, glycerol, karion 83 (consisting of sorbitol, mannitol, hydrogenated hydrolysed starch), titanium dioxide (E171), red iron oxide (E172).

Printing ink: black iron oxide (E172), modified shellac, propylene glycol.

What Roaccutane looks like and contents of the pack

Roaccutane 10 mg capsules: soft gelatin capsules - brown-red, opaque with the imprint ROA 10, available in blister packs containing 30 or 60 capsules.

Roaccutane 20 mg capsules: soft gelatin capsules - one half brown-red, opaque and the other half white, opaque with the imprint ROA 20, available in blister packs containing 30 or 60 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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0157

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This leaflet was last revised on: 12 August 2022

Registration numbers

Roaccutane 10 mg capsules: R/13.4.2/118

Roaccutane 20 mg capsules: R/13.4.2/119