Package leaflet: Information for the user

Roaccutane 10 mg and 20 mg
soft capsules

isotretinoin

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

▼This medicine 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 because it contains important information for you.

- Keep the leaflet. You may need to read it again.
- If you have more 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 Roaccutane is and what it is used for
2. What you need to know before you 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 contains *isotretinoin* – a substance related to vitamin A, and one of a group of medicines called *retinoids* (for treatment of acne).

Roaccutane is used to treat severe forms of acne (such as *nodular* or *conglobate* acne, or acne that is at risk of causing permanent scarring) in adults and adolescents. You will use Roaccutane when your acne has not got better with anti-acne treatments, including antibiotics and skin treatments.
Roaccutane should not be used to treat prepubertal acne and not in children aged less than 12 years of age.

Roaccutane treatment must be supervised by a dermatologist (a doctor specialised in the treatment of skin problems).

Your prescriber must have considered that there is no other appropriate treatment before starting your isotretinoin therapy.

2. What you need to know before you take Roaccutane

Do not take Roaccutane:

- If you are pregnant or breast-feeding
- If there is any chance you could become pregnant, you must follow the precautions under "Pregnancy prevention programme", see section on "Warnings and precautions".
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking isotretinoin.
- If you are allergic to *isotretinoin*, peanut or soya or any other ingredients of this medicine (listed in section 6).
- If you have liver disease
- If you have very high levels of blood fats (e.g. high cholesterol or triglycerides)
- If you have very high levels of vitamin A in your body (*hypervitaminosis A*)
- If you are receiving treatment with tetracyclines (*a type of antibiotic*) at the same time (see "Other medicines and Roaccutane")

If any of these apply to you, go back to your doctor before taking any Roaccutane.

Warnings and precautions

Talk to your doctor or pharmacist before taking Roaccutane:

- If you have ever had any kind of mental health problems. This includes depression, aggressive tendencies or mood changes. It also includes thoughts about hurting yourself or ending your life. This is because your mood may be affected while taking Roaccutane. Your doctor will discuss how best to monitor your mental health during your treatment.

Talk to your doctor if you experience persistent pain in your lower back or buttocks during treatment with Roaccutane. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with Roaccutane and refer you to a specialist for treatment of inflammatory back pain. Further evaluation may be needed including imaging modalities such as MRI.

This medicine can cause serious skin reactions. Stop using Roaccutane and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Pregnancy prevention programme

Women who are pregnant must not take Roaccutane

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 Roaccutane is taken only for a short time during pregnancy.

- You must not take Roaccutane if you are pregnant or if you think you might be pregnant.
- You must not take Roaccutane if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.
- You must not take Roaccutane if you could get pregnant during treatment.
- You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed Roaccutane 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 Roaccutane.

Women must use effective contraception before, during and after taking Roaccutane

- 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 Roaccutane, during treatment and for a month 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 Roaccutane

- 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, 1 month after stopping Roaccutane (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 a month 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 Roaccutane, **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 one month after you stop taking Roaccutane, you should contact your doctor. Your doctor may send you to a specialist for advice.

Your doctor has written information on pregnancy prevention for the users of Roaccutane which should be given to you.

A new prescription is needed for more treatment. Each prescription is only valid for 7 days.

Advice for men
The levels of oral retinoid in the semen of men taking Roaccutane 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 1 month after stopping Roaccutane 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 you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor about.

Advice for all patients

- **Tell your doctor if you have ever had any mental illness** (including depression, suicidal behaviour or psychosis), or if you take medicines for any of these conditions.
- **Severe Skin reactions** (e.g. erythema multiforme (EM), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)) **have been reported with the use of Roaccutane**. The rash may progress to widespread blistering or peeling of the skin. You should also look for ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
- **Rarely, Roaccutane may cause severe allergic reactions** some of which can affect skin in the form of eczema, hives and bruises or red patches on arms and legs. If you develop an allergic reaction, stop taking Roaccutane, seek urgent advice from a doctor and tell him that you are taking this medicine.
- **Cut down on intensive exercise and physical activity.** Roaccutane can cause muscle and joint pain particularly in children and teenagers undertaking vigorous physical activity.
- **Roaccutane has been associated with inflammatory bowel disease.** Your doctor will take you off Roaccutane if you have severe bloody diarrhoea without any history of gastrointestinal disorders.
- **Roaccutane may cause dry eyes, intolerance to contact lenses and visual difficulties including decreased night vision.** Cases of dry eyes not resolving after discontinuation of therapy have been reported. Tell your doctor if you have any of these symptoms. Your doctor may ask you to use lubricating eye ointment or tear replacement therapy. If you use contact lenses and you have developed intolerance to contact lenses, you may be advised to wear glasses during the treatment. Your doctor may refer you to a specialist for advice if you develop visual difficulties and you may be asked to stop taking Roaccutane.
- **Benign intracranial hypertension has been reported with Roaccutane use** and in some cases where Roaccutane was used together with tetracyclines (a type of antibiotic). Stop taking Roaccutane and seek urgent advice from your doctor if you develop symptoms like headache, nausea, vomiting and visual disturbances. Your doctor may refer you to a specialist to check for swelling of optic disk in the eye (papilloedema).
- **Roaccutane may increase liver enzyme levels.** Your doctor will do blood tests before, during and after Roaccutane treatment to check these levels. If they stay high, your doctor may lower your dose or take you off Roaccutane.
- **Roaccutane commonly increases blood fats,** such as cholesterol or triglycerides. Your doctor will test these levels before, during and after Roaccutane treatment. It is best that you do not drink alcoholic drinks or that you at least reduce the amount you usually drink while on treatment. Tell your doctor if you already have high blood fats, diabetes (high blood sugars), are overweight, or an alcoholic. You may need blood tests more often. If your blood fats stay high, your doctor may lower your dose, or take you off Roaccutane.
- **Tell your doctor if you have any kidney problems.** Your doctor may start you on a lower dose of Roaccutane and then increase it to the maximum tolerated dose.
- **Roaccutane may increase blood sugar levels.** In rare cases, people become diabetic. Your doctor may monitor blood sugar levels during treatment, particularly if you already have diabetes, are overweight, or are an alcoholic.
- **Your skin is likely to get dry**. Use a skin moisturising ointment or cream and a lip balm during treatment. To prevent skin irritation you should avoid using exfoliating or anti-acne products.
- **Avoid too much sun and do not use a sun-lamp or sun-bed.** Your skin may become more sensitive to sunlight. Before you go out in the sun, use a sun-protection product with a high protection factor (SPF 15 or higher).

- **Don't have any cosmetic skin treatments.** Roaccutane may make your skin more fragile. Don't have any waxing (hair removal), dermabrasion or laser treatments (removing horny skin or scars) during treatment, or for at least 6 months after treatment. They could cause scarring, skin irritation, or rarely, changes in the colour of your skin.
- **Isotretinoin has been associated with sexual problems**. These include problems getting or maintaining an erection, lower libido, vaginal dryness, orgasm difficulties and reduced sensation in the genitals. There have been reports of long-lasting sexual problems where the symptoms have continued despite stopping treatment with isotretinoin. Talk to your doctor if you experience any sexual problems during treatment.

Children and adolescents
The use of Roaccutane in children under the age of 12 is not recommended. This is because it is not known if it is safe or effective in this age group.
Roaccutane should not be used to treat prepubertal acne and not in children aged less than 12 years of age.

Other medicines and Roaccutane
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including herbal and non-prescription products.

- **Do not take vitamin A supplements or tetracyclines** (a type of antibiotic), or use any skin treatments for acne while you are on Roaccutane. It is fine to use moisturisers and emollients (skin creams or preparations that prevent water loss and have a softening effect on the skin).
- **Avoid the use of topical keratolytic or exfoliative anti-acne agents** while you are on Roaccutane.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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

Driving and using machines
You may not see as well at night during your treatment. This can happen suddenly. In rare cases this has continued after the treatment has stopped. Drowsiness and dizziness have been reported very rarely. If this happens to you, you should not drive or operate machinery.

Roaccutane contains sorbitol and soya-bean oil
This medicine contains 2.00 mg – 3.05 mg sorbitol in each 10 mg capsule.
This medicine contains 3.20 mg - 4.86 mg sorbitol in each 20 mg capsule.

If you are allergic to peanut or soya, do not use this medicine.

3. How to take Roaccutane

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

The usual starting dose is 0.5 mg per kilogram body weight per day (0.5 mg/kg/day). So if you weigh 60 kg, your dose will usually start at 30 mg a day.

Take the capsules once or twice daily.

Take on a full stomach. Swallow them whole, with a drink or a mouthful of food.

After a few weeks your doctor may adjust your dose. This depends on how you are getting on with your medicine. For most patients the dose will be between 0.5 and 1.0 mg/kg/day. If you think that Roaccutane is too strong or too weak, talk to your doctor or pharmacist.

If you have severe kidney problems, you will usually start on a lower dose (such as 10 mg/day) which will be increased up to the highest dose your body can tolerate. If your body can't tolerate the recommended dose, you may be prescribed a lower dose: that can mean you are treated for longer and your acne might be more likely to come back.

A course of treatment usually lasts for 16 to 24 weeks. Most patients only need one course. Your acne may continue to improve for up to 8 weeks after treatment. You won't usually start another course until then.

Some people find their acne gets worse during the first weeks of treatment. It usually improves as treatment goes on.

If you take more Roaccutane capsules than you should
If you take too many capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital immediately.

If you forget to take a dose
If you miss a dose take it as soon as you can. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose (two doses close together).

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the side effects associated with the use of isotretinoin are related to the dose. The side effects are generally reversible after changing the dose or stopping treatment, however some may continue after treatment has stopped. Some side effects can be serious and you must immediately contact your doctor.

Side effects requiring immediate medical attention:

Skin problems
Frequency not known *(frequency cannot be estimated from available data)*
Stop using isotretinoin and seek medical attention immediately if you notice any of the following symptoms of serious skin reactions:

- reddish non elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN)).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment [acute generalised exanthematous pustulosis (AGEP)].

Mental problems
Rare effects *(may affect up to 1 in every 1000 people)*

- Becoming violent or aggressive.

Very rare effects *(may affect up to 1 in every 10,000 people)*

- Unusual behaviour.
- Signs of psychosis: a loss of contact with reality, such as hearing voices or seeing things that are not there.

Frequency not known *(frequency cannot be estimated from available data)*

- Depression or related disorders. Signs of this include sad or altered mood, anxiety, feelings of emotional discomfort,
- Existing depression getting worse.
- Some people have had thoughts about hurting themselves or ending their own lives (suicidal thoughts), have tried to end their own lives (attempted suicide), or have ended their lives (suicide). These people may not appear to be depressed.

Contact your doctor straight away if you get signs of any of these mental problems. Your doctor may tell you to stop taking Roaccutane. That may not be enough to stop the effects: you may need more help, and your doctor can arrange this.

Allergic reactions
Rare effects *(may affect up to 1 in every 1000 people)*

- Serious *(anaphylactic)* reactions: difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips and mouth. Also sudden swelling of the hands, feet and ankles.

Very rare effects *(may affect up to 1 in every 10,000 people)*

- Sudden tight chest, shortness of breath and wheezing, particularly if you have asthma.

If you have a serious reaction, get emergency medical help immediately.
If you have any allergic reaction, stop taking Roaccutane and contact your doctor.

Bones and muscles
Frequency not known *(frequency cannot be estimated from available data)*

- Muscle weakness which can be potentially life-threatening, may be associated with trouble moving arms or legs, painful, swollen, bruised areas of the body, dark-coloured urine, reduced or no urine output, confusion or dehydration. These are signs of rhabdomyolysis, a breakdown of muscle tissue which can lead to kidney failure. This may occur if you are doing intensive physical activity while you're on Roaccutane.

Liver and kidney problems
Very rare effects *(may affect up to 1 in every 10,000 people)*

- Yellow skin or eyes, and feeling tired. These can be signs of hepatitis.
  Stop taking Roaccutane straight away and contact your doctor.
- Difficulty urinating (passing water), swollen and puffy eyelids, feeling excessively tired. These may be signs of kidney inflammation.
  Stop taking Roaccutane straight away and contact your doctor.

Nervous system problems
Very rare effects *(may affect up to 1 in every 10,000 people)*

- Lasting headache, along with feeling sick *(nausea)*, being sick *(vomiting)* and change in your eyesight including blurred vision. These may be signs of *benign intracranial hypertension,* especially if Roaccutane is taken with antibiotics called tetracycline.
  Stop taking Roaccutane straight away and contact your doctor.

Gut and stomach problems
Very rare effects *(may affect up to 1 in every 10,000 people)*

- Severe abdominal (tummy) pain, with or without severe bloody diarrhoea, feeling sick *(nausea)* and being sick *(vomiting)*. These can be signs of serious gut conditions. **Stop taking Roaccutane straight away and contact your doctor.**

Frequency not known *(frequency cannot be estimated from the available data)*

- anal fissure (a small tear in the thin, moist tissue that lines the anus)
- rectal bleeding or blood in your stools

Eye disorders
Very rare effects *(may affect up to 1 in every 10,000 people)*

- Blurred vision.

If you get blurred vision, stop taking Roaccutane straight away and contact your doctor. If your sight is affected in any other way tell a doctor as soon as you can.

Other side effects:
Very common side effects with Roaccutane: ***(****may affect more than 1 in 10 people)*

- Dryness of the skin, especially of the lips and face; inflamed skin, chapped and inflamed lips, rash, mild itching and slight peeling. Use a moisturising cream from the start of treatment.
- Skin becomes more fragile and redder than usual, especially the face.
- Back pain; muscle pain; joint pain particularly in children and teenagers.
- **To avoid making any bone or muscle problems worse**, cut down on intensive physical activity while you're on Roaccutane.
- Inflammation of the eye (conjunctivitis) and eyelid area; eyes feel dry and irritated. Ask a pharmacist for suitable eye drops. If you get dry eyes and wear contact lenses, you may need to wear glasses instead.
- Raised liver enzymes seen in blood tests.
- Changed levels of fats in the blood (including HDL or triglycerides).
- Bruising, bleeding or clotting more easily - if clotting cells are affected.
- Anaemia – weakness, dizziness, pale skin – if red blood cells are affected.

Common side effects with Roaccutane: ***(****may affect up to 1 in 10 people)*

- Headache.
- Higher levels of cholesterol in the blood.
- Protein or blood in the urine.
- More liable to get infections - if the white blood cells are affected.
- Inside of the nose becomes dry and crusted, causing mild nosebleeds.
- Sore or inflamed throat and nose.
- Allergic reactions such as rash, itchiness. If you have any allergic reaction, stop taking Roaccutane and contact your doctor.

Rare side effects with Roaccutane: ***(****may affect up to 1 in 1,000 people)*

- Hair loss *(alopecia)*. This is usually only temporary. Your hair should return to normal after the treatment ends.

Very rare side effects with Roaccutane: ***(****may affect up to 1 in 10,000 people)*

- You may see less well at night; colour blindness and colour vision gets worse.
- Sensitivity to light may increase; you may find that you need to wear sunglasses to protect your eyes from too bright sunlight.
- Other sight problems including blurred vision, distorted vision, cloudy surface on the eye (*corneal opacity, cataracts*).
- Excessive thirst; frequent need to urinate; blood tests show an increase in your blood sugar. These can all be signs of diabetes.
- Acne can get worse in the first few weeks, but symptoms should improve with time.
- Skin inflamed, swollen, and darker than usual, especially on the face.
- Excess sweating or itching.
- Arthritis; bone disorders (delayed growth, extra growth and changes to bone density); growing bones may stop growing.
- Calcium deposits in soft tissue, sore tendons, high levels of muscle breakdown products in your blood if you exercise vigorously.
- Increased sensitivity to light.
- Bacterial infections at the base of the nail, changes to nails.
- Swellings, discharging, pus.
- Thickened scarring after surgery.
- Increased body hair.

- Convulsions, drowsiness, dizziness.
- Lymph glands may become swollen.
- Dry throat, hoarseness.
- Hearing difficulties.
- Generally feeling unwell.
- High levels of uric acid in the blood.
- Bacterial infections.
- Inflammation of the blood vessels (sometimes with bruising, red patches).

Unknown frequency: ***(****frequency cannot be estimated from the available data)*
- Dark or cola-coloured urine
- Problems getting or maintaining an erection
- Lower libido
- Breast swelling with or without tenderness in males
- Vaginal dryness
- Difficulties having an orgasm
- Reduced sensation in the genitals
- Sacroiliitis, a type of inflammatory back pain causing pain in your buttocks or lower back
- Inflammation of the urethra

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).
United Kingdom Website: 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.

5. How to store Roaccutane

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP) stated on the pack and blister.

Do not store above 25° C.

Store in the original package and keep blister in the outer carton in order to protect from moisture and light.

Return left over capsules to your pharmacist. Only keep them if your doctor tells you to.

6. Contents of the pack and other information

What Roaccutane contains:
- **The active substance** in Roaccutane is isotretinoin.
- **The other ingredients** are refined soya-bean oil, hydrogenated soya-bean oil, partially hydrogenated soya-bean oil, yellow beeswax, gelatin, glycerol 85 %, sorbitol (E420) (see section 2), mannitol, hydrogenated hydrolysed starch, titanium dioxide (E171), red iron oxide (E172), printing ink containing modified shellac, black iron oxide (E172) and propylene glycol.

What Roaccutane looks like and contents of the pack:
Roaccutane comes in soft capsules containing either 10 mg or 20 mg isotretinoin.
The 10 mg capsules are oval, opaque, coloured brown-red and marked ROA 10.

The 20 mg capsules are oval, opaque, coloured brown-red and white and marked ROA 20.

The capsules come in blister packs of 20, 30, 50 or 100 capsules

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the web site of the member state.

United Kingdom
The Medicines and Healthcare Products Regulatory Agency (www.mhra.gov.uk)