

PACKAGE LEAFLET: INFORMATION FOR THE USER

ROACCUTANE

10mg and 20mg soft capsules

ISOTRETINOIN

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

What is in this leaflet?

1. What ROACCUTANE is and what it is used for
2. Before you take ROACCUTANE
3. How to take ROACCUTANE
4. Possible side effects
5. How to store ROACCUTANE
6. Further information

1. WHAT ROACCUTANE IS AND WHAT IS IT 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 types of acne (such as *nodular* or *conglobate* acne, or acne that is at risk of causing permanent scarring) in adults and adolescents from 12 years of age only after puberty. You will use ROACCUTANE when your acne has not got better with anti-acne treatments, including antibiotics and skin treatments.

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

2. BEFORE YOU TAKE ROACCUTANE

Do not take ROACCUTANE:

- **If you are pregnant** or think you may be

- **If you are breastfeeding**
- **If you are able to become pregnant but are unable or unwilling to follow** the necessary pregnancy prevention measures that are listed in the **ROACCUTANE**

Pregnancy Prevention Programme

- **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.

Important advice for women

ROACCUTANE is likely to damage an unborn baby (in medical language it is *teratogenic*). **It also increases the risk of miscarriage.**

- **You must not take ROACCUTANE when you’re 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 it if you could get pregnant during treatment**, or during the month after treatment.

Women who could get pregnant are only prescribed ROACCUTANE under strict rules, because of the risk of birth defects (damage to the unborn baby).

These are the rules:

- **You must only take ROACCUTANE if you have severe acne** that has not got better after any other anti-acne treatments, including antibiotics and skin treatments.
- **Your doctor must have explained the risk of birth defects:** you understand why you must not get pregnant and what you need to do to prevent it.
- **You must have discussed contraception** (birth control) with your doctor. They will give you information on preventing pregnancy. He or she may refer you to a specialist for contraceptive advice.
- **You must agree to use one or preferably two effective methods of contraception, including condoms or a cap plus spermicide**, for a month before taking ROACCUTANE, during treatment and for a month afterwards. Before you start treatment your doctor will ask you to take a pregnancy test, which must be negative.
- **You must use contraception even if you do not have periods** or are not currently sexually active (unless your doctor decides this is not necessary).
- **You must be capable of complying with** the necessary pregnancy prevention measures that are listed in the **ROACCUTANE Pregnancy Prevention Programme**.
- **You must accept the need for monthly follow up visits** and more pregnancy tests as decided by your doctor. You may have a test 5 weeks after stopping ROACCUTANE. You must not get pregnant during treatment and for a month afterwards.
- **Your doctor may ask you (or a guardian) to sign a form** that confirms that you have been told about the risks, and that you accept the necessary precautions.

If you do get pregnant while taking ROACCUTANE, or in the month after treatment has stopped, **stop taking the medicine straight away**, and contact your doctor. He or she may refer you to a specialist for advice.

Your doctor has written information on pregnancy and contraception for the users of ROACCUTANE which he should show you. If you haven't seen this material already, ask your doctor.

Prescriptions for women who could get pregnant are limited to 30 days treatment. A new prescription is needed for more treatment. Each prescription is only valid for 7 days.

Advice for men

ROACCUTANE does not appear to damage sperm. Very low levels of isotretinoin are present in the semen of men taking ROACCUTANE, which is too little to harm the unborn baby of your partner. You must remember not to share your medication with anyone, particularly not women.

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.** 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.
- **Tell your doctor if you have problems of fructose intolerance.** Your doctor will not prescribe ROACCUTANE if you have intolerance to fructose or sorbitol.
- **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.
- **You must remember not to share your medication with anyone else.** You should return unused capsules at the end of your treatment. Talk to your doctor or pharmacist regarding where to return the capsules.
- **Do not donate blood** while you are taking ROACCUTANE or for one month afterwards. If someone who is pregnant is given your blood, the baby may be born with birth defects.

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.

Use in adolescents over 12 years of age only after puberty.

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.

Pregnancy

ROACCUTANE must not be used during pregnancy. If you are able to get pregnant, you should use effective contraception during and up to one month after ROACCUTANE treatment.

If you do get pregnant while taking ROACCUTANE, or in the month after treatment has stopped, **stop taking the medicine straight away**, and contact your doctor. He or she may refer you to a specialist for advice.

If used during pregnancy, ROACCUTANE is likely to damage an unborn baby (in medical language it is *teratogenic*). It also increases the risk of miscarriage.

ROACCUTANE can cause serious abnormalities of brain, face, ear, eye, heart and some glands (called the thymus gland and parathyroid gland) of the unborn baby.

Breast-feeding

You must not take ROACCUTANE if you are breastfeeding. The medicine is likely to pass into your breast milk and may harm your baby.

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

- **Soya-bean oil.** If you are allergic to peanut or soya, do not take this medicinal product.
- **Sorbitol.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking 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. skip the missed dose and carry on as before. together).

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The effects often wear off, or stop when treatment is stopped. Others 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*)

- Serious skin rashes (erythema multiforme, Stevens- Johnson syndrome, and toxic epidermal necrolysis), which are potentially life-threatening and require immediate medical attention. These appear initially as circular patches often with central blisters usually on arms and hands or legs and feet, more severe rashes may include blistering of the chest and back. Additional symptoms such as infection of the eye (conjunctivitis) or ulcers of the mouth, throat or nose may occur. Severe forms of rash may progress to widespread peeling of the skin which can be life threatening. These serious skin rashes are often preceded by headache, fever, body aches (flu-like symptoms).

If you develop a serious rash or these skin symptoms, stop taking ROACCUTANE and contact your doctor immediately.

Mental problems

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

- Depression or related disorders. Signs of this include sad or empty mood, mood changes, anxiety, crying spells, irritability, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down or trouble concentrating.
- Existing depression getting worse.
- Becoming violent or aggressive.

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

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

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.

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

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 via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

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. FURTHER 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, sorbitol (see section 2), mannitol, hydrogenated hydrolysed starch, titanium dioxide (E171), red iron oxide (E172), printing ink containing 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.

Marketing Authorisation Holder

Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom

Manufacturer

Roche Pharma AG, Emil-Barell-Str. 1, D-79639 Grenzach-Wyhlen, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium, Estonia, Ireland, Latvia, Lithuania, Luxembourg, The Netherlands, Slovakia, Slovenia, United Kingdom:
ROACCUTANE

Finland, Hungary: Roaccutan