

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about ROACCUTANE capsules. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ROACCUTANE capsules against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What ROACCUTANE is used for

ROACCUTANE contains the active ingredient isotretinoin.

ROACCUTANE is used to treat acne.

ROACCUTANE belongs to a group of medicines called retinoids, which are similar to vitamin A.

The retinoids work by reducing the amount of the oily substance (i.e. sebum) made by glands in your skin, reducing bacteria, reducing inflammation and opening clogged pores.

There are many different types of medicines used to treat acne.

ROACCUTANE is used for more severe cases.

**Your doctor, however, may have prescribed ROACCUTANE for another purpose.**

**Ask your doctor if you have any questions about why ROACCUTANE has been prescribed for you.**

This medicine is available only with a doctor's prescription.

ROACCUTANE is not addictive.

### Before you take ROACCUTANE

#### When you must not take it

Do not take ROACCUTANE if:

- 1. you are pregnant, or for at least one month before you plan to fall pregnant**  
If you fall pregnant while taking ROACCUTANE there is an extremely high risk of having a baby that is severely deformed. You must use effective contraception for one month before, during and one month after treatment.
- 2. you are breastfeeding**  
Breastfeeding must stop before treatment begins. Do not breastfeed while taking ROACCUTANE.
- 3. you have had an allergic reaction to ROACCUTANE, vitamin A, other retinoids or any other ingredients of ROACCUTANE (listed at the end of this leaflet)**
- 4. you are taking tetracycline antibiotics (such as Akamin®, Vibramycin®, doxycycline hydrochloride, Doryx®, Frakas®, Minomycin®)**
- 5. you have severe liver disease**
- 6. you have very high fat levels (cholesterol, triglycerides) in your blood**
- 7. you have hypervitaminosis A**

This is a condition caused by an excessive amount of vitamin A in the diet.

- 8. the packaging is torn or shows signs of tampering**
- 9. the expiry date (EXP) printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

**If you are not sure if you should start taking ROACCUTANE, contact your doctor.**

**Do not give ROACCUTANE to children.**

There is limited information on the use of ROACCUTANE in children before puberty.

#### Before you start to take it

You must tell your doctor if:

- 1. you have any allergies to any other medicines, foods, preservatives or dyes**  
ROACCUTANE capsules contain soya oil, which may contain traces of arachidic acid (a component of peanut oil)
- 2. you have or have had any other health problems or issues including:**
  - diabetes, or a history of diabetes in your family
  - depression
  - liver disease
  - kidney disease
  - lipid (cholesterol or triglyceride) disorder
  - hormone disorder
  - stomach or bowel disease
- 3. you drink large amounts of alcohol.**

**If you have not told your doctor about any of the above, tell them before you start taking ROACCUTANE.**

## ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription, from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with ROACCUTANE. These include:

- tetracycline antibiotics (such as Akamin, doxycycline hydrochloride, Frakas, Vibramycin, Doryx, Minomycin)
- vitamin A, or preparations containing vitamin A (including vitamin supplements)
- other medicines you are using to treat your acne
- the “mini-pill”, a progestogen-only oral contraceptive pill.

These medicines may be affected by ROACCUTANE, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ROACCUTANE.

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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## **How to take ROACCUTANE**

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### ***How much to take***

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**Take ROACCUTANE exactly as your doctor has prescribed.**

Your doctor will tell you how many ROACCUTANE capsules to take each day.

This dose will be calculated to suit your individual needs and your body weight. This dose may be adjusted during treatment when the doctor knows how you respond to ROACCUTANE.

### ***How to take it***

Capsules should be swallowed whole with a glass of water or milk.

Do not open the capsules and do not take any capsules that are damaged.

### ***When to take it***

ROACCUTANE may be taken once or twice a day and must always be taken with meals.

**Female patients should wait until the 2nd or 3rd day of the next normal menstrual period before starting ROACCUTANE treatment.**

This helps ensure that you aren't pregnant before you start taking ROACCUTANE.

### ***How long to take ROACCUTANE***

**Continue taking ROACCUTANE for as long as your doctor prescribes.**

Acne treatment with ROACCUTANE will usually last 4 to 8 months. In the first few weeks of treatment your acne will probably get a little worse before it gets better. Do not worry about this, it is a sign that ROACCUTANE is working.

At the end of this time your acne should have cleared up significantly. Most patients notice their skin condition continues to improve even after ROACCUTANE treatment is finished.

Please note that ROACCUTANE cannot improve scars or pitting that were present before treatment started,

but it will help prevent such skin damage in the future.

### ***If you forget to take ROACCUTANE***

**Do not try to make up for missed doses by taking an extra dose.**

This may increase the chance of getting an unwanted side effect.

**If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.**

If you have missed several doses, please inform your doctor and follow the advice given to you.

### ***If you take too much ROACCUTANE (overdose)***

**Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much ROACCUTANE. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Signs of overdose include transient headache; vomiting; facial flushing; reddened, cracked lips; stomach pain; headache; dizziness and unsteady walking.

**Keep telephone numbers for these places handy.**

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## **While you are taking ROACCUTANE**

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### ***Things you must do***

**If you become pregnant while taking ROACCUTANE, stop taking it and tell your doctor immediately.**

ROACCUTANE can cause birth defects (damage to unborn babies). You must use strict birth control, starting at least 1 month before you begin taking ROACCUTANE, for the whole time you are taking ROACCUTANE and for 1 month after you finish taking ROACCUTANE.

There is no known risk to males who wish to father children.

**Tell all doctors, dentists and pharmacists who are treating you that you are taking ROACCUTANE.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**Tell your doctor if you feel ROACCUTANE capsules are not helping your condition.**

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor may ask you to have regular blood tests to monitor your liver function, blood sugar levels and blood cholesterol levels.

**If you are intending to do a lot of heavy lifting or exercise, tell your doctor.**

Your muscles and joints may be more prone to tenderness or stiffness if you do a lot of heavy exercise while taking ROACCUTANE.

### ***Things you must not do***

**Do not stop taking ROACCUTANE or change the dose without first checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

**Do not give ROACCUTANE to anyone else even if their symptoms seem similar to yours.**

**Do not use ROACCUTANE to treat other complaints unless your doctor says to.**

**Do not donate blood during treatment with ROACCUTANE or for at least 1 month after stopping treatment.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how ROACCUTANE affects you.**

Normally ROACCUTANE would not affect your ability to drive a car or operate machinery. However altered night vision and other visual disturbances may occur when taking ROACCUTANE. Make sure you know how you react to ROACCUTANE before you drive a car, operate machinery or do anything else that may be dangerous if your vision is affected.

**Wearing contact lenses during treatment with ROACCUTANE may cause discomfort.**

ROACCUTANE may cause dry eyes. An eye lubricant or artificial tears, available from your pharmacist, should relieve this problem. Otherwise, you may temporarily need to wear your lenses for shorter periods or wear glasses instead.

**Avoid excessive sun exposure and solariums and apply a sunscreen while taking ROACCUTANE.**

Your skin may be more prone to sunburn while on ROACCUTANE.

**Avoid waxing and dermabrasion while taking ROACCUTANE and for 5 to 6 months after stopping ROACCUTANE treatment.**

Your skin may be more sensitive while on ROACCUTANE. Waxing may cause dermatitis and dermabrasion may cause scarring during and for several months after ROACCUTANE treatment.

**Avoid using facial peels, electrolysis and some hair treatments.**

Your skin and hair may be more delicate during treatment and for a while after ROACCUTANE treatment.

### ***Further Information***

Further information may also be obtained from Roche Products Pty Limited, telephone toll free 1 800 659 789.

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## **Side Effects**

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ROACCUTANE helps most people with acne but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- dryness of the lips, mouth, nose and skin.  
A moisturiser or petroleum jelly can be used to soften the lining of the nose, lips and the skin areas not affected by the acne
- fragile skin
- change in colour of the skin
- peeling palms of the hands and soles of the feet
- itchy skin rash
- an increased susceptibility to sunburn
- sweating
- changes to the nails
- eye problems such as dry, sore, swollen or itchy eyes, discharge or trouble seeing at night
- nosebleeds

- tenderness or stiffness in your bones, joints or muscles
- tiredness
- headache
- hair loss (sometimes occurs and is usually temporary but in rare cases, has persisted)
- excessive hairiness
- hoarseness

These side effects are usually mild and dose related. Most of them disappear completely in a few days to a few weeks after the dose of ROACCUTANE is lowered or stopped.

Tell your doctor immediately if you experience any of the following:

- nausea
- vomiting
- persistent headache
- blurred vision or visual disturbances
- changes in your hearing or ringing in your ears
- severe upper stomach pain
- blood in stools or severe diarrhoea
- severe bruising
- sudden red, often itchy spots, similar to the rash of measles starting on the face, hands or feet. The spots may blister or change to flat round raised, red, pale-centered marks. Also, you may have fever, sore throat, headache and/ or diarrhoea.
- painful red areas, that change to large blisters and end with peeling of layers of skin, that may occur on lips, mouth, eyes, nose and genitals. Those affected may have fever and chills, aching muscles and generally feel unwell.
- thinking, seeing or hearing things that are not real
- feeling depressed, with or without suicidal thoughts

Symptoms of depression may include;

- feeling sad or having crying spells

- losing interest in activities you once enjoyed
- sleeping too much or having trouble sleeping
- changes in your appetite or body weight
- having trouble concentrating
- withdrawing from your friends or family
- feeling like you have no energy
- feelings of worthlessness or inappropriate guilt

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

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## After taking ROACCUTANE

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### Storage

**Keep your capsules in the blister pack until it is time to take them.**

If you take the capsules out of the packaging they will not keep well.

**Keep the blister pack in a cool dry place where the temperature stays below 25 °C.**

**Do not store ROACCUTANE, or any other medicine, in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep ROACCUTANE where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Protect ROACCUTANE from light.**

### Disposal

**If your doctor tells you to stop taking ROACCUTANE, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.**

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## Product Description

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### Availability

ROACCUTANE capsules come in two strengths, 10 mg and 20 mg.

ROACCUTANE 10 mg and 20 mg capsules are available in packs of 60 capsules.

### What ROACCUTANE looks like

The 10 mg capsule is soft, oval, opaque brown-red in colour and has "ROA 10" printed on it.

The 20 mg capsule is soft, oval, half brown-red and half opaque white in colour and has "ROA 20" printed on it.

### Ingredients

#### Active ingredient - isotretinoin

- each 10 mg capsule contains 10 mg isotretinoin
- each 20 mg capsule contains 20 mg isotretinoin.

#### Inactive ingredients -

The capsules also contain:

- soya oil
- yellow beeswax
- partially hydrogenated soya oil
- hydrogenated soya oil.

Soya oil may contain traces of arachidic acid (a component of peanut oil).

The capsule shell contains:

- gelatin
- glycerol
- sorbitol
- mannitol
- maize starch product
- titanium dioxide
- iron oxide, red

The printing ink contains:

- shellac
- iron oxide, black.

ROACCUTANE does not contain sucrose or gluten.

### ***Manufacturer***

ROACCUTANE is distributed by:

Roche Products Pty Limited  
ABN 70 000 132 865  
4 - 10 Inman Road  
Dee Why NSW 2099

Customer enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers:

- ROACCUTANE 10 mg capsules - AUST R 50840
- ROACCUTANE 20 mg capsules - AUST R 50839

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