

ROZEX® CREAM

0.75% metronidazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ROZEX CREAM. Please read this leaflet carefully before you start using the cream. It does not contain all the information available on this medicine.

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 using ROZEX CREAM against the benefits it might have for you. If you have any concerns about taking this medicine ask your doctor or pharmacist.

Keep this leaflet with your tube. You may wish to read it again later.

What ROZEX CREAM is used for

ROZEX CREAM is used for the treatment of inflammatory papules and pustules of rosacea. Skin affected by rosacea has one or more of the following features: a redness that looks like a blush; pimples; small knobbly lumps on the nose and / or thin red lines due to enlarged blood vessels.

The active ingredient in ROZEX CREAM is metronidazole which belongs to the class of medicines known as antiprotozoals and antibacterials.

It is not clear how ROZEX CREAM works however it may have antibacterial and anti-inflammatory action.

Preparations that are applied to the skin such as ROZEX CREAM can be used in combination with other oral medications prescribed by your doctor.

Ask your doctor if you have any questions about why ROZEX CREAM has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you use ROZEX CREAM

When you must not use it

- if you have an allergy to metronidazole or any of the other ingredients listed at the end of this leaflet.
- if you have or ever have had a blood disorder
- to treat your child's skin problem. ROZEX CREAM has not been studied for use in children.
- if you are pregnant. There are no well-controlled studies of therapy with ROZEX CREAM in pregnant women.

Symptoms of an allergic reaction may include:

- swelling of the face, lips, tongue or other parts of the body
- rash, itching, or hives of the skin, especially on the areas of the skin where the cream was applied.

Tell your doctor if you think you have an allergy.

Do not use ROZEX CREAM after the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your doctor or pharmacist for disposal.

Before you start to use it

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant.

With not enough information available on the effect of ROZEX CREAM on pregnant women, ROZEX CREAM is not recommended for use during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the risks and benefits of using ROZEX CREAM while breast-feeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using ROZEX CREAM.

Taking other medicines

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

Some medicines and ROZEX CREAM may interfere with each other. Your doctor and pharmacist may have more information on medicines to be careful with while using ROZEX CREAM.

How to use ROZEX CREAM

Things you must do

- Wash and dry your hands before applying the cream.
- Apply morning and evening to a dry, clean face.
- Squeeze a small quantity of ROZEX CREAM onto your fingertips and rub a thin film onto the affected areas.
- Avoid getting ROZEX CREAM into your eyes.
- Use a sunscreen when exposure to the sun cannot be avoided.

ROZEX CREAM is only for use on the skin.

Continue to use it even though there may not be an immediate effect. Medicines can take several weeks to show an effect. The average period of treatment is usually three to four months. The recommended duration of treatment should not be exceeded.

While you are taking ROZEX CREAM

Things you must do

- Tell all doctors and nurses who are treating you that you are using ROZEX CREAM.
- If you feel that ROZEX CREAM is not helping your condition, tell your doctor or nurse.
- Tell your doctor if you become pregnant while using ROZEX CREAM.

Things you must not do

- Do not use cosmetic products that contain alcohol or are abrasive.
- Do not use medicated soaps. These may have an extra drying or irritant effect.
- It is not known if ROZEX CREAM can increase the likelihood of skin cancers developing in people who have excessive exposure to sunlight. Therefore you should avoid or minimise

exposure of areas treated with ROZEX CREAM to sunlight or other sources of UV light.

- Unnecessary or prolonged use of ROZEX CREAM should be avoided as the long-term safety is unknown.

Things you can do

- Apply makeup over ROZEX CREAM.

Things to be careful of

ROZEX CREAM should not come into contact with the eyes or mucous membranes. If accidental contact occurs, rinse thoroughly with water and pat dry.

Avoid conditions known to make rosacea worse such as hot, spicy foods, alcohol, extremes of temperature, and excessive exposure to sunlight.

Use ROZEX CREAM less frequently if your face becomes hot, red, itchy, or swollen.

Do not exceed the recommended duration of treatment.

Stop using ROZEX CREAM and see your doctor if the problem persists.

If you forget to use it

If you forget to apply ROZEX CREAM use it again as directed, as soon as you remember.

Do not apply a double dose to make up for forgotten individual doses.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well whilst you are using ROZEX CREAM.

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

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:

- dry skin
- superficial reddening of skin
- severe itching of the skin
- skin discomfort (burning, dryness, pain of skin/stinging)
- skin irritation
- worsening of rosacea
- hyperpigmentation and other pigmentation disorders

These are more common side effects of ROZEX CREAM.

Tell your doctor or pharmacist if you notice any of the following:

- contact dermatitis
- reduced sense of touch or sensation
- tingling or pricking sensation ('pins and needles')
- numbness in the extremities
- dysgeusia (metallic taste)
- seborrhoea (red, itchy rash and white scales)
- sunburn
- skin infection

- hives
- gastritis
- bronchitis
- stuffy, runny nose
- skin exfoliation
- swelling face
- nausea
- excess watery fluid collection on the face or eyelids

These are uncommon side effects of ROZEX CREAM.

Tell your doctor or pharmacist if you notice any of the following:

- hypothyroidism
- Bursitis (inflammation or irritation of the bursa)
- Myalgia (muscle pain)
- osteoporosis
- conjunctivitis
- abscess

These are rare side effects of ROZEX GEL.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

In case of accidental swallowing

Immediately telephone your doctor or Poisons Information Centre for advice on telephone 13 11 26 if in Australia or 0800 POISON or 0800 764 766 if in New Zealand.

After using ROZEX CREAM

If you have queries about any aspect of your medicine or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Do not store it, or any other medicine, in a bathroom, near a sink, or on a window sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop using ROZEX CREAM or it has passed its expiry date, ask your pharmacist what to do with any that is left over. Return any unused medicine to your pharmacist.

Product Description

What it looks like

ROZEX CREAM is a smooth white cream in a plastic tube with a screw cap containing 3g, 5g, 15g, 30g and 50g of cream.

Not all pack sizes may be available.

Ingredients

Each gram of ROZEX CREAM contains 7.5 mg/g of metronidazole as the active ingredient.

It also contains the following inactive ingredients:

- benzyl alcohol,
- isopropyl palmitate,
- glycerol,
- sorbitol,
- emulsifying wax,
- lactic acid or sodium hydroxide,
- purified water.

Sponsor / Distributor

Galderma Australia Pty Ltd
Level 18, 1 Denison Street
North Sydney, NSW 2060
Telephone 1800 800 765

Distributed in New Zealand by:

Healthcare Logistics'
58 Richard Pearce Drive
Airport Oaks
Auckland
Telephone 0800 174 104

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