

ZORAC[®] cream

(tazarotene 0.5 and 1.0 mg/g)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZORAC[®] cream. 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 using ZORAC[®] against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What ZORAC[®] cream is used for

ZORAC[®] 0.05% and 0.1% w/w cream is used to treat plaque psoriasis. In addition, 0.1% w/w is used to treat facial acne.

Acne is characterised by inflamed pimples and non-inflamed pimples on the skin.

Psoriasis is characterised by inflamed red skin with red, thickened areas often with silvery scales called plaques.

ZORAC[®] cream contains tazarotene as the active ingredient which is a retinoid. The exact mechanisms of action for psoriasis and acne are not known. It is thought to act by helping skin cells to grow normally as well as having an anti-inflammatory effect in psoriasis and acne.

ZORAC[®] cream is only available with a doctor's prescription from pharmacies. Your doctor may have prescribed ZORAC[®] cream for another reason.

Ask your doctor if you have

any questions about why ZORAC[®] cream has been prescribed for you.

Before you use ZORAC[®] cream

When you must not use it

Do not use ZORAC[®] cream if:

- you have an allergy to tazarotene or any of the ingredients listed at the end of this leaflet.
- you are pregnant or plan to become pregnant.
- you have a skin condition called eczema. ZORAC[®] may cause severe irritation if used on eczematous skin.
- the tube /packaging shows signs of tampering.
- the product does not look quite right.
- the expiry date on the bottle has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

It is not known whether ZORAC[®] cream is safe and useful for children and adolescents under 18 years, in psoriasis, or under 12 years in acne.

This cream is for topical use only. Avoid contact with eyes, eyelids and mouth.

Before you start to use it

Tell your doctor if:

1. you have had an allergy to any medicines or any other substances, such as foods, preservatives, or dyes.

2. if you are pregnant or intend to become pregnant.

Like many medicines, ZORAC[®] cream should not be used during pregnancy. Talk to your doctor about effective birth control if you are a woman who is able to become pregnant.

Talk to your doctor about a time period after which pregnancy can be contemplated after using ZORAC[®].

If you become pregnant while using this drug, stop using it and contact your doctor immediately as this product may cause birth defects.

3. you are breast feeding or intend to breast feed.
4. you have sunburn. You should wait until your skin has fully recovered from the sunburn before using ZORAC[®] cream.

Taking other medicines

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

Tell your doctor if you are taking drugs that are known to cause sun sensitivity e.g. thiazides, tetracyclines, fluoroquinolones, phenothiazines, and sulfonamides. If you take these medicines while using ZORAC[®] cream your skin may become more sensitive to the sun.

Watch your reaction to ZORAC[®] cream carefully if you are also using other skin products with a strong drying effect or high amounts of alcohol, astringents, spices, lime peel, medicated soaps or shampoos, permanent wave solution, electrolysis, hair depilatories or waxes, or other

products or processes that may dry or irritate the skin.

Ask your doctor or pharmacist if you have any concerns about using ZORAC[®] cream as well as other medications.

How to use ZORAC[®] cream

How much to use

Your doctor will tell you how much cream you need to use each day. Use ZORAC[®] cream only as prescribed by your doctor.

For psoriasis: apply ZORAC[®] cream once a day, in the evening, to the psoriatic lesions using enough to cover only the lesions with a thin film.

For acne: apply a thin film of ZORAC[®] 0.1% once a day in the evening to the skin where acne lesions appear.

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

Use ZORAC[®] cream every day, at about the same time each day, unless your doctor tells you otherwise.

How to use it: ***Psoriasis:***

Remove makeup (if present) before applying ZORAC[®] cream. If you wash your face prior to application you should allow your skin to dry before applying ZORAC[®] cream.

After the skin is dry, apply a thin layer of ZORAC[®] cream once a day to the areas of your skin with psoriasis.

Carefully avoid application of the cream to other areas that are not affected by psoriasis. If the cream is applied to areas that are not required to be treated wash the cream off.

Follow your doctor's directions for other routine skin care and the use of make-up.

Wash your hands after applying medication unless you are treating your hands for psoriasis. If you are

treating hands avoid contact with the eyes.

Do not use more ZORAC[®] than instructed or more often than instructed.

While using ZORAC[®] cream weather extremes, such as wind or cold, may irritate your skin more than usual. Application of the cream may cause burning or stinging for a short time. If this persists talk to your doctor or pharmacist. You should avoid using a solarium and when outside you should use a sunscreen with an SPF of at least 15 and protective clothing during the day.

Ask your doctor or pharmacist any questions you may have.

How to use it: ***Acne:***

Remove makeup (if present) before applying ZORAC[®] cream. If you wash your face prior to application you should allow your skin to dry before applying ZORAC[®] cream.

After the skin is dry, apply a thin layer of ZORAC[®] once a day to the skin where the acne lesions appear.

Use enough to cover the entire affected area. All skin prone to acne should be treated.

Carefully avoid application of the cream to other areas that are not affected by acne. If the cream is applied to areas that are not required to be treated, wash the cream off.

Follow your doctor's directions for other routine skin care and the use of make-up. You should talk to your doctor about the use of sunscreens, moisturisers and cosmetics.

If emollients or a moisturiser are used, they can be applied before or after ZORAC[®] cream, but whichever one is applied first should be allowed to absorb into the skin before the next one is applied.

Wash your hands after applying medication. If the cream is applied

to areas that are not required to be treated, wash the cream off.

Keep ZORAC[®] away from your eyes and mouth. If the cream gets in your eyes, wash them with large amounts of cool water. Contact your doctor if eye irritation continues.

While using ZORAC[®] cream weather extremes such as wind or cold, may irritate your skin more than usual.

Application of the cream may cause burning or stinging for a short time. If this persists talk to your doctor or pharmacist. You should avoid using a solarium and when outside you should use a sunscreen with an SPF of at least 15 and protective clothing during the day.

Ask your, doctor or pharmacist any questions you may have.

How long to use it

Continue using ZORAC[®] cream for as long as your doctor prescribes.

If you forget to use it

If you miss a dose, do not try to make it up. Continue your normal schedule.

Do not use double the amount to make up for the dose that you missed.

If you use too much ***(overdose)***

If you accidentally put ZORAC[®] in your eye(s), immediately rinse your eye(s) with large amounts of cool water. Contact your doctor if eye irritation continues.

If you think that you or anyone else may have swallowed ZORAC[®] cream, immediately telephone your doctor or **Poisons Information Centre (Australia : telephone 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766)** for advice, or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using ZORAC[®] cream

Things you must do

You should use adequate contraception (e.g. the pill, condoms) while using ZORAC[®] cream.

If you become pregnant while using ZORAC[®] cream, stop use and tell your doctor immediately.

Tell your doctor if your condition gets worse or does not get better while using ZORAC[®] cream.

If you are about to start any new medicine tell your doctor and pharmacist that you are using ZORAC[®] cream.

Things you must not do

Do not give ZORAC[®] cream to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ZORAC[®] cream.

Check with your doctor as soon as possible if you have any problems while using ZORAC[®] cream even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Ask your, doctor or pharmacist any questions you may have.

Side effects in psoriasis:

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

- Itching
- Redness of the skin
- Burning

Less often the following effects have been seen:

- irritation of the skin
- peeling of the skin
- stinging
- skin rash
- eczema (a skin condition with itching, redness and a burning feeling and often include blisters that weep and become crusted.)

- worsening of psoriasis
- skin pain
- dry skin
- skin inflammation
- general swelling

Rarely: cracking of the skin, flaking of the skin, bleeding skin, weeping skin, erosion of the skin, blistering rash, skin rash with pus filled blisters, redness of the nose and cheeks, skin reaction, hives (itchy rash), allergic skin rash, skin blisters, eyelid irritation, redness of the eyelids, pain, chills, headache, infection, itchy scalp, high triglycerides in the blood, swelling, SGOT and SGPT enzyme levels increased, high cholesterol levels in the blood, mouth ulcers, nausea, aching muscles not caused by exercise and sleeplessness.

Side effects in acne:

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

- Peeling of the skin
- Dry skin
- Redness of the skin
- Burning sensation

Less often the following effects have been seen:

- itching
- irritation of the skin
- stinging of the skin
- face pain

Rarely: acne, skin discolouration, rash, worsening acne, sun-induced redness of the skin, flaking of the skin, eczema (a skin condition with itching, redness and a burning feeling which often includes blisters that weep and become crusted), skin pain, lumps on the skin and tightness of the skin, skin blisters, pain, infection, headache, cracking or inflammation of the lips, sore throat (discomfort when swallowing) and diminished sensitivity.

After using ZORAC[®] cream

Storage

Keep your ZORAC[®] cream in a cool place where the temperature

stays below 25°C. Do not put it in the refrigerator or freezer.

Keep the tube where children cannot reach it.

Do not leave the top/lid off the tube for any length of time to avoid contaminating the cream.

Disposal

Throw out any remaining cream after 12 months from the date of opening.

If your doctor tells you to stop using the cream or it has passed the expiry date, ask your pharmacist what to do with any remaining cream.

Product description

What ZORAC[®] cream looks like:

A white opaque cream.

IngredientsActive ingredient:

Tazarotene 1.0 mg/mL (0.1%w/w)
or
Tazarotene 0.5 mg/mL (0.05% w/w)

Preservative:

Benzyl alcohol

Inactive ingredients:

Sodium thiosulfate
Disodium edetate
Liquid paraffin
Medium chain triglycerides
Carbomer 1342
Sorbitan mono-oleate
Carbomer 934P
Sodium hydroxide
Purified water

Manufactured by Allergan.

Supplier

EpiPharm Pty. Ltd.
Level 13, 1 Collins St
Melbourne, Victoria, 3000
Telephone: 1800 028 880

ZORAC[®] cream can be identified by registration numbers:

0.05% w/w AUST R 101328
0.1% w/w AUST R 101327

Date of preparation:

September 2005