ZORAC® 0.05% gel
ZORAC® 0.1% gel
Tazarotene

Read all of this leaflet carefully before you start using 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 of the 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 ZORAC gel is and what it is used for
2. What you need to know before you use ZORAC gel
3. How to use ZORAC gel
4. Possible side effects
5. How to store ZORAC gel
6. Contents of the pack and other information

1. What ZORAC gel is and what it is used for

ZORAC gel is a drug for the treatment of psoriasis. It is applied to the skin.
ZORAC gel is used for the treatment of mild to moderate plaque psoriasis (the most common form of psoriasis) if only small areas are to be treated and only up to 10% of the body surface area is affected. This is approximately equivalent to the area of skin on one arm.

2. What you need to know before you use ZORAC gel

Do not use ZORAC gel
• if you are allergic to tazarotene or any of the other ingredients of this medicine (listed in section 6),
• if you are pregnant or breast-feeding or if you are considering becoming pregnant,
• in children under 18 years of age,
• for the treatment of suppurating, pustulating psoriasis (psoriasis pustulosa) or psoriasis with increased scale formation (exfoliative psoriasis),
• on the face,
• on the hair-covered scalp,
• in moist, hair-covered areas such as armpits, groin etc.,
• under tightly secluded bandages (occlusive bandages) or in combination with other drugs for psoriasis that are for external use (including shampoos with coal tar).

Warnings and precautions
• Do not apply ZORAC gel on more than 10% of the total surface of the body (which is approximately equivalent to the area of the skin on one arm).
• Do only apply ZORAC gel to affected areas of skin. Application of ZORAC gel to healthy, eczematosus or inflamed skin may cause irritation.
• In case of psoriasis lesions on the hands, you should be extra careful not to get any gel on the facial skin or in the eyes. In case of accidental contact with the eyes, rinse generously with lots of water.
• Avoid excessive exposure to UV rays (sun, solarium, PUVA therapy or UVB therapy) during the treatment. This is especially relevant when taking certain other medicines also known to cause sensitivity to light (see below (Other medicines and ZORAC gel)).

Children
Do not give this medicine to children under the age of 18 years as safety and efficacy of ZORAC gel has not been established in this age group.

Other medicines and ZORAC gel
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Simultaneous use of other preparations on the skin should be avoided if these have a pronounced drying effect. This applies to certain medicines (e.g. disinfectants) and also cosmetics (e.g. soaps and shampoos). Nevertheless, if such products are applied, it is advisable to leave a one hour interval before and after application of ZORAC gel. Coal tar shampoos should also be avoided.

Use of ZORAC gel with certain medicines (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) is known to cause sensitivity to light. See section 2 above (Warnings and precautions).

Pregnancy, breast-feeding and fertility
ZORAC gel should not be taken during pregnancy, breast-feeding (because this medicine passes into breast milk) and in women who are considering becoming pregnant.
Animal studies have revealed damage to the unborn baby.
Women of child-bearing age should be informed of the potential risk and adopt adequate contraceptive measures when treated with ZORAC gel.
If you discover you are pregnant during treatment, stop application of this medicine and consult your doctor immediately.

Driving and using machines
Treatment with ZORAC gel has no known effect on the ability to drive or use machinery.

ZORAC gel contains butylhydroxyanisole and butylhydroxytoluene. They can cause local skin reactions (e.g. skin inflammation due to contact with the additional ingredients, the so called contact dermatitis), irritate the eyes, skin and mucous membranes.

3. How to use ZORAC gel

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

ZORAC gel is available in two different concentrations: 0.05% gel and 0.1% gel. Your doctor will prescribe the concentration best suited to your symptoms.

Dosage and duration of use

Apply ZORAC gel once daily (evenings) in a thin film to the affected areas.
Treatment usually lasts for up to 3 months. Clinical experience, particularly concerning tolerance, has been documented over a period of up to 12 months.
Method of application

- Use the tip of the cap to break the seal.
- Dry your skin well after bathing or showering, before applying ZORAC gel.
- Only apply ZORAC gel to the affected skin areas. The use of ZORAC gel on healthy, eczematous or inflamed skin should be avoided, as this may cause irritations (itching, redness, inflammation).
- Not more than 10% of the body surface should be treated (this is approximately equivalent to the surface of the skin of the arm).
- Do not cover areas to be treated with dressings or bandages.
- Please wash your hands after applying the gel, unless your hands themselves are being treated. Do not get the gel in your eyes.
- In cases of very dry skin or skin irritations, it is recommended to apply an inert fatty ointment base to the affected skin areas at least one hour before using ZORAC gel, in order to improve tolerance and/or to apply zinc ointment to the healthy skin surrounding the psoriasis plaques.
- Note that you should not use skin care products or cosmetics within one hour before or after applying ZORAC gel. Nevertheless, if such products are used, make sure these preparations have been fully absorbed by the skin before application of ZORAC gel.
- In case of skin irritation, treatment with ZORAC gel should be discontinued. Seek advice from the dermatologist or doctor who is treating you.

Use in elderly patients
There are no special warnings for elderly patients.

If you use more ZORAC gel than you should
Overdoses to the skin can cause redness, scaling and discomfort. If ZORAC gel is swallowed accidentally, symptoms such as those associated with excessive vitamin A intake may develop. These include severe headache, vomiting, tiredness, irritability and itchy skin. It can be expected, however, that these symptoms will subside. If these symptoms persist please contact your doctor. ZORAC gel is intended for once daily external application only. More frequent application will not provide faster or better results.

If you forget to use ZORAC gel
Do not use a double dose to make up for a forgotten dose. Return to your normal application schedule once a day (in the evening).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people)
- itchy skin,
- burning sensation on the skin,
- redness and irritation.
Common side effects (may affect up to 1 in 10 people)
- scaling,
- non-specific skin rash,
- skin inflammation (contact dermatitis) caused by a reaction to certain substances,
- painful skin and exacerbation of the psoriasis,
- stinging,
- inflamed and dry skin.

The frequency of the following side effects is not known (frequency can not be estimated from the available data)
- blister,
- alteration of the pigmentation of the skin (including hyperpigmentation or hypopigmentation).

The frequency of these undesirable effects appears to depend on the dose and the duration of the treatment. The more concentrated gel (0.1%) may cause skin irritation more frequently than the less concentrated gel (0.05%), especially during the first 4 weeks of treatment.

After applying ZORAC gel, some people notice a feeling of itching, burning or stinging of the affected skin areas. This sensation may lessen as your skin gets used to the medication. Contact your doctor if the irritation becomes troublesome.

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

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 Yellow Card Scheme; Website: 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 ZORAC gel

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

Do not use this medicine after the expiry date which is stated on the crimped end of the tube and on the carton. The expiry date refers to the last day of that month.

Keep the tube tightly closed between applications.

Do not use any remaining gel after 6 months from when the pack was first opened.

Do not store this medicine at temperatures above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ZORAC gel contains
- The active substance is tazarotene. This belongs to the retinoid group of substances, derived from vitamin A.
• The other ingredients are: benzyl alcohol; macrogol 400; hexylene glycol; carbomer 974P; trometamol; poloxamer 407; polysorbate 40; ascorbic acid; butylhydroxyanisole (E320); butylhydroxytoluene (E321); disodium edetate; purified water.

What ZORAC gel looks like and contents of the pack
ZORAC gel is a colourless to light yellowish, translucent to slightly cloudy, homogeneous gel. It is available in aluminium tubes, internally lacquered, epoxyphenolic, with white polypropylene cap containing 10 g, 15 g, 30g, 50 g, 60g or 100 g gel. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

Manufacturer
Allergan Pharmaceuticals Ireland
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IF YOU WOULD LIKE FURTHER INFORMATION, OR REQUIRE THIS LEAFLET IN A LARGER FORMAT PLEASE CONTACT MEDICAL INFORMATION AT ALLERGAN LTD, UK. TEL: 01628 494026 OR EMAIL: UK_MEDINFO@ALLERGAN.COM

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