P3913T

Package leaflet: Information for the user

Tacrolimus 0.03% Ointment

tacrolimus monohydrate

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 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 Tacrolimus is and what it is used for
2. What you need to know before you use Tacrolimus
3. How to use Tacrolimus
4. Possible side effects
5. How to store Tacrolimus
6. Contents of the pack and other information

1. What Tacrolimus is and what it is used for

The active substance of Tacrolimus, tacrolimus monohydrate, is an immunomodulating agent.

Tacrolimus 0.03% ointment is used to treat moderate to severe atopic dermatitis (eczema) in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids and in children (2 years of age and older) who failed to respond adequately to conventional therapies such as topical corticosteroids.

Once moderate to severe atopic dermatitis is cleared or almost cleared after up to 6 weeks treatment of a flare, and if you are experiencing frequent flares (i.e. 4 or more per year), it may be possible to prevent flares coming back or prolong the time you are free from flares by using Tacrolimus 0.03% ointment twice weekly.

In atopic dermatitis, an over-reaction of the skin's immune system causes skin inflammation (itchiness, redness, dryness). Tacrolimus alters the abnormal immune response and relieves the skin inflammation and the itch.

2. What you need to know before you use Tacrolimus

Do not use Tacrolimus
- If you are allergic to tacrolimus or any of the other ingredients of this medicine (listed in section 6) or to macrolide antibiotics (e.g. azithromycin, clarithromycin, erythromycin).

Warnings and precautions

Talk to your doctor before using Tacrolimus:
- If you have **liver failure.**
- If you have any **skin malignancies** (tumours) or if you have a **weakened immune system** (immuno-compromised) whatever the cause.
- If you have an **inherited skin barrier disease** such as Netherton's syndrome, lamellar ichthyosis (extensive scaling of the skin due to a thickening of the outer layer of the skin), or if you have an inflammatory skin disease such as pyoderma gangrenosum, or if you suffer from **generalised erythroderma** (inflammatory reddening and scaling of the entire skin).
- If you have a cutaneous Graft Versus Host Disease (an immune reaction of the skin which is a common complication in patients who have undergone a bone marrow transplant).
- If you have **swollen lymph nodes** at initiation of treatment. If your lymph nodes become swollen during treatment with Tacrolimus, consult your doctor.
- If you have **infected lesions.** Do not apply the ointment to infected lesions.
- If you notice any **change to the appearance of your skin**, please inform your physician.
- Based on the results of long-term studies and experience, a link between Tacrolimus ointment treatment and the development of malignancies has not been confirmed, but definitive conclusions cannot be drawn.
- Avoid exposing the skin to long periods of sunlight or artificial sunlight such as tanning beds. If you spend time outdoors after applying Tacrolimus, use a sunscreen and wear loose fitting clothing that protects the skin from the sun. In addition, ask your doctor for advice on other appropriate sun protection methods. If you are prescribed light therapy, inform your doctor that you are using Tacrolimus as it is not recommended to use Tacrolimus and light therapy at the same time.
- If your doctor tells you to use Tacrolimus twice weekly to keep your atopic dermatitis cleared, your condition should be reviewed by your doctor at least every 12 months, even if it remains under control. In children, maintenance treatment should be suspended after 12 months, to assess whether the need for continued treatment still exists.
- It is recommended to use Tacrolimus ointment at the lowest possible strength, at the lowest frequency and for the shortest possible duration necessary. This decision should be based on your doctor's assessment of how your eczema responds to Tacrolimus ointment.

Children
- Tacrolimus ointment is **not approved for children younger than 2 years of age.** Therefore, it should not be used in this age group. Please consult your doctor.
- The effect of treatment with Tacrolimus on the developing immune system in children, especially the young, has not been established.

Other medicines, cosmetics and Tacrolimus

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

You may use moisturising creams and lotions during treatment with Tacrolimus but these products should not be used within two hours of applying Tacrolimus.

The use of Tacrolimus at the same time as other preparations to be used on the skin or while taking oral corticosteroids (e.g. cortisone) or medicines which affect the immune system has not been studied.

Tacrolimus with alcohol

While using Tacrolimus, drinking alcohol may cause the skin or face to become flushed or red and feel hot.

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 or pharmacist for advice before taking this medicine.

Tacrolimus contains butylated hydroxytoluene (E321)

Tacrolimus contains butylated hydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

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Product:	Tacrolimus 0.03% Ointment
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3. How to use Tacrolimus

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

- Apply Tacrolimus as a thin layer to affected areas of your skin.
- Tacrolimus may be used on most parts of the body, including the face and neck and in the creases of your elbows and knees.
- Avoid using the ointment inside your nose or mouth or in your eyes. If the ointment gets on any of these areas, it should be thoroughly wiped off and/or rinsed off with water.
- Do not cover the skin being treated with bandages or wraps.
- Wash your hands after applying Tacrolimus unless your hands are also being treated.
- Before applying Tacrolimus after a bath or shower, be sure your skin is completely dry.

Children (2 years of age and older)
Apply Tacrolimus 0.03% ointment twice a day for up to three weeks, once in the morning and once in the evening. Afterwards the ointment should be used once a day on each affected region of the skin until the eczema has gone away.

Adults (16 years of age and older)
Two strengths of Tacrolimus (Tacrolimus 0.03% and Tacrolimus 0.1% ointment) are available for adult patients (16 years of age and older). Your doctor will decide which strength is best for you.

Usually, treatment is started with Tacrolimus 0.1% ointment twice a day, once in the morning and once in the evening, until the eczema has cleared. Depending on the response of your eczema your doctor will decide if the frequency of application can be reduced or the lower strength, Tacrolimus 0.03% ointment, can be used.

Treat each affected region of your skin until the eczema has gone away. Improvement is usually seen within one week. If you do not see any improvement after two weeks, see your doctor about other possible treatments.

You may be told by your doctor to use Tacrolimus ointment twice weekly once your atopic dermatitis has cleared or almost cleared (Tacrolimus 0.03% for children and Tacrolimus 0.1% for adults). Tacrolimus ointment should be applied once a day twice weekly (e.g. Monday and Thursday) to areas of your body commonly affected by atopic dermatitis. There should be 2–3 days without Tacrolimus treatment between applications.

If symptoms reappear you should use Tacrolimus twice daily as outlined above and arrange to see your doctor to review your treatment.

If you accidentally swallow some ointment
If you accidentally swallow the ointment, consult your doctor or pharmacist as soon as possible. Do not try to induce vomiting.

If you forget to use Tacrolimus
If you forget to apply the ointment at the scheduled time, do it as soon as you remember and then continue as before.

If you have any further questions on the use of this medicine, 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 (may affect more than 1 in 10 people):

- burning sensation and itching

These symptoms are usually mild to moderate and generally go away within one week of using Tacrolimus.

Common (may affect up to 1 in 10 people):

- redness
- feeling of warmth
- pain
- increased skin sensitivity (especially to hot and cold)
- skin tingling
- rash
- local skin infection regardless of specific cause including but not limited to: inflamed or infected hair follicles, cold sores, generalised herpes simplex infections
- facial flushing or skin irritation after drinking alcohol is also common

Uncommon (may affect fewer than 1 in 100 people):

- acne

Following twice-weekly treatment application site infections have been reported in children and adults. Impetigo, a superficial bacterial skin infection that usually produces blisters or sores on skin, has been reported in children.

Rosacea (facial redness), rosacea-like dermatitis, lentigo (presence of flat brown spots on the skin), oedema at the application site and herpes eye infections have been reported during post-marketing experience.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Tacrolimus

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 tube and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Discard open tubes 180 days after opening, even if they are not empty. They should not be kept for future use. Write down the date you open the tube the first time on outer carton, to help you remember when to discard it.

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 Tacrolimus contains

- The active substance is tacrolimus monohydrate.
  One gram of Tacrolimus 0.03% ointment contains 0.3mg tacrolimus (as tacrolimus monohydrate).
- The other ingredients are white soft paraffin, liquid paraffin, propylene carbonate, white beeswax, hard paraffin and butylated hydroxytoluene (E321).

What Tacrolimus looks like and contents of the pack
Tacrolimus is a white to slightly yellowish ointment.

It is supplied in tubes containing 10, or 30 grams of ointment.

Not all pack sizes may be marketed.

Tacrolimus is available in two strengths (Tacrolimus 0.03% and Tacrolimus 0.1% ointment).

Marketing Authorisation Holder
Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

Manufacturer
BELTAPHARM S.R. L. (Formerly known as Beltapharm S.P.A)
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