PATIENT INFORMATION LEAFLET

Tacrolimus Monohydrate Ointment
(0.1% & 0.03%)

TACRON

Read all of this leaflet carefully before you start taking 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.

What is in this leaflet

1. What TACRON is and what it is used for

TACRON contains active substance of Tacrolimus Monohydrate Ointment which is an immunomodulating agent. TACRON 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 TACRON 0.03% ointment twice weekly.

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

2. What you need to know before you use TACRON

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

Warnings and precautions

Talk to your doctor before using TACRON:
- 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 TACRON, 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 TACRON 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 TACRON, 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 TACRON as it is not recommended to use TACRON and light therapy at the same time.
- If your doctor tells you to use TACRON 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 TACRON 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 TACRON ointment.

Children
- TACRON 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 TACRON on the developing immune system in children, especially the young, has not been established.

Other medicines, cosmetics and TACRON

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 TACRON but these products should not be used within two hours of applying TACRON.

The use of TACRON 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.

TACRON with alcohol

While using TACRON, 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.

TACRON contains butylhydroxytoluene

TACRON contains butyl hydroxy toluene, which may cause local skin reactions (e.g., contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use TACRON

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Apply TACRON as a thin layer to affected areas of your skin.
- TACRON 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 TACRON unless your hands are also being treated.
- Before applying TACRON after a bath or shower, be sure your skin is completely dry.

Children (2 years of age and older)
Apply TACRON 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 TACRON (TACRON 0.03% and TACRON FORTE 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 TACRON FORTE 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 TACRON 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 TACRON ointment twice weekly once your atopic dermatitis has cleared or almost cleared (TACRON0.03% for children and TACRON FORTE 0.1% for adults). TACRON 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 TACRON treatment between applications.

If symptoms reappear you should use TACRON 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 TACRON
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 TACRON.

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.

5. How to store TACRON
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.
Do not store above 25°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 TACRON contains
The active substance is Tacrolimus.

TACRON 0.03% Ointment
Composition:
Tacrolimus USP 0.03% w/w
In an ointment base q.s.

TACRON FORTE 0.1% Ointment
Composition:
Tacrolimus USP 0.1% w/w
In an ointment base q.s.

What TACRON looks like and contents of the pack
TACRON 0.03% Ointment is white, opaque and semisolid uniform mass. It is available in printed lami tube in the pack of 15 g. Each filled tube is packed in a printed paper carton.

TACRON FORTE 0.1% Ointment is white, opaque and semisolid uniform mass. It is available in printed lami tube in the pack of 15 g. Each filled tube is packed in a printed paper carton.

Manufactured by :
Quest Pharmaceuticals Pvt. Ltd.
Chhata Pipara, Bara, Nepal

For further information
Quest Pharmaceuticals Pvt. Ltd.
Tripureshwor, Kathmandu
Tel. 01-4240304, Email : quest.ktm@quest.com.np,
Website : www.quest.com.np