# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS

S4

## PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PROTOPIC® 0,03 % ointment

PROTOPIC® 0,1 % ointment

**Read all of this leaflet carefully before you start using PROTOPIC®**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PROTOPIC® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## 1. WHAT PROTOPIC® CONTAINS

- The active substance is tacrolimus (as tacrolimus monohydrate). 1 g of PROTOPIC® 0,03 % ointment contains 0,3 mg of tacrolimus.1 g of PROTOPIC® 0,1 % ointment contains 1,0 mg of tacrolimus.
- The other ingredients are hard paraffin, liquid paraffin, propylene carbonate, white beeswax, white soft paraffin.

## 2. WHAT PROTOPIC® IS USED FOR

PROTOPIC® 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 topical corticosteroids and in children (2 years of age and older) who failed to respond adequately to topical corticosteroids.
PROTOPIC® 0,1 % ointment is used to treat moderate to severe atopic dermatitis (eczema) in adults who are not adequately responsive to or are intolerant of topical corticosteroids.

## 3. BEFORE YOU USE PROTOPIC®

**Do not use PROTOPIC®:**

- If you are hypersensitive (allergic) to tacrolimus or any of the other ingredients of PROTOPIC® or to macrolide antibiotics (e.g. azithromycin, clarithromycin, erythromycin).
- If your immune system has been weakened.
- If you are pregnant or breastfeeding your baby.
- If you are due to receive a live virus vaccine, allow 28 days to pass between vaccination and the use of PROTOPIC®. Before receiving a vaccination tell your doctor that you are using PROTOPIC® Vaccinations should not be given during treatment and for a certain time after treatment with PROTOPIC®. For live attenuated vaccinations (e.g. measles, mumps, rubella or oral polio) the waiting time is 28 days, for inactivated vaccines (e.g. tetanus, diphtheria, pertussis or influenza) 14 days.
- PROTOPIC® 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.

**Take special care with PROTOPIC®:**

**Exposure of the skin to sunlight should be minimised and the use of ultraviolet (UV) light from a solarium, therapy with UVB or UVA in combination with psoralens (PUVA) should be avoided during the use of PROTOPIC® ointment. Appropriate sun protection methods such as minimisation of the time in the sun, use of a sunscreen product and covering of the skin with appropriate clothing is advised.**

- The safety of using PROTOPIC® for a long time is not known. Some people who have used PROTOPIC® ointment have had cancers (for example, skin or lymphoma).
- Do not apply the ointment to infected lesions.
- Avoid contact with the eyes or mucous membranes (inside of your nose or mouth).

Inform your doctor:

- If you have liver failure.
- If you have any skin malignancies (cancers).
- If you have a weakened immune system (immunocompromised) whatever the cause.
- If you have an inherited skin barrier disease such as Netherton's syndrome or if you suffer from generalised erythroderma (inflammatory reddening and scaling of the entire skin).
- If you have swollen lymph nodes at the beginning of your treatment or if your lymph nodes become swollen during treatment with PROTOPIC®
- Do not expose your skin to long periods of sunlight or artificial sunlight such as tanning beds. If you spend time outdoors after applying PROTOPIC®, 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 PROTOPIC® as it is not recommended to use PROTOPIC® and light therapy at the same time.
- If you notice any change to the appearance of your skin, please inform your doctor.

**Using PROTOPIC®with food and drink:**

While using PROTOP1C®, drinking alcohol may cause the skin or face to become flushed or red and feel hot.

**Pregnancy and breastfeeding:**

Do not use PROTOPIC® if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before using PROTOPIC®.

**Driving and using machinery:**

PROTOPIC® ointment is administered topically and is unlikely to have an effect on the ability to drive or use machines.

**Using other medicines with PROTOPIC®:**

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you are taking any of the following medicines, please consult your healthcare provider:

Erythromycin, itraconazole, ketoconazole, diltiazem.

## 4. HOW TO USE PROTOPIC®

Do not share medicines prescribed to you with any other person.

Always use PROTOPIC® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not double the dose.

Two strengths of PROTOPIC® ointment (PROTOPIC® 0,03 % and PROTOPIC® 0,1 %) are available. Your doctor will decide which strength is best for you.

Children aged 2-15 years should not use PROTOPIC® 0,1 %.

Apply PROTOPIC® as a thin layer to affected areas of your skin.

PROTOPIC® may be used on most parts of the body, including the face and neck and in the creases of your elbows and knees.

Do not use 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 **PROTOPIC®** unless your hands are also being treated.

Before applying PROTOPIC® after a bath or shower, make sure your skin is completely dry.

**For how long should you use PROTOPIC®?**

The attending doctor must decide on the length of the treatment.

Safe use beyond 12 months has not been demonstrated.

**If you forget to use PROTOPIC®:**

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

**What should you do if you want to interrupt the treatment or stop using PROTOPIC® before the end of the course?**

You should always consult your doctor before deciding to interrupt the course of treatment or stop using PROTOPIC® altogether.

**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.

## 5. POSSIBLE SIDE EFFECTS

PROTOPIC® can have side effects.

Not all side effects reported for PROTOPIC® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PROTOPIC®, please consult your healthcare provider for advice.

Approximately half of the patients who use PROTOPIC® have some type of skin irritation where they have applied the ointment. Burning sensation and itching are reported frequently. These

symptoms are usually mild to moderate and generally go away within one week of using **PROTOPIC®.** Other frequent side effects are redness, feeling of warmth, pain, increased skin sensitivity (especially to hot and cold), skin tingling, rash, folliculitis (inflamed or infected hair follicles) and herpes viral infections (e.g. cold sores, generalised herpes simplex infections). Facial flushing or skin irritation after drinking alcohol is also frequent. Acne is a less frequent side effect. Rosacea and rosacea-like dermatitis (red colouring of the skin with acne) have also been reported. Following twice-weekly treatment, impetigo (crusty bacterial infection of the skin) in children, and application site infections (in children and adults) have been reported.

## 6. STORING AND DISPOSING OF PROTOPIC®

Store at or below 25 °C. Keep well closed.

Store all medicines out of reach of children.

Do not use PROTOPIC® 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 dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicine to your pharmacist.

## 7. PRESENTATION OF PROTOPIC®

PROTOPIC® 0,03 % and 0,1 % ointment are filled into white linear LOPE laminate tubes, with HOPE shoulders fitted with a white polypropylene screw cap. The tubes have a laminate orifice membrane seal.

Package sizes: 10 g, 30 g and 60 g.

## 8. IDENTIFICATION OF PROTOPIC®

PROTOPIC® 0,03 % ointment: A white to slightly yellow ointment.

PROTOPIC® 0,1 % ointment: A white to slightly yellow ointment.

## 9. REGISTRATION NUMBERS

PROTOPIC®0,03 %: A40/13.12/0219

PROTOPIC®0,1 %: A40/13.12/0231

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

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## 11. DATE OF PUBLICATION

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