PATIENT INFORMATION LEAFLET

ALMATIL 1 % CREAM

SCHEDULING STATUS: S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ALMATIL 1 % CREAM

Each gram contains 10 mg terbinafine hydrochloride.

Read this leaflet carefully because it contains important information for you

ALMATIL 1 % CREAM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **ALMATIL 1 % CREAM** carefully to get the best results from it.

- Keep this leaflet as you may need to read it again.
- Do not share your medicine with other people.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after four weeks.

1. WHAT ALMATIL 1 % CREAM CONTAINS:

Each gram contains 10 mg terbinafine hydrochloride as the active ingredient.

The other inactive ingredients are benzyl alcohol as the preservative, sodium hydroxide, cetostearyl alcohol, cetyl alcohol, cetylpalmitate, isopropyl myristate, polysorbate 60, sorbate monostearate and purified water.

2. WHAT ALMATIL 1 % CREAM IS USED FOR:

Terbinafine the active ingredient of **ALMATIL 1 % CREAM** and belongs to the group of medicine called antifungals. It is used to treat fungal infections of the scalp, body and feet (athlete's foot).

3. BEFORE YOU USE ALMATIL 1 % CREAM:

Do not apply ALMATIL 1 % CREAM:

- If you are allergic to terbinafine or any of the other ingredients.
- If you are younger than 12 years old.

Take special care with ALMATIL 1 % CREAM:

- If you are suffering from psoriasis.
- If your skin problem does not improve within 4 weeks, or if it becomes worse, consult your doctor.

Pregnancy and Breast-feeding:

If you become pregnant while using **ALMATIL 1 % CREAM** please consult your doctor, pharmacist or other health care professional for advice before using this medicine. It is not known if this medicine is safe for pregnant women. Oral terbinafine passes into breast milk. Mothers who are breast-feeding their babies should not apply this cream onto their breasts.

Driving and using machinery:

ALMATIL 1 % CREAM when applied to the skin will not affect your skills to drive or skills to operate any machinery.

Taking other medicines with ALMATIL 1 % CREAM:

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

4. HOW TO USE ALMATIL 1 % CREAM:

Always apply **ALMATIL 1 % CREAM** exactly as instructed in the leaflet. You should check with your pharmacist if you are unsure.

Do not share medicines prescribed for you with others.

The dose of **ALMATIL 1 % CREAM** will be different for each different fungal infection.

ALMATIL 1 % CREAM, unless otherwise prescribed, should be used as follows:

Apply enough to cover the affected and surrounding skin areas and rub in gently. Keep **ALMATIL 1 % CREAM** away from the eyes, nose, mouth and other mucous membranes. Do not apply an occlusive dressing (airtight covering, such as a tight bandage or plastic kitchen wrap) over this cream.

To help clear up your infection completely, it is very important that you keep using **ALMATIL 1 % CREAM** for the full duration of treatment, even if your symptoms begin to clear up after a few days. The duration of treatment will depend upon your condition, or as directed by your doctor or pharmacist.

The cream should be applied once to twice daily for one week or in the case of *pityriasis versicolor*, (a condition where flaky discoloured patches of skin occur mainly on the chest and back), for two weeks, even if the affected area starts healing sooner.

For the treatment of *tinea corporis* (ringworm) or *tinea cruris* (jock itch), apply one to two times daily for at least one week after the symptoms improve. Do not use for more than four weeks.

For the treatment of *tinea pedis* (athletes foot), apply twice daily for at least one week after the symptoms improve. Do not use for more than four weeks.

For the treatment of cutaneous candidiasis (skin thrush) apply one to two times daily

for one week.

If there are no signs of improvement after two weeks of therapy, consult your doctor.

If you have applied more ALMATIL 1 % CREAM than you should:

In the event of overdosage your side-effects may worsen. Consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining cream with you so the doctor will know what you have applied on your skin.

If you forget to apply your ALMATIL 1 % CREAM:

Apply as soon as possible. However, if it is almost time for your next application, continue to apply the next application at the usual time.

5. POSSIBLE SIDE EFFECTS:

ALMATIL 1 % CREAM can cause side effects.

Contact your doctor if you experience any of the following side effects:

- Dryness, redness, itching, burning, peeling or loosening of skin, rash, stinging, tingling or other signs of skin irritation not present before use of **ALMATIL 1 % CREAM.**

Not all side-effects reported for ALMATIL 1 % CREAM are included in this leaflet. Should you notice any other effects or your condition worsens while applying ALMATIL 1 % CREAM, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSAL OF ALMATIL 1 % CREAM:

Store in a cool (at or below 25 °C), dry place.

Do not store the cream in the bathroom.

FOR EXTERNAL USE ONLY**. KEEP OUT OF REACH OF CHILDREN**.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION:

ALMATIL 1 % CREAM is available in a 7,5 g, 15 g or 30 g white aluminium tube, with a white high density polyethylene screw-on cap.

8. IDENTIFICATION:

ALMATIL 1 % CREAM is a white or almost white cream, with a slight almond odour, washes off with water.

9. REGISTRATION NUMBER:

42/20.2.2/0382

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

ACINO PHARMA (Pty) Ltd
106 16th Road
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