

**What is in this leaflet?**

- What PHYTORAL SHAMPOO and what it is used for
- What you need to know before you use PHYTORAL SHAMPOO
- How to use PHYTORAL SHAMPOO
- Possible Side Effects
- How to store PHYTORAL SHAMPOO
- Contents of the pack and other information

**1. WHAT PHYTORAL SHAMPOO WHAT IT IS USED FOR?**

Phytoral shampoo contains a medicine called ketoconazole. This belongs to a group of medicines called ‘antifungals’. Like other shampoos, it also contains ingredients to clean your hair.

Ketoconazole shampoo is used for fungal infections on the scalp and body such as:

- Dandruff
- Dry or greasy scaling of the scalp and other parts of the body called ‘seborrhoeic dermatitis’
- White to brown patches on the body that sometimes appear after being in the sun called ‘tinea versicolor’ or ‘pityriasis versicolor’

These conditions can be itchy. They are caused by a fungus (yeast) called ‘Malassezia’. This fungus is found on everyone’s skin, but sometimes it can overgrow and cause problems. Ketoconazole shampoo works by killing the fungus and stopping it from coming back.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE PHYTORAL SHAMPOO**

Do not use Ketoconazole shampoo if:

- You are allergic to anything in Ketoconazole shampoo (listed in section 6 below)

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Ketoconazole shampoo.

**Warnings and precautions**

Talk to your doctor or pharmacist before using this medicine:

- If you use a lotion or cream on your hair that contains a steroid, such as betamethasone or hydrocortisone:
- You should use less and less of the lotion or cream during the first 2 to 3 weeks of Ketoconazole shampoo treatment
- This will stop your condition flaring up while Ketoconazole shampoo starts to work

If you have any questions about stopping your steroid lotion or cream, ask your doctor or pharmacist.

***Children and adolescents***

Ketoconazole Shampoo is not recommended for use in infants and children.

***Other medicines and Ketoconazole Shampoo***

Ketoconazole shampoo does not normally react with other medicines. However, tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

***Pregnancy and breast-feeding***

Ketoconazole shampoo can be used if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

***Driving and using machines***

Ketoconazole shampoo is not likely to affect you being able to drive or use any tools or machines.

### **3. HOW TO USE PHYTORAL SHAMPOO**

Always use this medicine exactly as your doctor has told you. Ketoconazole shampoo is for use on your hair or skin only. Check with your doctor or pharmacist if you are not sure.

*How often you should use Ketoconazole shampoo*

The recommended dose is:

*For dandruff or dry or greasy scaling of the skin*

- Start by using the shampoo twice a week
- You should use it every 3 or 4 days for 2 to 4 weeks
- You should then use the shampoo once every 1 to 2 weeks to stop the symptoms coming back
- Do not use the shampoo more often than your doctor has told you

*For white to brown patches on the skin*

- You should use the shampoo on the white to brown patches of skin once daily for 1-5 days
- Do not use the shampoo more often than your doctor has told you

*Using Ketoconazole shampoo*

- Wash your hair or infected part of skin with the shampoo
- Leave it on for 3 to 5 minutes
- Rinse thoroughly

*If Ketoconazole shampoo gets in your eyes*

Gently bathe your eyes in cold water.

*Using your normal shampoo*

- If you need to wash your hair between treatments, use a normal shampoo
- If your hair is very thick or long, you can wash it with your usual shampoo and then use Ketoconazole shampoo

***If you swallow Ketoconazole shampoo***

If you swallow any shampoo, tell your doctor straight away.

***If you forget to use Ketoconazole shampoo***

- If you miss a treatment with Ketoconazole shampoo, you should use it as soon as you remember
- Do not use the shampoo twice to make up for a missed treatment

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.

Stop using Ketoconazole shampoo and tell your doctor straight away if you notice or suspect any of the following.

You may need urgent medical treatment.

- Allergic reaction, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. This can affect fewer than 1 in 1000 people
- Severe irritation or reddening of the skin where the shampoo has been used, or other signs of allergy during the first few days of treatment. This can affect fewer than 1 in 100 people
- Peeling or blistering of the skin. This can affect fewer than 1 in 1000 people

Tell your doctor or pharmacist if you notice or suspect any of the following side effects:

Uncommon side effects (affects fewer than 1 in 100 people)

- •Infection of the hair roots
- •Increase in production of tears
- •Unusual hair loss or thinning
- •Dry skin, rash, burning feeling
- •Changes in how your hair feels

**Rare side effects (affects less than 1 in 1000 people)**

Taste impairment

- Irritation of the eyes
- Acne

- Flaking skin

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is classed as unknown

- Hives (also known as nettle rash or urticaria)
- Hair colour changes

## **5. HOW TO STORE PHYTORAL SHAMPOO**

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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 it contains***

Ketoconazole USP .....2.0% w/v

*Active ingredients:* Ketoconazole

*In active ingredients:* Propylene glycol; Sodium Lauryl Sulphate; Cresmer SB; Erythrosine Color Supra; Freshna S1072; Swiss bouquet P3043; Forestall

### ***What PHYTORAL SHAMPOO looks like and contents of the pack,***

Pink coloured thick solution

100ml solution is packed in a 100 ml HDPE Bottle such 1 bottle is packed in a carton along with pack insert

### **Manufacturer**

**MICRO LABS LIMITED**

At KNM Pharma Pvt. LTD

No 13, Mahagujarat Industrial Estate,

Opp. Nova Petrochem, Sanand Bavla Road,

Changodar, Dist: Ahmedabad Gujarath, India

### **Marketing Authorization Holder**

**MICRO LABS LIMITED**

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INDIA

### **Marketing Authorization Numbers**

Rwanda FDA-HMP-MA-0042

### **Date of Revision:**

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