

DERMAVENS

(ketoconazole) 2% shampoo

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

1. What DERMAVENS shampoo is and what it is used for?
2. Before you use DERMAVENS shampoo.
3. How to use DERMAVENS shampoo?
4. Possible side effects.
5. How to store DERMAVENS shampoo?
6. Further information.

1. What DERMAVENS shampoo is and what it is used for?

DERMAVENS shampoo contains a medicine called ketoconazole. This belongs to a group of medicines called 'antifungals'.

DERMAVENS 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. DERMAVENS shampoo works by killing the fungus and stopping it from coming back.

2. Before you use DERMAVENS shampoo

Do not use DERMAVENS shampoo if:

- You are allergic to anything in DERMAVENS 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 DERMAVENS shampoo.

Take special care with DERMAVENS shampoo

Check with 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 DERMAVENS shampoo treatment.
 - This will stop your condition flaring up while DERMAVENS shampoo starts to work.

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

Taking other medicines

DERMAVENS shampoo does not normally react with other medicines. However, please 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.

Children and adolescents

DERMAVENS shampoo is not recommended for use in infants and children.

Pregnancy and breast-feeding

DERMAVENS 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

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

3. How to use DERMAVENS shampoo

Always use DERMAVENS shampoo exactly as your doctor has told you. DERMAVENS shampoo is for use on your hair or skin only. You should check with your doctor or pharmacist if you are not sure.

How often you should use DERMAVENS shampoo

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 a day for up to 5 days.
- If the white to brown patches become more noticeable when you have been in the sun:
 - You should use the shampoo once a day for 3 days before you next expose your skin to the sun.
- Do not use the shampoo more often than your doctor has told you.

Using DERMAVENS shampoo

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

If DERMAVENS 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 DERMAVENS shampoo.

If you swallow DERMAVENS shampoo

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

If you forget to use DERMAVENS shampoo

If you miss a treatment with DERMAVENS 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, DERMAVENS shampoo can cause side effects, although not everybody gets them.

Stop using DERMAVENS 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 fewer 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.

If you get any of these side effects, or other side effects not listed in this leaflet, tell your doctor or pharmacist straight away.

5. How to store DERMAVENS shampoo

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use your medicine after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

The active substance in DERMAVENS shampoo is ketoconazole.

Each gram (g) of DERMAVENS shampoo contains 20 milligrams (mg) of ketoconazole (2% w/w).

The other ingredients are: disodium laureth sulfosuccinate, cocamide diethylamide, lauryl dimethyl hydroxypropyl hydrolysed collagen, imidurea, perfume heliotrope 2184, hydrochloric acid water purified.

What DERMAVENS shampoo looks like and contents of the pack

DERMAVENS shampoo is clear, viscous, light pink liquid with characteristic pleasant odor.

Pack size:

Box with shampoo (2%) in plastic bottle of 120 ml.

Dispensing status:

Over the counter medicine (OTC).