

Sebizole[®]

ketoconazole

2% w/w shampoo

What is in this leaflet

This leaflet answers some common questions about Sebizole. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sebizole against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Sebizole is used for

Sebizole contains the active ingredient ketoconazole.

Sebizole is a broad-spectrum anti-fungal agent which inhibits the growth of sensitive fungi.

Sebizole is used to treat:

- Seborrhoeic dermatitis (waxy skin condition)
- Severe dandruff of the scalp in adults

Ask your doctor or pharmacist if you have any questions about why Sebizole has been recommended for you.

This medicine is available only from a pharmacy.

Before you use Sebizole

When you must not use it

Do not use Sebizole if you have an allergy to:

- ketoconazole
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching

Do not use Sebizole if you are under 12 years of age.

Do not use Sebizole if the packaging is torn or shows signs of tampering or if the shampoo shows visible signs of deterioration.

Do not use Sebizole after the expiry date (EXP) printed on the pack. If you use this medicine after the expiry date has passed, it may not work as well.

Before you start to use it

- Tell your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.
- If a reaction suggesting sensitivity or chemical irritation should occur, discontinue use of Sebizole.
- Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. They will discuss the risks and benefits of using this medicine during pregnancy.
- Tell your doctor or pharmacist if you are breastfeeding or planning to breastfeed. They will discuss the risks and benefits of using this medicine while breastfeeding.
- Irritation may occur when Sebizole is used immediately after prolonged treatment

with topical (applied to certain area of the skin) corticosteroids on the same area. It is recommended to wait about two weeks after stopping treatment with topical corticosteroids before using Sebizole.

- Rarely, hair loss may be experienced
- The safe use of Sebizole beyond four weeks has not been adequately established. Follow instructions carefully.
- Avoid contact with the eyes. If contact does occur, rinse with cold water.

There is no evidence this medicine is addictive.

Using other medicines

Tell your doctor if you are using any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines such as corticosteroids may interfere with Sebizole.

You should also tell any health professional who is prescribing a new medication for you that you are taking Sebizole.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while using this medicine.

How to use Sebizole

How much to use

Do not use unnecessarily large quantities of Sebizole during treatment.

How to use it

Carefully follow all directions given to you by your doctor or pharmacist. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

1. Apply to the wet scalp and work into a lather.
2. Leave on for three to five minutes.

3. Rinse thoroughly with water.

Avoid contact with the eyes. If shampoo enters the eyes, rinse with cold water.

How long to use it

Use twice weekly for no longer than four weeks at any one time. An interval of at least four weeks should be allowed between consecutive courses.

This medicine is not to be taken orally.

While you are using Sebizole

Things you must do

If you become pregnant while you are using Sebizole tell your doctor.

If you are about to start using a new medicine tell your doctor and pharmacist that you are using Sebizole.

Things you must not do

Do not give Sebizole to anyone else, even if they have the same condition as you.

Do not use Sebizole to treat any other complaints unless your doctor tells you to.

Things to be careful of

Sebizole is unlikely to produce an effect on the ability to drive or use machinery, however, care should be taken until you know how this medicine affects you.

In case of overdose

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON

or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may be experiencing severe side effects due to Sebizole.

In the event of accidental ingestion, contact the above numbers even if there are no signs of discomfort or poisoning. Oral ingestion is usually followed by nausea and vomiting due to the detergent.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor if you notice any of the following and they worry you:

-
-

Uncommon side effects

- Infection of the hair roots
- Increase in production of tears
- Unusual hair loss or thinning
- Dry skin, rash,
- Irritation or reddening of skin where shampoo has been used
- Changes in hair texture

Rare side effects

- Change in taste
- Irritation of the eyes
- Acne
- Flaking skin

Itchy rash or hives, and hair colour changes have been reported, however the precise frequency is unknown.

Tell your doctor immediately, or go to the nearest Accident and Emergency Department at your hospital if you notice any of the following:

Rare

- skin rash
- hives or welts
- difficulty breathing
- swelling

Tell your doctor if you notice any other effects.

Other adverse effects not listed above may also occur in some patients.

Do not be alarmed by this list. You may not experience any of the side effects listed above.

After using Sebizole

Storage

Store Sebizole below 25°C, protected from light. Do not leave it in the car or on a window sill. Heat can destroy some medicines.

Keep it out of reach of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

When you have stopped using Sebizole or if it has passed its expiry date, ask your pharmacist what to do with any leftover solution.

Product description

What it looks like

Sebizole is a clear pink coloured, viscous liquid with a fragrant smell.

Ingredients

Active ingredient:

- ketoconazole (each mL contains 20.6 mg of ketoconazole)

Inactive ingredients:

- sodium laureth sulfate

- cocamide diolamine
- sodium lauryl sarcosinate
- polyethylene glycol distearate
- hydrochloric acid
- diazolidinyl urea
- Herb Flower fragrance
- erythrosine sodium
- purified water.

Sponsor details

Sebizole is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

19 March 2018

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