NINAZOL SHAMPOO®

Ketoconazole (2.0% w/v)

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What Ninazol is used for

Ninazol is used for pityriasis capitis (dandruff) and seborrheic dermatitis (itchy rash and flaky scales) of scalp.

How Ninazol works

It inhibits the growth of fungi and yeast. It also relieves scaling and pruritus (itching)

Before you use Ninazol

- When you must not use it

Do not use Ninazol if you are hypersensitive to ketoconazole or any other ingredients in Ninazol.

- Before you start to use it

Tell your doctor if you:

• Have been using steroids for a long period of time.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you.

- Pregnancy and lactation

Ninazol Shampoo should only be used during pregnancy if the potential benefits justify the possible risks to the foetus. It is also not advisable to breastfeed during therapy with Ninazol.

How to use Ninazol

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Apply sufficient amount of Ninazol to the wet hair to produce enough lather to wash the hair and scalp. Massage gently over the entire scalp for about one minute and then rinse off. Repeat and allow the shampoo to remain on the scalp for an additional 3 minutes. Rinse hair and scalp thoroughly after this and dry hair in the normal way.

- When to use it

Use twice weekly for 4 weeks, with at least 3 days lapse between each shampooing.

- How long to use it

Continue taking Ninazol for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- <u>If you use too much (overdose)</u>

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do
- Always use Ninazol exactly according to the instructions given by your doctor or pharmacists. Check with your doctor or pharmacist if you are unsure.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects get serious or anything else that make you feel unwell.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Ninazol.
- Things you must not do
- Do not stop using Ninazol without consulting your doctor
- Do not use Ninazol after the expiry date which is stated on the carton and bottle.

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

- Things to be careful of

• Driving and using machines Ninazol is unlikely to affect your ability to drive or operate machinery.

Contact with eyes should be avoided. Wash eyes thoroughly with cold water should the shampoo gets into the eyes.

Side effects

Like all medicines, Ninazol can cause side effects, although not everybody get them.

Tell your doctor if you have any of these symptoms:

- Irritation
- Dermatitis
- Burning sensation
- Dryness/oiliness of the hair and scalp
- Dry skin
- Pruritus
- Loss of the curl from permanently waved hair
- Discolouration of chemically damaged hair or grey hair

Tell your doctor or pharmacist if you notice any other side effects and it worries you.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public -> Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of Ninazol

Storage

Store in a cool, dry place below 30° C. Protect from light.

Keep out of reach of children.

- Disposal

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

Product Description

- What it looks like

Ninazol shampoo is a clear, red viscous solution.

- Ingredients

- Active ingredient

Each ml contains Ketoconazole 2.0% w/v.

- Inactive ingredients

Texapon N28, comperlan KD, dehyton K, polyethylene glycol 400, citric acid, edetate disodium, butylated hydroxytoluene, alcohol, polyquartH81, ponceau 4R, colour perfume, purified water.

- Packing

It is packed in a high density polyethylene bottle of 100ml.

- MAL Number

MAL20033676AZ

Manufacturer

T.O. CHEMICALS (1979) LTD. 280 Soi Sabaijai, Suthisarn Road, Bangkok 10310, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur.

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