

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

VARI MICONAZOLE 2 % *m/m* ORAL GEL

Miconazole

Contains sweetener (3,06 mg sodium saccharin in each gram).

Read all of this leaflet carefully because it contains important information for you.

VARI MICONAZOLE 2 % *m/m* ORAL GEL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **VARI MICONAZOLE 2 % *m/m* ORAL GEL** carefully to get best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **VARI MICONAZOLE 2 % *m/m* ORAL GEL** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What **VARI MICONAZOLE 2 % *m/m* ORAL GEL** is and what it is used for.
2. What you need to know before you use **VARI MICONAZOLE 2 % *m/m* ORAL GEL**.
3. How to use **VARI MICONAZOLE 2 % *m/m* ORAL GEL**.
4. Possible side effects.
5. How to store **VARI MICONAZOLE 2 % *m/m* ORAL GEL**.
6. Contents of the pack and other information.

1. What **VARI MICONAZOLE 2 % *m/m* ORAL GEL is and what it is used for**

VARI MICONAZOLE 2 % *m/m* ORAL GEL is an antifungal gel used to treat fungal infections in the mouth such as thrush or inflammation of the mouth.

2. What you need to know before you use VARI MICONAZOLE 2 % *m/m* ORAL GEL

Do not apply VARI MICONAZOLE 2 % *m/m* ORAL GEL:

- If you are hypersensitive (allergic) to miconazole or any of the inactive ingredients of **VARI MICONAZOLE 2 % *m/m* ORAL GEL** (see section 6).
- If you have liver problems.
- If you are taking any of the following medicines:
 - Medicines for hayfever or allergies called terfenadine, astemizole or mizolastine.
 - Medicines taken to lower cholesterol called lovastatin or simvastatin.
 - Midazolam (by mouth) or triazolam - for anxiety or to help you sleep.
 - Pimozide or sertindole - for conditions affecting thoughts, feelings and behaviour.
 - Medicines taken for an irregular heartbeat called quinidine or dofetilide.
 - Ergotamine – used to treat migraine.
 - Bepridil – used to treat high blood pressure and angina (chest pain).
 - Cisapride – used to treat heartburn.
 - Warfarin – used to treat or prevent blood clots.

VARI MICONAZOLE 2 % *m/m* ORAL GEL should not be used in children under the age of 4 months, in cases where the child's ability to swallow has not fully developed yet, or in prematurely born infants under the age of 6 months.

Warnings and precautions

Take special care with **VARI MICONAZOLE 2 % *m/m* ORAL GEL**:

- Avoid contact with the eyes.
- If you are giving the gel to a child or infant, make sure that the gel does not close off the throat of the child or infant, as they could choke on it. Divide each application in smaller portions (never put the whole amount in the mouth of the child at once). You should place the gel with a clean finger at the front of the mouth – never put it at the back of the throat. If you are breastfeeding your baby, never apply the gel to your nipple to treat your baby.

- If you are taking a medicine called phenytoin for epilepsy.
- If you are taking medicines by mouth for diabetes (high blood sugar). Your doctor may need to change the dose of these medicines.

VARI MICONAZOLE 2 % *m/m* ORAL GEL may cause a hypersensitivity reaction or a severe skin reaction. If a hypersensitivity reaction or irritation occur, or if you develop a skin rash, you should stop using **VARI MICONAZOLE 2 % *m/m* ORAL GEL**.

Other medicines and VARI MICONAZOLE 2 % *m/m* ORAL GEL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) The use of **VARI MICONAZOLE 2 % *m/m* ORAL GEL** with these medicines may cause undesirable interactions. Please consult with your doctor, pharmacist or healthcare provider for advice if you need to take any other medicines.

The following medicines may cause an interaction when used in combination with **VARI MICONAZOLE 2 % *m/m* ORAL GEL**:

- Medicines taken for HIV infection such as saquinavir and ritonavir. They are called protease inhibitors.
- Medicines used in the treatment of cancer such as busulfan, docetaxel and a group of medicines known as the *Vinca* alkaloids.
- Medicines that act on the heart and blood vessels called calcium channel-blockers, such as dihydropyridines and verapamil.
- Medicines that are usually given after an organ transplant called ciclosporin, tacrolimus or sirolimus.
- Medicines taken for epilepsy called phenytoin or carbamazepine.
- Alfentanil – used for the treatment of pain.
- Medicines used for anxiety or to help you sleep (tranquillisers), such as buspirone, alprazolam or brotizolam.
- Midazolam – used to help you relax or sleep when given by an injection.

- Rifabutin – used for tuberculosis (TB).
- Methylprednisolone – used for inflammation (given by mouth or injection).
- Ebastine – used for the treatment of allergies.
- Reboxetine – used for the treatment of mood disorders such as depression.
- Sulphonylureas such as chlorpropamide and glibenclamide (medicines used to treat diabetes taken by mouth).
- Sildenafil – used to treat erection problems.
- Trimetrexate – used in the treatment of a type of pneumonia.

VARI MICONAZOLE 2 % *m/m* ORAL GEL with food and drink:

VARI MICONAZOLE 2 % *m/m* ORAL GEL should be applied after meals preferably.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using **VARI MICONAZOLE 2 % *m/m* ORAL GEL**.

DO NOT use **VARI MICONAZOLE 2 % *m/m* ORAL GEL** if you are pregnant, suspect that you are pregnant or breastfeeding. Contact your doctor immediately.

Driving and using machines:

VARI MICONAZOLE 2 % *m/m* ORAL GEL is not likely to impair your ability to drive a vehicle or use machinery. However, take special care if you are performing tasks requiring your attention until you know how **VARI MICONAZOLE 2 % *m/m* ORAL GEL** affects you.

3. How to use VARI MICONAZOLE 2 % *m/m* ORAL GEL

Always use **VARI MICONAZOLE 2 % *m/m* ORAL GEL** exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

How to apply the gel:

VARI MICONAZOLE 2 % *m/m* ORAL GEL is for oral use only.

- Each tube of the gel is sealed - use the cap to pierce the seal.
- Keep the gel in the mouth as long as possible. Do not swallow it straight away.
- If the infection is just in the mouth, apply directly to the affected area with a clean finger.
- If you are wearing dentures, remove them at bedtime and rub them with the gel. This helps stop your dentures becoming infected too.
- Do not use more than the stated dose.
- Use after meals.
- If you are giving the gel to a child or infant aged 4 months and over, make sure that the gel does not become a choking hazard by making sure you place the gel at the front of the mouth.

How much gel to use:

Your doctor or pharmacist will tell you how much **VARI MICONAZOLE 2 % *m/m* ORAL GEL** to use and for how long you should use it. Your doctor will probably suggest the following treatment course:

Adults and children 2 years and older: ½ measuring spoonful (2,5 mL) of gel, applied four times a day after meals.

Children 4 months to 2 years: ¼ measuring spoonful (1,25 mL), applied four times a day after meals.

Each dose is to be divided into smaller portions and the gel applied to the affected area(s) with a clean finger.

Apply three to four times daily depending on the severity of the infection.

Apply the gel regularly until all signs of the infection have disappeared.

Continue using for another two days after the infection has cleared.

If you have the impression that the effect of **VARI MICONAZOLE 2 % *m/m* ORAL GEL** is too strong or too weak, tell your doctor or pharmacist.

If you use more VARI MICONAZOLE 2 % *m/m* ORAL GEL than you should

In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and any remaining oral gel with you, so that the doctor knows what you have taken.

If you forget a dose of VARI MICONAZOLE 2 % *m/m* ORAL GEL

Do not apply the missed dose. Apply the next dose of gel as usual and keep using it as your doctor or pharmacist has instructed you. Do not use a double dose of gel to make up for a missed dose.

4. Possible side effects

VARI MICONAZOLE 2 % *m/m* ORAL GEL can have side effects.

Not all side effects reported for VARI MICONAZOLE 2 % *m/m* ORAL GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using VARI MICONAZOLE 2 % *m/m* ORAL GEL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop using VARI MICONAZOLE 2 % *m/m* ORAL GEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden swelling of the face, lips, tongue or throat, which may cause difficulty in swallowing or breathing.
- Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin.
- Light headedness, rash or generalised itch, wheezing or difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **VARI MICONAZOLE 2 % *m/m* ORAL GEL**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Painful, blistering or peeling of your skin, mouth, eyes and genitals (Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Red rash covered with small pus-filled bumps that can spread over your body sometimes with a fever (acute generalised exanthematous pustulosis (AGEP)).
- Severe rash over your body, usually with fever and swollen lymph nodes, affecting the blood cells and organs (drug reaction with eosinophilia and systemic symptoms (DRESS)).
- Yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems (hepatitis).
- Choking.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- Abnormal taste in your mouth.
- Nausea (feeling sick), vomiting (being sick), diarrhoea, dry mouth, mouth discomfort, sore mouth.
- Food flows back up from your stomach and into your mouth (regurgitation of food).

Side effects occurring with an unknown frequency:

- Tongue discolouration.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of **VARI MICONAZOLE 2 % *m/m* ORAL GEL**.

5. How to store VARI MICONAZOLE 2 % *m/m* ORAL GEL

- Store at or below 25 °C.
- Do not freeze.
- Keep the tube tightly closed.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use after the expiry date printed on the tube or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VARI MICONAZOLE 2 % *m/m* ORAL GEL contains

Each gram contains 20 mg miconazole.

The other ingredients are glycerol, methyl paraben, pineapple essence (as flavourant), polysorbate 80, pregelatinised potato starch, propyl paraben, purified water and sodium saccharin.

Contains preservatives: 0,2 % *m/m* methyl paraben and 0,02 % *m/m* propyl paraben.

What VARI MICONAZOLE 2 % *m/m* ORAL GEL looks like and contents of the pack

A translucent, homogeneous gel, free from any visible contaminants, with a pineapple flavour.

VARI MICONAZOLE 2 % *m/m* ORAL GEL is supplied in aluminium tubes with white plastic caps containing 30 g or 40 g gel.

Holder of certificate of registration

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