

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Miconazole Oromucosal Gel BP

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist

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1. What Miconazole Oromucosal Gel BP are and what they are used for

Oral treatment of candidosis of the oropharynx.

Miconazole gel is for use in adults, children and infants 4 months and older.

Consideration should be given to official guidance on the appropriate use of antifungal agents

2. What you need to know before you use Miconazole Oromucosal Gel BP

Do not use and tell your doctor if you have:

- Hypersensitivity to the active substance or to any of the excipients.

If you are not sure, talk to your doctor or pharmacist before using Miconazole Oromucosal Gel BP.

Warnings and precautions

Talk to your doctor before taking Miconazole Oromucosal Gel BP

If you are pregnant or breast-feeding

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

3. How to use Miconazole Oromucosal Gel BP

For oral administration.

1 measuring spoon(provided) is equivalent to 124 mg miconazole per 5 mL gel.

Oropharyngeal candidosis

Infants: 4-24 months: 1.25 mL (1/4 measuring spoon) of gel, applied four times a day after meals. Each dose should be divided into smaller portions and the gel should be applied to the affected area(s) with a clean finger. The gel should not be applied to the back of the throat due to possible choking. The gel should not be swallowed immediately, but kept in the mouth as long as possible.

Adults and children 2 years of age and older: 2.5 mL (1/2 measuring spoon) of gel, applied four times a day after meals.

The gel should not be swallowed immediately, but kept in the mouth as long as possible.

The treatment should be continued for at least a week after the symptoms have disappeared.

For oral candidosis, dental prostheses should be removed at night and brushed with the gel.

4. Possible side effects

If you experience any of the following, stop using the medicine and seek immediate medical help

Like all medicines, this medicine can cause side-effects although not everybody gets them.

Adult Patients

common adverse reactions reported included nausea (4.5%), product taste abnormal (4.5%), oral discomfort (3.4%), dry mouth (2.3%), dysgeusia (1.1%), and vomiting (1.1%).

Paediatric Patients

Paediatric Patients the frequency of nausea (13.0%) and vomiting (13.0%) was very common, and regurgitation (8.7%) was common. As identified through post-marketing experience, choking may occur in infants and young children (See Section 4.3 Contraindications and Section 4.4 Special Warnings and Special Precautions). The frequency, type, and severity of other adverse reactions in children are expected to be similar to that in adults.

Description of selected adverse reactions

Increases in INR and bleeding events such as epistaxis, contusion, haematuria, melaena, haematemesis, haematoma and haemorrhages have been reported in patients treated with oral anticoagulants such as warfarin in association with miconazole oral gel (see sections 4.4 and 4.5).

Some events had fatal outcomes.

If you experience any side-effects not included in this leaflet or are not sure about anything, talk to your doctor or pharmacist

Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist. This includes any possible side-effects not listed in this leaflet.

5. How to store Miconazole Oromucosal Gel BP

Keep well closed. Do not store above 30°C. Do not freeze

KEEP OUT OF REACH OF CHILDREN

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 Miconazole Oromucosal Gel BP contain:

Miconazole BP

What Miconazole Oromucosal Gel BP looks like and contents of the pack:

Miconazole Oromucosal Gel BP is White homogenous translucent oral gel, sweet in taste and free from gritty particle.

They are packaged as

- 15g Aluminium Collapsible tubes with epoxy phenol lacquered with latex lining.
- 30g Aluminium Collapsible tubes with epoxy phenol lacquered with latex lining

Manufactured by:

**S Kant**
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.