

# DECOZOL ORAL GEL

Miconazole (2% w/w)

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

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Decozol Oral Gel against the benefits they expect it will have for you.

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

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

## What Decozol Oral Gel is used for

Decozol Oral Gel is used to treat fungal infections of the mouth, throat, stomach or intestines in adults and children 6 months and older. For a child between 4 and 6 months of age, be sure they do not have any swallowing problems before treating them with the oral gel.

## How Decozol Oral Gel works

Decozol Oral Gel contains miconazole, which possesses an antifungal activity against the common dermatophytes and yeasts as well as an antibacterial activity against certain bacteria.

Ask your pharmacist or doctor if you have any questions about this medicine.

## Before you use Decozol Oral Gel

### -When you must not use it

Do not take Decozol Oral Gel:

- if you are allergic to miconazole or any components in this preparation.
- if you suffer from liver problems

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Decozol Oral Gel.

Do not Decozol Oral Gel if you are on warfarin therapy.

### -Before you start to use it

If you are giving the gel to an infant or child, make sure that the gel does not close off the infant's or child's throat as they could choke on it.

Pregnancy and breast feeding:

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

### -Taking other medicines

Tell your pharmacist or doctor if you are taking any other products (such as over the counter drug, prescribed drug and herbal products).

Use of Decozol Oral Gel in combination with anti-coagulant

effect such as warfarin is subjected to metabolism by CYP2C9 (enzyme) should be carefully monitored.

## How to use Decozol Oral Gel

### -How much to use

Your doctor will tell you how much Decozol Oral Gel to take and for how long you should take it. Your doctor will probably suggest the following treatment course:

Infections of the mouth and throat:

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

Children 6 months to 2 years: 1/4 measuring spoonful (1.25 mL) of gel, applied four times a day after meals. Divide each dose into smaller portions and apply to the affected areas with a clean finger.

Infections of the stomach or intestines with or without infections of the mouth or throat:

The dose depends on body weight. Do not exceed 2 measuring spoonful (10 mL) four times per day.

- Body weight  $\leq 11.9$ kg: 1/4 measuring spoonful (1.25 mL) of gel, four times a day;
- Body weight from 12-24.9kg: 1/2 measuring spoonful (2.5 mL) of gel, four times a day;
- Body weight from 25- 36.9 kg: 1 measuring spoonful (5 mL) of gel, four times a day;
- Body weight from 37- 49.9 kg: 1 and 1/2 measuring spoonfuls (7.5 mL) of gel, four times a day;
- Body weight of  $\geq 50$  kg: 2 measuring spoonfuls (10 mL) of gel, four times a day.

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

If the infant is 4-6 months old, and is premature or has slow development, check with your doctor before using this medicine.

-When to use it

Decozol Oral Gel should be taken after mealtimes.

-How long to use it

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

-If you forget to use it

If you forget to use at the right time, use it as soon as you remember, then carry on as before.

Do not double the dose to catch up.

-If you use too much (overdose)

If you suspect that you are overdosed, please consult your pharmacist or doctor. Bring any remaining medicine with you.

**While you are using Decozol Oral Gel**

-Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Decozol Oral Gel.

Please tell your doctor before using Decozol Oral Gel if you are pregnant, think you may be pregnant or might become pregnant. You may still be able to use Decozol Oral Gel if your doctor thinks you need to.

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

The benefits of Decozol Oral Gel must be assessed against possible effects on your child.

-Things you must not do

Do not take Decozol Oral Gel to treat any other complaints unless your doctor tells you to.

-Things to be careful of

If you suffer from liver problems, consult your doctor before taking Decozol Oral Gel.

**Side effects**

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Decozol Oral Gel.

Occasionally, Decozol Oral Gel may cause side effects of:

- gastrointestinal discomfort
- nausea
- vomiting
- diarrhea
- allergic reactions

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npa.gov.my](http://npa.gov.my) (Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of Decozol Oral Gel**

-Storage

Store below 30°C.  
Keep out of reach of children.

-Disposal

Dispose the medicine after the expiry date.

Consult your pharmacist on how to safely dispose of any medicines no longer required.

**Product description**

-What it looks like

Decozol Oral Gel is an off-white gel with orange flavor, available in 10g and 15g aluminium tube.

-Ingredients

-Active ingredient:  
Miconazole 2%w/w

-Inactive ingredients:  
Methylparaben, Propylparaben, Orange Flavour, Pregelatinised Potato Starch, Saccharin Sodium, Xanthan Gum, Propylene Glycol, Polysorbate 20 and Purified Water.

-MAL number:  
MAL07010892AZ

**Manufacturer and Product Registration Holder**

HOE Pharmaceuticals Sdn. Bhd.  
Lot 10, Jalan Sultan Mohamed 6,  
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