

# DECOZOL

Miconazole 2% w/w Oral Gel

## Consumer Medicine Information

### What is in this leaflet

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

**If you have any concerns about using DECOZOL Oral Gel, ask your doctor or pharmacist.**

Your doctor and pharmacist have more information.

**Keep this leaflet with your DECOZOL Oral Gel.**

You may need to read it again.

### What DECOZOL Oral Gel is used for

DECOZOL Oral Gel is used for treating infections of the mouth and throat (e.g. thrush).

Miconazole, the active ingredient in DECOZOL Oral Gel, is a medicine used for treating infections caused by fungi, including yeast.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

### Before you use DECOZOL Oral Gel

*When you must not use it*

**Do not use DECOZOL Oral Gel if you know you are allergic to it or any of the ingredients** (see the last

section of this leaflet for a full list of ingredients).

Symptoms of an allergic reaction may include:

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

**Do not use DECOZOL Oral Gel if you have liver disease.**

There is a slight risk of your symptoms getting worse if you use DECOZOL Oral Gel when you have liver problems.

**Do not give DECOZOL Oral Gel to an infant below the age of 6 months.**

The safety of this medicine in infants under 6 months of age has not been established.

**Do not use DECOZOL Oral Gel if you are taking any of the following medicines** because it may affect the way these medicines work:

- cisapride (used for digestive problems)
- simvastatin or lovastatin (used to lower your cholesterol)
- certain medicines used to relieve anxiety or to help you sleep (midazolam or triazolam)
- pimozide (used to treat mental disorders)
- quinidine (used to treat irregular heart beats).

**Do not take DECOZOL Oral Gel if:**

- the packaging is torn or shows signs of tampering.
- the expiry date (month and year) printed on the pack has passed. If

you take it after the expiry date it may not work.

### Before you start to use it

**Tell your doctor or pharmacist if you are pregnant or breast-feeding.**

Your doctor or pharmacist will advise whether you should use DECOZOL Oral Gel.

*Taking other medicines*

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may be affected by DECOZOL Oral Gel or may affect how well DECOZOL Oral Gel works. You may need different amounts of your medicines, or you may need to take different medicines. Examples of these medicines are:

- medicines which slow blood clotting (warfarin or other anticoagulants) because bleeding or bruising may occur
- medicines used to treat AIDS, such as saquinavir
- medicines used to treat cancer, such as docetaxel
- certain calcium channel blockers (used to treat high blood pressure or heart problems) such as verapamil and bepridil
- Cyclosporine, tacrolimus and sirolimus which are medicines usually given after an organ transplant to prevent organ transplant rejection

- certain medicines taken by mouth for diabetes such as tolbutamide, tolazamide, glipizide and glimepiride
- medicines for epilepsy (phenytoin or carbamazepine)
- alfentanil (used in surgery for pain relief and to help anaesthesia)
- sildenafil (used to treat male impotence)
- medicines for anxiety or to help you sleep (tranquillisers) such as triazolam
- medicines used to treat tuberculosis
- methylprednisolone (given by injection to reduce inflammation)
- ergot alkaloids (used to treat migraine)
- disopyramide (used to treat unusual heart beat)
- halofantrine (used to treat malaria)

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking DECOZOL Oral Gel.

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## How to use DECOZOL Oral Gel

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### *How to use it*

Opening Instructions:

1. Unscrew the cap.
2. Reverse the cap and push it firmly into the neck of the tube to fully puncture the safety seal.

**Note: Use the spoon provided for accurate measurements.**

Follow these steps to ensure you use DECOZOL Oral Gel properly.

**After you have finished eating, drop the measured amount of gel on to the tongue and keep it in the mouth for as long as possible before swallowing.**

The gel is sticky to make sure it stays in the mouth as long as possible.

If you are giving the gel to infants and young children the measured dose should be given in small amounts placed in the front of the mouth. **Do not give the whole amount at once. Do not put the gel in the back of the mouth.** This is to make sure that the throat does not become blocked by the gel.

### *How much to use*

Usual dose:

**Unless otherwise directed by your doctor or pharmacist, use the following quantities of DECOZOL Oral Gel:**

Adults and children 2 years of age and older: Half (1/2) a spoonful (2.5 mL) four times a day. Infants (6-24 months): One quarter (1/4) of a spoonful (1.25 mL) four times a day.

### *How long to use it*

**Continue treatment for at least a week after symptoms have disappeared.**

This is to ensure that the treatment is complete.

See your doctor if the symptoms persist.

### *If you forget to use it*

**If you forget to use DECOZOL Oral Gel, do so as soon as you remember, and then go back to using it as you would normally.**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the one you missed.**

**If you have problems remembering when to take your medicine, ask your pharmacist for some hints.**

### *If you have used too much (overdose)*

**If you have swallowed too much DECOZOL Oral Gel, contact your doctor or pharmacist or the Poisons Information Centre who will advise you what to do.**

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

You may experience nausea, vomiting and diarrhoea. If you do, you may need to take a preparation to replace the water and minerals, which are lost during vomiting and diarrhoea.

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## While you are using DECOZOL Oral Gel

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### *Things you must do*

- Wash and dry the measuring spoon after use.
- If you wear dentures, as well as applying DECOZOL Oral Gel to the mouth, apply a thin layer of the Gel to the dentures in the evening and leave it on overnight. Make sure you wash your dentures before putting them back in, in the morning.
- Avoid contact with eyes.

### *Things you must not do*

**Do not use this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give it to anyone else, even if their condition seems similar to yours.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how DECOZOL Oral Gel affects you.**

It may cause difficulty in focusing in some people.

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## Side Effects

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All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

DECOZOL Oral Gel may have some unwanted side effects in a few people, even though it is usually well tolerated at the recommended dose.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

**Tell your doctor if any of the following symptoms happen and they worry you:**

- nausea
- vomiting
- diarrhoea
- loss of appetite
- generally feeling unwell
- chills

**Tell your doctor immediately if you notice any of the following:**

- yellowing of the skin and eyes
- fever
- dark coloured urine
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

**Tell your doctor immediately and do not take your next dose of DECOZOL Oral Gel if you experience:**

- signs of allergy such as skin rash, reddening, blisters or itching, swelling of the face, lips or other parts of the body, shortness of breath or wheezing

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

### *Storage*

- Keep your DECOZOL Oral Gel in a cool dry place where the temperature stays below 30°C.
- Do not store it, or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Keep it where young children cannot reach it. A locked cupboard at least one and a half metres above the

ground is a good place to store medicines.

- Medicines cannot be stored indefinitely. Do not use DECOZOL Oral Gel beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly.

### *Disposal*

**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product Description

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### *What it looks like*

DECOZOL Oral Gel is an off-white, jelly-like substance with an orange flavour. It comes in a tube size of 15 and 40 grams of the gel. The tube and a 5 mL measuring spoon are included in the carton.

### *Ingredients*

Each gram of DECOZOL Oral Gel contains:

- 20 milligrams of miconazole as the active ingredient
- methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, potato starch, polysorbate 20, xanthan gum, saccharin sodium, orange flavour and purified water

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## Sponsor

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### **AFT Pharmaceuticals Ltd**

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