

# Dizole<sup>®</sup>

contains the active ingredient fluconazole

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some common questions about DIZOLE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking DIZOLE against the benefits expected for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may need to read it again.

### What DIZOLE is used for

DIZOLE capsules containing fluconazole as the active ingredient are used to treat certain fungal and yeast infections that cause:

- thrush in the mouth, food pipe or vagina (also called candida or monilia)
- tinea of the body, groin or feet
- meningitis, where the membrane around the brain and spinal cord are inflamed due to infection.

Fluconazole belongs to a group of medicines called azole antibiotics.

It works by preventing the growth of the fungal and yeasts organisms causing your infection.

**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.

DIZOLE is available only with a doctor's prescription.

This medicine is not addictive.

### Before you take DIZOLE

#### **When you must not take it**

**Do not take DIZOLE if you have an allergy to:**

- any medicine containing fluconazole
- any other azole antifungals related to fluconazole such as itraconazole (Sporanox), ketoconazole (Nizoral), miconazole (Daktarin), clotrimazole (Canesten).
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

**Do not take DIZOLE if you are taking cisapride (Prepulsid), a medicine used to treat stomach problems.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### **Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have or have had, any of the following medical conditions:**

- any liver problems
- any kidney problems
- any heart problems.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start taking DIZOLE.**

#### **Taking other medicines**

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

Some medicines and DIZOLE may interfere with each other. These include:

- warfarin (eg Marevan, Coumadin), a medicine used to stop blood clots
- phenytoin (Dilantin), a medicine used to treat epilepsy
- ciclosporin (eg Neoral, Sandimmun), sirolimus (eg. Rapamune) or tacrolimus (eg. Prograf), or tofacitinib medicines

used to prevent organ transplant rejection or to treat certain problems with the immune system

- certain medicines for diabetes such as tolbutamide, glibenclamide (eg. Daonil, Glimel) and glipizide (eg. Minidiab, Melizide)
- rifampicin (eg Rifadin, Rimycin) or rifabutin (eg. Mycobutin), antibiotics used to treat infections
- theophylline (eg. Nuelin), a medicine used to treat asthma
- certain benzodiazepines, medicines used as sedatives or to treat anxiety, such as midazolam (eg. Hypnovel) and triazolam (eg. Halcion)
- some drugs used for heart problems, such as quinidine or verapamil
- zidovudine (eg Retrovir), a medicine used to treat patients with HIV infection
- hydrochlorothiazide, a medicine used to treat fluid problems and high blood pressure
- the contraceptive pill (birth control pill)
- amphotericin B (amphotericin) (eg. Fungilin), a medicine used to treat fungal infection
- erythromycin (eg. E-Mycin), an antibiotic used to treat certain types of bacterial infections
- voriconazole
- cyclophosphamide monohydrate, olaparib or ibrutinib a medicine used to treat certain types of cancers
- tolvaptan (used to treat low levels of sodium in your blood or for kidney problems)
- carbamazepine (eg. Tegretol), a medicine used in the treatment of epilepsy and bipolar disorder
- NSAIDS such as naproxen, diclofenac and celecoxib (eg. Celebrex)

- Opioid pain killers such as alfentanil, fentanyl and methadone
- Losartan, a medicine used to treat high blood pressure
- antidepressants such as amitriptyline (eg. Endep) and nortriptyline.

These medicines may be affected by DIZOLE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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## How to take DIZOLE

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.**

### How much to take

#### Adults

The dose will depend on your infection and how you respond to DIZOLE. It usually ranges from 50 to 400 mg once daily.

#### Children

The dose for a child will depend on body weight and usually ranges from 3 mg to 12 mg per kilogram of body weight. In very young children (below 4 weeks of age), DIZOLE is usually given every second or third day.

However, depending on how serious the infection is, and how you react to the medicine, your doctor may ask you to take a different dose.

People with kidney problems may require smaller doses.

### How to take it

**Swallow the capsules whole with a glass of water.**

### When to take it

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

DIZOLE can be taken with or without food.

### How long to take it for

**Continue taking DIZOLE for as long as your doctor tells you**

The length of time you take DIZOLE will depend on the sort of infection you have.

Patients with a weakened immune system or those with difficult infections may need long-term treatment to prevent the infection from returning.

**Do not stop taking DIZOLE because you are feeling better.**

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

### If you forget to take it

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

**Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints**

### ***If you take too much (overdose)***

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much DIZOLE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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## **While you are taking DIZOLE**

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### ***Things you must do***

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking DIZOLE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking DIZOLE.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking DIZOLE.

If you become pregnant while taking DIZOLE, tell your doctor immediately.

This medicine is not recommended for use in pregnancy.

If the symptoms of your infection do not improve within a few days or if they become worse, tell your doctor.

Keep all your doctor's appointments so that your progress can be checked.

### ***Things you must not do***

Do not take DIZOLE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

**Do not stop taking your medicine or change the dosage without checking with your doctor.**

If you do not complete the full course prescribed by your doctor, all of the organisms causing your infection may not be killed. These organisms may continue to grow and multiply so that your infection may not clear completely or may come back.

### ***Things to be careful of***

**Follow your doctor's advice if regular checks on your liver are recommended.**

In rare cases, DIZOLE may affect the liver and may need to be stopped.

**Be careful driving or operating machinery until you know how DIZOLE affects you.**

This medicine may cause dizziness light-headedness or drowsiness (rarely) in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

**If you suffer from HIV or have a weakened immune system and develop a rash while taking DIZOLE, tell your doctor immediately.**

If this rash worsens, DIZOLE may need to be stopped.

Be careful when driving vehicles or operating machinery as occasional dizziness or seizures may occur.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DIZOLE.**

This medicine helps most people with fungal and yeast infections, but it may have unwanted side effects in a few people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following list of side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea or feeling sick, vomiting
- stomach pain, diarrhoea, indigestion
- headache
- acne.

The above list includes the most common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- rash
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fainting, seizures or fits
- flaking of the skin
- yellowing of the skin or eyes, also called jaundice
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- symptoms of liver disease such as yellowing of the skin or eyes; dark urine, pale stools; loss of appetite; unusual tiredness
- passing more urine than normal, kidney pain (pain on the sides of the body)
- irregular heart beat or palpitations
- increased sweating.

The above list includes serious side effects that may require medical attention. Serious side are rare.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

This is not a complete list of all possible side effects. Others may also occur in some people and there may be some side effects not yet known.

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## After taking DIZOLE

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### Storage

**Keep your capsules in the pack until it is time to take them.**

If you take the capsules out of the pack they may not keep well.

**Keep your capsules in a cool dry place where the temperature stays below 25°C.**

**Do not store DIZOLE or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a windowsill.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking DIZOLE, 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

DIZOLE capsules are available in 3 different strengths:

#### DIZOLE 50

Hard gelatin capsules with one half white and the other half dark blue. The white half has "FC 50" and the dark blue half has "G" printed in black. Each pack contains 28 capsules.

#### DIZOLE 100

Hard gelatin capsule with one half white and the other half blue. The white half has "FC 100" and the blue half has "G" printed in black. Each pack contains 28 capsules.

#### DIZOLE 200

Hard gelatin capsules with one half white and the other half blue. The white half has "FC 200" and the blue half has "G" printed in black. Each pack contains 28 capsules.

### Ingredients

The active ingredient in DIZOLE is fluconazole.

Each DIZOLE 50 mg, 100 mg and 200 mg capsule contains 50 mg, 100 mg and 200 mg of fluconazole respectively.

The capsules also contain:

- lactose monohydrate
- maize starch
- silicon dioxide
- magnesium stearate
- sodium lauryl sulfate
- Capsugel Part #G4ICS000361 Empty Hard Gelatin Capsule (ARTG PI No: 10350), TekPrint SW-9008 Black Ink (ARTG PI No: 2328) and TekPrint SW-9009 Black Ink (ARTG PI No: 2343) – 50 capsule mg only
- Capsugel Part #G2HCSRA0036 Empty Hard Gelatin Capsule (ARTG PI No: 10309) – 100 mg capsule only
- Capsugel Part #G0HCSRA0132 Empty Hard Gelatin Capsule (ARTG PI No: 10312) – 200 mg capsule only

DIZOLE contains sulfites and sugars as lactose. This medicine does not contain gluten.

### Supplier

DIZOLE is supplied in Australia by:

**Alphapharm Pty Ltd trading as Viatrix**

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

Australian registration numbers:

DIZOLE 50 - AUST R 162640

DIZOLE 100 - AUST R 159620

DIZOLE 200 - AUST R 132789

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DIZOLE® is a Viatrix company trade mark

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