

DIZOLE ONE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using DIZOLE ONE?

DIZOLE ONE contains the active ingredient Fluconazole. DIZOLE ONE is used to treat a fungal infection known as vaginal thrush (vaginal candidiasis).

For more information, see Section [1. Why am I using DIZOLE ONE?](#) in the full CMI.

2. What should I know before I use DIZOLE ONE?

Do not use if you have ever had an allergic reaction to Fluconazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use DIZOLE ONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DIZOLE ONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use DIZOLE ONE?

- DIZOLE ONE should be taken as single dose of one capsule. The whole capsule is to be swallowed with one glass of water.

More instructions can be found in Section [4. How do I use DIZOLE ONE?](#) in the full CMI.

5. What should I know while using DIZOLE ONE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using DIZOLE ONE.• Are about to be started on any new medicine, remind your doctor or pharmacist that you have taken this medicine.• If you become pregnant while taking this medicine, tell your doctor immediately.• If the symptoms of your infections do not improve after 03 days, or if they become worse, tell your doctor or pharmacist.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if they have the same condition as you.• Do not take this medicine to treat any other complaint unless your doctor or pharmacist tells you to do.
Driving or using machines	<ul style="list-style-type: none">• No effects on driving or using machines.
Drinking alcohol	<ul style="list-style-type: none">• No effects on drinking alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in its pack until it is time to take it.• If you take your medicine out of its pack it may not keep well.

For more information, see Section [5. What should I know while using DIZOLE ONE?](#) in the full CMI.

6. Are there any side effects?

The common side effects include nausea, vomiting, stomach pain, indigestion, wind, diarrhoea, muscle or back pain and head ache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DIZOLE ONE®

Active ingredient(s): Fluconazole

Consumer Medicine Information (CMI)

This leaflet provides important information about using DIZOLE ONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DIZOLE ONE.**

Where to find information in this leaflet:

- [1. Why am I using DIZOLE ONE?](#)
- [2. What should I know before I use DIZOLE ONE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DIZOLE ONE?](#)
- [5. What should I know while using DIZOLE ONE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DIZOLE ONE?

DIZOLE ONE contains the active ingredient Fluconazole. Fluconazole belongs to a group of medicines known as azole antifungals. These medicines work by preventing the growth of these fungi causing your infection.

DIZOLE ONE is used to treat a fungal infection known as vaginal thrush (vaginal candidiasis).

What is vaginal thrush

Vaginal thrush is a common name for vaginal candidiasis, an infection caused by a yeast-like fungus called Candida.

Candida is one of many organisms that live in the vagina. Your body's natural balance (immune system) normally keeps Candida under control, but when this natural balance is upset, Candida can multiply and can cause thrush symptoms.

Common symptoms of vaginal thrush include:

- itching, burning or soreness around the vagina
- cottage-cheese like discharge
- swelling or irritation of the infected area.

Things that may help you to avoid thrush in the future:

- wear cotton briefs, stockings and loose-fitting clothing rather than tight synthetic clothing
- wash regularly, but do not wash and dry yourself harshly
- avoid perfumed soaps, bath additives and vaginal deodorants.

Your doctor or pharmacist may have more information on things you can do to avoid thrush in the future.

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.

There is no evidence that DIZOLE ONE is addictive.

DIZOLE ONE is a "Pharmacist Only Medicine". It is available without a doctor's prescription but your pharmacist's advice is required.

DIZOLE ONE is not recommended for children under 18 years of age except under doctor supervision.

2. What should I know before I use DIZOLE ONE?

Warnings

Do not use DIZOLE ONE if:

- you are allergic to Fluconazole, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other azole antifungals e.g., miconazole (e.g. Daktarin), ketoconazole (e.g. Nizoral), clotrimazole (e.g. Canestan, Clonea), or itraconazole (Sporanox)

Some of the symptoms of an allergic reaction may include

- Shortness of breath
- Wheezing or breathing difficulty
- Swelling of the face, lips, tongue, throat, or other parts of the body
- Rash, itching or hives on the skin.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Fluconazole may affect your developing baby if you take it during pregnancy. Your pharmacist will discuss with you the risks and benefits involved.

Do not use this medicine if you are a female of childbearing age unless you are using adequate contraception.

Effective contraception should be taken during treatment and for about 1 week after the final dose.

Do not take this medicine if you are breast-feeding.

Fluconazole may pass into breast milk and affect your baby.

3. What if I am taking other medicines?

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

Some medicines may interfere with Fluconazole and affect how it works. Do not take Fluconazole if you are taking:

- Astemizole, used for allergies.
- Cisapride, used to treat stomach problems.
- Quinidine, used to treat heart problems.
- Erythromycin, as an antibiotic
- Pimozide, used to treat mood disorders.
- Voriconazole, used as an anti-fungal medicine.

Combining Fluconazole with the above medicines may cause serious side effects such as an abnormal heart rhythm.

Medicines to be taken with care with Fluconazole.

- Terfenadine (do not take this medicine if you are receiving fluconazole at multiple doses of 400mg/day)
- Amiodarone, used for heart problems
- Some medicines used to treat diabetes (e.g., glipizide, chlorpropamide, tolbutamide, glibenclamide, glimepiride, gliclazide, pioglitazone, rosiglitazone)
- Some antibiotics and antiviral drugs (e.g., erythromycin, amphotericin B, rifampicin, rifabutin, zidovudine, saquinavir)
- Some medicine used to impress the immune system (e.g., ciclosporine, tacrolimus, sirolimus, prednisone)
- Some medicines used to treat cancer (e.g., cyclophosphamide, ibrutinib, Olaparib, vincristine, vinblastine)
- Vitamin A
- Antidepressants (e.g., amitriptyline, nortriptyline)
- Warfarin or ticlopidine, used to stop blood clots.
- Phenytoin and carbamazepine used to treat epilepsy.
- Theophylline, used to treat asthma.
- Medicine used during anaesthetics (e.g., alfentanil, midazolam, fentanyl, methadone)
- Benzodiazepines (e.g., triazolam)
- Hydrochlorothiazide, used for treating fluid problems.

- Medicines used to treat high blood pressure (e.g. losartan, nifedipine, amlodipine, felodipine)
- Medicines used to treat high cholesterol (e.g., simvastatin, Fluvastatin, atorvastatin)
- Medicines to treat low levels of sodium in the blood (e.g., tolvaptan)
- Some medicines used for pain relief (e.g., methadone, celecoxib)
- Halofantrine, used to treat malaria.
- the contraceptive pill
- cimetidine, a medicine used to relieve heartburn and indigestion

Talk to your doctor or pharmacist about the need for an additional method of contraception while taking fluconazole.

Fluconazole may decrease the effectiveness of some birth control pills.

If you are taking any of these, you may need a different dose, or you may need to take different medicines. Other medicines not listed above may interact with Fluconazole.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DIZOLE ONE.

4. How do I use DIZOLE ONE?

How much to take / use

- Follow all directions given to you by your pharmacist carefully.
- They may differ from this information contained in this leaflet.
- Follow the instructions provided and use DIZOLE ONE until your doctor tells you to stop.

When to take / use DIZOLE ONE

- DIZOLE ONE should be taken as single dose of one capsule.
- The whole capsule is to be swallowed with one glass of water.
- It does not matter whether you take this medicine with or without food.

If you forget to use DIZOLE ONE

DIZOLE ONE should be used regularly at the same time each day. If you miss your dose at the usual time, take immediately before the next dose.

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 dose you missed.

If you use too much DIZOLE ONE

If you think that you have used too much DIZOLE ONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using DIZOLE ONE?

Things you should do

Call your doctor straight away if you:

- Are about to be started on any new medicine, remind your doctor or pharmacist that you have taken this medicine.
- Tell any other doctors, dentists and pharmacists who are treating you that you have taken this medicine.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If the symptoms of your infections do not improve after 03 days, or if they become worse, tell your doctor or pharmacist.

Remind any doctor, dentist, or pharmacist you visit that you are using DIZOLE ONE.

Things you should not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take this medicine to treat any other complaint unless your doctor or pharmacist tells you to do.

Things to be careful of

Tell your doctor or pharmacist immediately if you develop rash soon after taking this medicine.

- People with AIDS or weak immune system may be prone to more serious side effects of the skin.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

No information on alcohol consumption with DIZOLE ONE.

Looking after your medicine

- Keep your medicine in its pack until it is time to take it.
- If you take your medicine out of its pack it may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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 or pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

This medicine helps most people and is generally well tolerated. However, it may have unwanted side effects in some people.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Nausea or vomiting• Stomach pain, indigestion, wind• Diarrhoea• Muscle or back pain• headache	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• skin reactions or rash• unusual muscle stiffness causing poor control of movement.• Frequent infections such as fever, severe chills, sore throat or mouth ulcers• Bleeding or bruising more easily than normal.• Passing more urine than normal, kidney pain (pain on the sides of the body)• Yellowing of the skin or eyes (jaundice); dark urine, pale stools; loss of appetite; unusual tiredness (signs of liver disease)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none">• Shortness of breath, wheezing, asthma or difficulty breathing; swelling of face lips, tongue, throat, or other parts of the body; rash itching or hives on the skin (signs of an allergic reaction)• Fast, slow, or irregular heartbeat or palpitation and/or fainting, seizures, fits• Increased sweating• Flaking of the skin• Severe blisters and bleeding of the lips, eyes, mouth, nose, and genitals.• A severe rash with skin peeling, fever, chills, and aching muscles.	These are very serious side effects which are very rare. You may need urgent medical attention or hospitalization

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What DIZOLE ONE contains

Active ingredient (main ingredient)	Fluconazole 150 mg
Other ingredients (inactive ingredients)	Gelatin Lactose monohydrate Maize starch Silicon dioxide Magnesium stearate Sodium lauryl sulfate Titanium dioxide (E171) TekPrint SW-9008 Black Printing Ink TekPrint SW-9009 Black Printing Ink
Potential allergens	Contains sulfites, phenylalanine and sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What DIZOLE ONE looks like

DIZOLE ONE is a hard white gelatin capsule, marked with "G" and "FC 150" in black ink.

Each pack contains 1 capsule.

Who distributes DIZOLE ONE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, VIC 3121
Australia
www.arrotex.com.au

Australian registration number:

DIZOLE ONE - AUST R 162766

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