Diflucan® IV

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 being treated with Diflucan IV?

Diflucan IV contains the active ingredient fluconazole. It is used to treat certain fungal and yeast infections.

For more information, see Section 1. Why am I being treated with Diflucan IV? in the full CMI.

2. What should I know before treatment with Diflucan IV?

Do not start treatment if you are allergic to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI, or any other similar medicines such as miconazole, ketoconazole or clotrimazole.

Tell the doctor if you have had any allergic reaction to any antifungal, or any foods, preservatives or dyes or any other medicines, if you are pregnant, plan to become pregnant or are breastfeeding. You must not be given Diflucan if you are taking certain medicines.

For more information, see Section 2. What should I know before treatment with Diflucan IV? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Diflucan IV 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 is Diflucan IV given?

Diflucan IV is given as a slow injection into the vein. The doctor will decide how much Diflucan IV will be given to you each day and for how long. It will depend on your condition and other factors.

More instructions can be found in Section <u>4. How is</u> <u>Diflucan IV given?</u> in the full CMI.

5. What should I know during treatment with Diflucan IV?

Things you should do

 Tell the doctor if you have any medical conditions, are on any medicines, or if you are pregnant, plan to

	 become pregnant or are breastfeeding For more information on "Things you should do" can be found in Section 6 in the full CMI
Things you should not do	 Do not start treatment if you have ever had an allergic reaction to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI, or any other similar medicines such as miconazole, ketoconazole or clotrimazole.
Looking after your medicine	 Diflucan IV should be stored in the pharmacy or on the hospital ward. Diflucan IV should be kept in a dry place where the temperature stays below 30°C.

For more information, see Section <u>5. What should I know while during treatment with Diflucan IV?</u> in the full CMI.

6. Are there any side effects?

DIFLUCAN IV is generally well tolerated. Side effects may include nausea, vomiting, abdominal pain, diarrhoea, headache, skin rash or redness and easy bruising of the skin, seizures, signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers or change in liver function.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Diflucan IV®

Fluconazole

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I being treated with Diflucan IV?
- 2. What should I know before treatment with Diflucan IV?
- 3. What if I am taking other medicines?
- 4. How is Diflucan IV given?
- 5. What should I know during treatment with Diflucan IV?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated with Diflucan IV?

Diflucan IV is used to treat certain fungal and yeast infections.

It belongs to a group of medicines called azole antibiotics.

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

Ask your doctor if you have any questions about why Diflucan IV has been prescribed for you.

Your doctor may have prescribed it for another reason.

Diflucan IV is available only with a doctor's prescription.

This medicine is not addictive.

2. What should I know before treatment with Diflucan IV?

Warnings

Do not use start treatment with Diflucan IV if you:

- are allergic to fluconazole, or any of the ingredients listed at the end of this leaflet, or any medicines related to fluconazole such as miconazole, ketoconazole or clotrimazole
- 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; skin rash, itching or hives.

You must not be given Diflucan IV if you are taking any of the following medicines:

 terfenadine or astemizole (a medicine used to treat allergy)

- cisapride (a medicine used to treat stomach problems)
- erythromycin (a medicine used to treat infections)
- pimozide (a medicine used to treat mental illness)
- quinidine (a medicine used to treat irregular heartbeat).

Check with your doctor if you have any:

- have allergies to any foods, preservatives or dyes or any other medicines
- are taking medicines for any other condition
- other medical conditions
- liver problems
- heart problems
- kidney problems

Your doctor may need to monitor the function of the liver using blood tests. Be sure to follow the doctor's advice if regular checks on your/ your child's liver are recommended.

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 <u>6</u>. 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.

DIFLUCAN IV use should be avoided during pregnancy except on doctor's advice for severe or life-threatening infections. Effective contraception should be used in women of childbearing potential and should continue throughout the treatment period and for approximately 1 week after the final dose. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor about the need for an additional method of contraception while being given Diflucan IV.

Diflucan IV may decrease the effectiveness of some birth control pills.

DIFLUCAN IV is not recommended for use whilst breastfeeding however your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor 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 should not be taken with Diflucan.

These are listed under Section 2. What should I know before treatment with Diflucan.

Some medicines and Diflucan IV may interfere with each other. These medicines and some others may be affected by Diflucan IV or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines. These include:

- some medicines for diabetes such as glipizide, tolbutamide or glibenclamide
- some antibiotics, antiviral and antifungal drugs such as rifampicin, rifabutin, zidovudine, amphotericin B, azithromycin, saquinavir or voriconazole
- some drugs used for heart problems, such as amiodarone or verapamil
- some drugs used in problems with the immune system, such as ciclosporin, everolimus, tacrolimus, sirolimus or tofacitinib
- some medicines used to lower cholesterol, such as atorvastatin, simvastatin or fluvastatin
- abrocitinib, used to treat atopic dermatitis (atopic eczema)
- cyclophosphamide, vincristine, vinblastine, olaparib or ibrutinib, used to treat certain types of cancers
- tolvaptan, used to treat low levels of sodium in your blood or for kidney problems
- halofantrine, used to treat malaria
- warfarin, used to stop blood clots
- phenytoin, used to treat epilepsy
- prednisone, used to treat inflammation or suppress the immune system
- theophylline, used to treat asthma
- some benzodiazepines such as midazolam
- lemborexant, used to treat insomnia or sleeping difficulties

- ivacaftor, used to manage cystic fibrosis
- lurasidone, used to manage schizophrenia
- hydrochlorothiazide, used for treating fluid problems
- the contraceptive pill (birth control pill)
- carbamazepine, used in the treatment of epilepsy and bipolar disorder
- NSAIDS such as naproxen, diclofenac and celecoxib
- Vitamin A
- opioid pain killers such as alfentanil, fentanyl and methadone
- losartan, used for treating high blood pressure
- antidepressants such as amitriptyline and nortriptyline.

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

4. How is Diflucan IV given?

How much will be given

- Diflucan IV is usually infused slowly into a vein.
- Diflucan IV will only be given by a doctor or nurse.
 Your doctor will decide how much DIFLUCAN IV you will be given each day.

How long will Diflucan IV need to be given?

 The amount of Diflucan IV you receive, and the length of your treatment, will depend on your body weight and kidney function. It will also depend on how quickly the infection is brought under control.

After a while, the injection may be stopped and you may begin to receive Diflucan capsules or oral suspension by mouth.

Follow the instructions provided by your/your child's doctor carefully.

If too much Diflucan IV is given

Because Diflucan IV is given to you by a health professional, overdose is unlikely to arise.

However, if you are concerned that you may have been given too much DIFLUCAN IV 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 during treatment with Diflucan IV?

Things you should do

If you are a woman of childbearing potential, talk to your doctor about the need for an additional method of contraception while being given Diflucan IV.

Diflucan IV may decrease the effectiveness of some birth control pills.

If you suffer from HIV or have a weakened immune system and develop a rash while being given Diflucan IV, tell your doctor immediately.

If this rash worsens, Diflucan IV may need to be stopped.

Remind any doctor, dentist, or pharmacist you visit that you are using Diflucan IV.

Things you should not do

 Do not start treatment if you have ever had an allergic reaction to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI

Driving or using machines

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

Drinking alcohol

No information available

Looking after your medicine

Your hospital pharmacy will store the Diflucan IV.

Diflucan IV should be kept in a dry place where the temperature stays below 30°C.

When to discard your medicine

Discard any medicine that has passed the expiry date.

This medicine should only be used for one patient on one occasion only.

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.

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

Less serious side effects	What to do
nausea or feeling sick, vomitingheadache	Speak to your doctor if you/your child have any of these less serious

Less serious side effects	What to do
stomach pain, indigestion, diarrhoea,acne	side effects and they worry you.
 soreness at the injection site 	
blurred or abnormal vision	
hot flushes	
constipation	
 low blood potassium which can result in fatigue, muscle cramps and abnormal heart rhythms * 	
changes in liver function*	
* These side effects may show up when you have a blood test.	

Serious side effects	What to do
Allergy or reaction related:	Call your/your child's doctor immediately, or
 swelling of the face, lips or tongue 	go to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
 difficulty in swallowing or breathing asthma, wheezing, shortness of breath 	notice any of these serious side effects.
Skin changes:	
 yellowing of the skin or eyes, also called jaundice sudden or severe itching, skin rash, hives bleeding or bruising more easily than normal reddish or purplish blotches under the skin flaking of the skin Changes to urine: 	
 dark urine and light-coloured bowel movements (cholestasis) Signs of frequent or worrying infections such as: 	
fever, severe chills, sore throat or mouth ulcersOther:	
• fainting, seizures or fits	

Serious side effects	What to do
fast or irregular heartbeat	
increased sweating.	

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/your child 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

This medicine is only available with a doctor's prescription.

What Diflucan IV contains

Active ingredient	Fluconazole
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Sodium chloride 0.9% solution

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

What Diflucan IV looks like

Diflucan IV is a clear, colourless solution and comes in clear glass vials of 50 mL and 100 mL.

Australian Registration Number:

Aust R 47461 - 100 mg/ 50 mL

AUST R 47462 - 200 mg/ 100 mL

Who distributes Diflucan IV

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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