

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Stabilanol 2 mg/ml Solution for Infusion Fluconazole

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What Stabilanol 2mg/ml Solution for Infusion is and what it is used for
2. Before you use Fluconazole Infusion
3. How to use Fluconazole Infusion
4. Possible side effects
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#### 1. What Stabilanol 2mg/ml Solution for Infusion is and what it is used for

##### Stabilanol 2mg/ml Solution for Infusion is for treating and preventing fungal infections.

Stabilanol 2 mg/ml Solution for Infusion belongs to a group of antifungal medicines called imidazoles and is used for the treatment of the following types of fungal infections (Simply called Fluconazole Infusion throughout the rest of this leaflet). The medicine works by stopping the growth of the fungus.

#### Adults

- Treatment of:
  - Candida fungal infections affecting the whole body
  - a fungal infection in the brain called cryptococcal meningitis
  - Severe Candida fungal infections affecting mucous membranes (mouth, throat, oesophagus, bronchuses and lungs) where oral treatment is not possible.
- Prevention of:
  - candida fungal infections in patients with reduced amounts of white blood cells (neutropenia) following bone marrow transplants

#### Children and adolescents

- Treatment of:
  - Candida fungal infections affecting the whole body
  - Severe Candida fungal infections affecting mucous membranes (mouth, throat, oesophagus, bronchuses and lungs) where oral treatment is not possible.

#### 2. Before you use Fluconazole Infusion

##### Do not use Fluconazole Infusion

- if you are allergic (hypersensitive) to fluconazole or other similar medicines such as ketoconazole and itraconazole or to any of the other ingredients of Fluconazole Infusion (see section 6).
- if you are taking other drugs known to affect your heart and be metabolised in the same way as fluconazole, such as cisapride, astemizole, terfenadine, pimozide and quinidine.

##### Take special care before you use Fluconazole Infusion

- If any of the below apply to you talk to your doctor or nurse:
- you have currently, or have previously had, problems with your liver
  - you have AIDS or have an infection that affects your whole body
  - you have heart disease
  - you receive warfarin or any other drug which prolongs blood coagulation
  - you have kidney disease

##### Using other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If Fluconazole infusion and certain other medications are taken at the same time, the effect of treatment may be affected. This applies for example to the following:

- **Alfentanil** (synthetic opioid analgesic drug - used against pain).
- **Amitriptyline** (for depression).
- **Amphotericin B** (for fungal infections).
- **Astemizole** (antihistamine)
- **Benzodiazepines** such as midazolam or triazolam (certain sleeping pills).
- **Calcium channel antagonists:** nifedipine, isradipine, nifedipine, amlodipine, felodipine (used in the control of heart rhythm and blood pressure).
- **Carbamazepine** (for epilepsy).
- **Celecoxib** (for inflammation).
- **Ciclosporin** (used in organ transplantation).
- **Cisapride** (used to treat heart burn and reduce the amount of acid in the stomach).
- **Didanosine** (treatment used in AIDS).
- **Halofantril** (for malaria).
- **HMG-CoA-reductase-inhibitors:** atorvastatin, simvastatin, fluvastatin (agents that reduce blood lipids).
- **Hydrochlorothiazide** (diuretic).
- **Losartan** (for high blood pressure).
- **Methadone** (opioid analgesic drug - used against pain).
- **Oral Contraceptives**
- **Phenytoin** (for epilepsy).
- **Prednisone** (used in inflammation and organ transplants).

- **Rifabutin and Rifampicin** (for tuberculosis and other infections).
- **Sulphonylureas** such as chlorpropamide, glibenclamide, glipizide and tolbutamide (used for diabetes).
- **Tacrolimus and sirolimus** (used in organ transplantation).
- **Terfenadine** (used to treat hay fever and allergies).
- **Theophylline** (for respiratory problems).
- **Trimetrexate** (used in pneumonia).
- **Warfarin** and other coumarin type medicines (certain blood-thinning agents).
- **Xanthine bases, other antiepileptic drugs and isoniazid.**
- **Zidovudine** (treatment used in AIDS).

##### Using Fluconazole Infusion with food and drink

- Fluconazole Infusion can be used with or without food.

##### Pregnancy and breast-feeding

- Before starting treatment you must inform your doctor if you are pregnant or intend to become pregnant. The doctor will then decide whether you should take Fluconazole Infusion. Women of child-bearing potential should use reliable contraception during long-term treatment with Fluconazole Infusion.
- Fluconazole enters breast milk so women are advised not to breastfeed their babies while they are taking fluconazole.

##### Driving and using machines

- Occasionally dizziness or fits can occur in people taking fluconazole so care should be taken when driving or operating machinery (see section 4 of this leaflet for more information on possible side effects).

##### Important information about some of the ingredients in Fluconazole Infusion

- Fluconazole Infusion contains sodium chloride (salt). The infusion contains 3.5mg of sodium per ml of infusion (a total of 88 mg sodium in a 25 ml bottle, 177 mg sodium in a 50 ml bottle, 354 mg sodium in a 100 ml bottle and 709 mg sodium in a 200 ml bottle). If you are on a low sodium (salt) diet tell your doctor, pharmacist or nurse before they give you Fluconazole Infusion.

#### 3. How to use Fluconazole Infusion

A doctor or nurse will administer the infusion via a drip (slow injection into a vein).

Treatment will normally continue until the infection has gone.

#### Adults

- Candida infections affecting the whole body:
  - The usual dose is 400-800 mg on the first day, then 200-400 mg once daily.
- Cryptococcal meningitis:
  - The usual dose is 400mg on the first day, then 200mg - 400mg once daily.
  - The maximum daily dose is 400mg daily.
  - Depending on how you respond, your treatment can last for 6 - 8 weeks.
- Candida infections affecting mucous membranes:
  - For oropharyngeal candidiasis the normal dose is 100 mg daily for 7-14 days.
  - For oesophageal mucocutaneous and non-invasive bronchopulmonary candidiasis the normal dose is 100 mg daily for 14-30 days.
- Prevention of candida infections in patients following bone marrow transplants:
  - The usual dose is 400mg per day.

#### Elderly

- If your kidneys are working normally you will be given the usual adult dose.

#### Children (4 weeks of age and older)

- Candidiasis infections affecting the whole body:
  - The usual dose is 6 - 12mg/kg per day.
- Treatment of mucosal candidiasis
  - The usual dose is 3-12 mg/kg per day. 6 mg/kg may be given on day 1.

#### Children (under 4 weeks of age)

- In the first two weeks of life babies can be given the same dose as children but the dose must be given every 72-hour.
- In weeks three and four of life babies can be given the same dose as children but the dose must be given every 48-hour.

#### Patients with kidney problems

- Your doctor will adjust the dose based on your kidney function.

#### 4. Possible Side Effects

Like all medicines, Fluconazole Infusion can cause side effects, although not everybody gets them.

##### Common (less than 1 in 10 patients to more than 1 in 100 patients)

- Headache
- Rash
- Feeling sick (nausea)
- Being sick (vomiting)
- Stomachache or pain
- Diarrhoea
- Increase in the blood of substances produced by the liver called liver enzymes

##### Uncommon (less than 1 in 100 patients to more than 1 in 1,000 patients)

- Decreases in certain blood cells (white blood cells and platelets)
- Changes in taste, dry mouth
- Dizziness

- Fits (convulsions)
- Indigestion
- Wind (flatulence)
- Yellowing of the skin and eyes (jaundice) and liver abnormalities
- Itching or rash, wheals, swelling or blistering (hives)
- Increased sweating
- Loss of appetite or increased appetite
- Changes to some body chemicals and liver and kidney enzymes
- Abnormal sleep
- Paresthesia, tremor, vertigo
- Pain in muscles
- Feeling weak and tired
- Fever

#### Rare (less than 1 in 1,000 patients to more than 1 in 10,000 patients)

- Lesions or ulcers in the throat, mouth, and skin due to changes in white blood cells
- Increased levels of fats in the blood (cholesterol and triglycerides)
- Decreased levels of potassium leading to weakness and an irregular or fast heart beat
- Liver problems and toxicity, including liver failure and hepatitis
- Hair loss (alopecia)
- Anaphylaxis (allergic reaction)

Fluconazole Infusion may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

You should stop taking Fluconazole Infusion and see your doctor immediately if you experience symptoms of angioedema, such as

- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

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

### 5. How to store Fluconazole Infusion

You will not be asked to store the medicine. It will be brought to you ready to be administered, which should be done straight away.

Do not use after the expiry date stated on the carton or bottle. The expiry date refers to the last day of that month.



Do not refrigerate or freeze.

Medicines should not be disposed of via wastewater or household waste. Any unused solution should be returned to the pharmacy for disposal. These measures will help to protect the environment.

Keep out of the reach and sight of children.

### 6. Further Information

#### What Fluconazole Infusion contains

- The active substance is Fluconazole. Each ml of infusion contains 2mg fluconazole.

Each 25ml bottle of Fluconazole Infusion contains 50mg of fluconazole. Each 50ml bottle of Fluconazole Infusion contains 100mg of fluconazole. Each 100ml bottle of Fluconazole Infusion contains 200mg of fluconazole. Each 200ml bottle of Fluconazole Infusion contains 400mg of fluconazole.

- The other ingredients are: sodium chloride, water for injections, hydrochloric acid for pH adjustment and sodium hydroxide for pH adjustment.

What Fluconazole Infusion looks like and contents of the pack  
Fluconazole Infusion is a clear sterile and colourless solution for infusion. The infusion is supplied in a glass bottle closed with a rubber stopper and a flip-off aluminium cap.

Fluconazole Infusion is available in a bottle containing 25ml, 50ml, 100ml or 200ml of solution for infusion. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Pharmathen S.A., 6 Dervenakion str, 15344 Pallini, Attiki, Greece  
Tel: 0030 210 66 65 067 Fax: 0030 210 66 66 749  
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#### Alternative Manufacturer

Kleiva S.A.  
189 Parnithos Ave.  
136 71 Acharnai Attiki  
Greece

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Fluconazol Docpharma 2 mg/ml Solution for Infusion  
Cyprus: Mycozal 2 mg/ml Solution for Infusion  
Germany: Fluconazol-GRY 2 mg/ml Infusionslösung  
Greece: Stabilanol 2 mg/ml Solution for Infusion  
Ireland: Fluconazole Niche 2mg/ml Solution for Infusion  
Luxembourg: Fluconazole Docpharma 2 mg/ml Solution for Infusion  
Netherlands: Fluconazol Novopharm 2 mg/ml Solution for Infusion

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The following information is intended for medical or healthcare professionals only:

#### 1. Administration

For intravenous use as infusion.

Fluconazole is dissolved in an isotonic saline solution, with an electrolyte content of 150 mmol Na<sup>+</sup> and 150 mmol Cl<sup>-</sup> per 1000 ml, and may be administered directly as an infusion. The product can be infused at a maximum rate of 10ml/minute. In children the rate of intravenous infusion should not exceed 5ml/minute. For premature infants the infusion time should be no less than 15 minutes. In patients requiring sodium- or fluid restriction, the rate of administration should be taken into consideration as Fluconazole consists of a salt solution. In such cases the infusion should be given over a longer period.

#### 2. Handling Instructions

For single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

The product should be inspected visually for particles and discoloration prior to administration. Only clear and colourless solutions should be used.

Stabilanol 2mg/ml solution for infusion is compatible with the following infusion fluids:

- glucose 20%
- Ringer's solution
- Hartmann's solution
- Potassium chloride in glucose
- sodium carbonate 4.2%
- 0.9% sodium chloride (isotonic saline)

Compatibility has been shown for short duration (10 minutes).

Dilution of Stabilanol 2mg/ml solution for infusion is not required prior to administration. If necessary, Fluconazole and the solutions mentioned above should be administered through separate infusion containers. The two reservoirs should be connected using a "Y" connection. The two solutions are then mixed in a single line and the administration is performed. The above method is recommended in order to avoid effects such as the "layering effect" if the two solutions were mixed in one infusion container for the total period of the administration.

#### 3. Storage information

Do not use after the expiry date stated on the carton or bottle. The expiry date refers to the last day of that month.  
Do not refrigerate or freeze.

#### After first opening

From the microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.