

**SCHEDULING STATUS****S4****Fluconazole 2 mg/ml B Braun solution for infusion**

(Fluconazole 2mg/mL)

Sugar free

**Read all of this leaflet carefully before you are given Fluconazole B Braun.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

**What is in this leaflet:**

- 1.What **Fluconazole B Braun** is and what it is used for
- 2.What you need to know before you are given Fluconazole B Braun
- 3.How to use Fluconazole B Braun
- 4.Possible side effects
- 5.How to store Fluconazole B Braun
- 6.Contents of the pack and other information

**1. What Fluconazole B Braun is and what it is used for**

Fluconazole B Braun is one of a group of medicines called 'antifungals'. The active substance is fluconazole. Fluconazole B Braun I.V Infusion is used to treat infections caused by fungi including yeasts and may also be used to stop you from getting a fungal infection.

## **2. What you need to know before you are given Fluconazole B Braun**

### **You should not be given Fluconazole B Braun if you**

- are allergic to fluconazole, to other medicines you have taken to treat fungal infections or to any of the other ingredients of Fluconazole B Braun. The symptoms may include itching, reddening of the skin or difficulty in breathing.
- are taking astemizole, terfenadine (antihistamine medicines for allergies)
- are taking cisapride (used for stomach upsets),
- are taking pimozide (used for treating mental illness)
- are taking quinidine (used for irregular/uneven heartbeats)
- are taking erythromycin (an antibiotic for treating infections)
- are pregnant or breastfeeding your baby

### **Warnings and precautions**

#### *Tell your doctor*

- if you have liver or kidney problems
- if you suffer from heart disease, including heart rhythm problems
- if you have abnormal levels of potassium, calcium or magnesium in your blood
- if you develop severe skin reactions (itching, reddening of the skin or difficulty in breathing).
- If you develop signs of 'adrenal insufficiency' where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol (chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain).
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using Fluconazole B Braun
- if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Fluconazole B. Braun treatment. Stop using Fluconazole B. Braun and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

### **Other medicines and Fluconazole B Braun**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor *immediately* if you are taking astemizole or terfenadine (antihistamines for treating allergies) or cisapride (used for stomach upsets) or pimozide (used for treating mental illness) or quinidine (used for irregular heartbeat) or erythromycin (an antibiotic for treating infections) as these should not be taken with Fluconazole B Braun (see section: 'Do not take Fluconazole B Braun').

There are some medicines that may interact with Fluconazole B Braun.

Make sure your doctor knows if you are taking any of the following medicines:

- rifampicin or rifabutin (antibiotics for treating tuberculosis)
- alfentanil, fentanyl (used as anaesthetic)
- amitriptyline, nortriptyline (used as anti-depressant)
- amphotericin B, voriconazole (anti-fungal)
- medicines that thin the blood to prevent blood clots (warfarin or similar medicines)
- benzodiazepines (midazolam, triazolam or similar medicines used to help you sleep or for anxiety)
- carbamazepine, phenytoin (used for treating fits)
- nifedipine, isradipine, amlodipine, felodipine and losartan (used for
- hypertension/high blood pressure)

- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines used for treating cancer)
- halofantrine (used for treating malaria)
- statins (atorvastatin, simvastatin, fluvastatin or similar medicines used for reducing high cholesterol levels)
- methadone (used for pain)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam and diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID) used for pain and inflammation)
- oral contraceptives
- prednisone (steroid)
- zidovudine, also known as AZT; saquinavir (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)
- vitamin A (nutritional supplement)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating irregular/uneven heartbeats )
- hydrochlorothiazide (a diuretic)

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not be given Fluconazole B Braun if you are pregnant, think you may be pregnant, are trying to become pregnant or breastfeeding, unless your doctor has told you to. Fluconazole B Braun may harm your baby.

Fluconazole B Braun taken during the first trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the bones and/or muscles.

You should not be given Fluconazole B Braun if you breastfeed your baby as it may harm your baby.

**Driving and using machines**

Fluconazole B Braun may cause dizziness or fits. You should not drive or operate machines until you know how treatment with Fluconazole B Braun affects you.

**Fluconazole B Braun contains sodium**

Talk to your doctor or pharmacist especially if you have been advised to follow a low salt (sodium) diet.

This medicine contains 177 mg of sodium (main component of cooking/table salt) in each bottle of 50 mL. This is equivalent to 8,9 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 354 mg of sodium (main component of cooking/table salt) in each bottle of 100 mL. This is equivalent to 17,7 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 709 mg of sodium (main component of cooking/table salt) in each bottle of 200 mL. This is equivalent to 35,5 % of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to administer Fluconazole B Braun**

This medicine will be given by your doctor or nurse as a slow injection (infusion) into your vein.

Fluconazole B Braun is supplied as a solution. It will not be diluted further.

The usual dose is 200 mg daily depending on the type and severity of the infection. The dose may be increased/decreased depending on the severity of the infection or your kidney function.

Your doctor will tell you how long your treatment with Fluconazole B Braun will last. If you have the impression that the effect of Fluconazole B Braun is too strong or too weak, tell your doctor, nurse or pharmacist.

#### ***Use in Children:***

The usual dose is 3 mg per kg of body weight. The dose may be increased/decreased depending on the severity of the infection or kidney function.

The doctor will determine the dose based on the child's weight in kilograms, the age and the type of infection.

Your doctor will tell you how long your treatment with Fluconazole B Braun for your child will last. If you have the impression that the effect of Fluconazole B Braun is too strong or too weak for your child, tell your doctor, nurse or pharmacist.

#### ***Use in Elderly***

The usual adult dose should be given unless you have kidney problems.

***Patients with kidney problems***

Your doctor may change your dose, depending on your kidney function.

**If you receive more Fluconazole B Braun than you should**

If you are concerned that you may have been given too much Fluconazole B Braun, tell your doctor or nurse immediately. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). Since a health care provider will administer Fluconazole B Braun, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If a dose of Fluconazole B Braun has been forgotten**

As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However, tell your doctor or pharmacist if you think that a dose has been forgotten.

**4. Possible side effects**

Fluconazole B Braun can cause side effects.

Not all side effects reported for Fluconazole B Braun are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given Fluconazole B Braun, please consult your health care provider for advice.

Stop using Fluconazole B Braun and seek medical attention immediately if you notice any of the following symptoms:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

**A few people develop allergic reactions although serious allergic reactions are rare. If you get any of the following symptoms, tell your doctor immediately:**

- sudden wheezing, difficulty in breathing or tightness in the chest
- swelling of eyelids, face or lips
- itching all over the body reddening of the skin or itchy red spots
- skin rash
- severe skin reactions such as rash that causes blistering (this can affect the mouth and tongue).
- Fluconazole B Braun may affect your liver. The signs of liver problems include:
  - tiredness
  - loss of appetite
  - vomiting
  - yellowing of your skin or the whites of your eyes (jaundice)

If any of these happen, stop taking Fluconazole B Braun and *tell your doctor immediately.*

**Other side effects:**

Additionally, if you have any of the following side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

*Frequent side effects:*

- Headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- increases in blood tests of liver function
- rash

*Less frequent side effects:*

- reduction in red blood cells which can make skin pale and cause

weakness or breathlessness

- decreased appetite
- inability to sleep, feeling drowsy
- lightheadedness, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste
- constipation, difficult digestion, wind, dry mouth
- muscle pain
- liver damage and yellowing of the skin and eyes (jaundice)
- wheals, blistering (hives), itching, increased sweating
- tiredness, general feeling of being unwell, fever
- lower normal white blood cells that help defend against infections and blood cells that help to stop

bleeding

- red or purple discoloration of the skin which may be caused by low platelet count, other blood cell

changes

- blood chemistry changes (high blood levels of cholesterol, fats)
- shaking
- low blood potassium
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- liver failure
- allergic reactions (sometimes severe), including widespread blistering rash and skin peeling,

severe skin reactions, swelling of the lips or face

- hair loss

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

**Reporting of side effects**

If you get side effects. Talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via “6.04 Adverse Drug Reaction

Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/index/>.

By reporting side effects, you can help provide more information on the safety of **Fluconazole B Braun**.

**5. How to store Fluconazole B Braun**

Keep this medicine out of the sight and reach of children.

Do not use Fluconazole B Braun after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Keep the bottles in the outer carton in order to protect from light.

Store at or below 25 °C. Do not freeze.

Fluconazole B Braun must be used immediately after first opening the container.

Use only if the solution is clear and free from visible particles. Do not use if the bottle is damaged.

The bottles are for single use only. Once having been used, bottles and any remaining contents must be disposed.

Return all unused medicines to the pharmacy.

**6. Contents of the pack and other information****What Fluconazole B Braun contains**

- The active substance is fluconazole
  - Each ml contains 2 mg of fluconazole
- The other ingredients are

Sodium chloride and water for injections

**What Fluconazole B Braun looks like and contents of the pack**

Fluconazole B Braun is a clear colourless solution of the above mentioned ingredients in water. It comes in bottles of polyethylene, containing 50 mL, 100 mL or 200 mL

Pack sizes: Packs of 10, 20 or 50 bottles

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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