PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BIO FLUCONAZOLE IV 200 mg fluconazole per 100 mL infusion

Fluconazole

Sugar free

Read all of this leaflet carefully before you are given BIO FLUCONAZOLE IV

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

What is in this leaflet

1. What BIO FLUCONAZOLE IV is and what it is used for
2. What you need to know before you are given BIO FLUCONAZOLE IV
3. How BIO FLUCONAZOLE IV is used
4. Possible side effects
5. How to store BIO FLUCONAZOLE IV
6. Contents of the pack and other information

1. What BIO FLUCONAZOLE IV is and what it is used for

Fluconazole, the active substance in BIO FLUCONAZOLE IV belongs to a group of medicines called antifungal medicines.

In adults:

BIO FLUCONAZOLE IV is usually used to prevent and treat fungal infections caused by organisms called

Cryptococcus (a fungal infection in the brain) and Candida which can cause meningitis, vaginal and penis infections, systemic infections, infections of the throat and oesophagus and infections of the skin e.g. ringworm, athlete's foot, jock itch and nail infections. BIO FLUCONAZOLE IV can also be used to prevent fungal infections in patients receiving cancer treatment.

In children:

BIO FLUCONAZOLE IV is usually used to prevent and treat fungal infections caused by organisms called Cryptococcus (a fungal infection in the brain) and Candida which can cause meningitis, systemic infections, infections of the throat and oesophagus. BIO FLUCONAZOLE IV can also be used to prevent fungal infections in patients receiving cancer treatment.

2. What you need to know before you are given BIO FLUCONAZOLE IV

BIO FLUCONAZOLE IV should not be administered to you:

- if you are hypersensitive (allergic) to fluconazole, other medicines you have taken to treat fungal infections, or any of the other ingredients of BIO FLUCONAZOLE IV (listed in section 6). The symptoms of an allergic reaction may include itching, reddening of the skin or difficulty in breathing.
- if you are taking an antihistamine medicine for allergies called astemizole or terfenadine.
- if you are taking a medicine called cisapride to increase your bowel movements.
- if you are taking pimozide (used for treating mental illness)
- if you are taking quinidine (used for treating irregular heartbeats)
- if you are taking erythromycin (an antibiotic for treating infections)
- if you are pregnant or breastfeeding

Warnings and precautions

Tell your doctor or healthcare provider before being given the infusion:

- if you suffer from liver or kidney problems

- if you have 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 are HIV positive, as you may be at higher risk of developing serious skin reactions
- 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 taking or being given fluconazole as contained in BIO FLUCONAZOLE IV
- if the fungal infection does not improve, as alternative antifungal therapy may be needed
- if you are taking halofantrine (anti-malaria medicine) (see "Other medicines and BIO FLUCONAZOLE IV" below)
- if you are taking medicines for which the levels in your blood need to be carefully monitored such as carbamazepine (for epilepsy), ciclosporin (to prevent transplant rejection), phenytoin (for epilepsy), theophylline (for asthma), and warfarin (for blood thinning to prevent clots) (see "Other medicines and BIO FLUCONAZOLE IV" below)

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with BIO FLUCONAZOLE IV treatment. Stop receiving BIO FLUCONAZOLE IV 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 BIO FLUCONAZOLE IV

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

Tell your doctor **immediately** if you are taking any of the following medicines, as these medicines should not be taken with BIO FLUCONAZOLE IV:

- cisapride (used to increase bowel movements)
- terfenadine or astemizole (antihistamines)
- pimozide (for mental illness)
- quinidine (for treating uneven heartbeats)
- erythromycin (antibiotic for bacterial infections)
- halofantrine (for malaria)

There are some medicines that may interact with BIO FLUCONAZOLE IV. Your doctor may need to make dose adjustments or carefully monitor your condition. Make sure your doctor knows if you are taking any of the following medicines:

- amiodarone (for treating uneven heartbeats "arrythmia")
- hydrochlorothiazide (a diuretic or water tablet, used to treat fluid retention and high blood pressure)
- rifampicin, rifabutin, or azithromycin (antibiotics for treating infections including tuberculosis/TB)
- alfentanil, fentanyl or methadone (for treating pain)
- amitriptyline or nortriptyline (for depression)
- amphotericin B or voriconazole (for fungal infections)
- warfarin (or similar medicines) that thin the blood to prevent blood clots
- benzodiazepines such as midazolam and triazolam (used to help you sleep or for anxiety)
- carbamazepine or phenytoin (used to control epilepsy)
- losartan or calcium channel blockers such as nifedipine, isradipine, nicardipine, amlodipine, and felodipine (for lowering blood pressure)
- celecoxib (used to treat certain types of arthritis)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide, ibrutinib, olaparib, or vinca alkaloids such as vincristine and vinblastine (used in

cancer treatment)

- atorvastatin, simvastatin, fluvastatin or similar medicines (for lowering cholesterol levels)
- ivacaftor (used for treating cystic fibrosis)
- flurbiprofen, naproxen, ibuprofen, meloxicam, diclofenac, aspirin or similar medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) (used to treat pain and inflammation)
- oral contraceptives (to prevent pregnancy)
- prednisone (steroid used for inflammation and in organ transplants)
- saquinavir, zidovudine also known as AZT, and nevirapine (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)
- tofacitinib (used for treating rheumatoid arthritis)
- tolvaptan (used to treat low levels of sodium in blood or to slow kidney function decline)
- vitamin A (as a trans-retinoid acid used to treat acne)

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 healthcare provider for advice before being given BIO FLUCONAZOLE IV.

You should not be given BIO FLUCONAZOLE IV while you are pregnant or if you are breastfeeding.

BIO FLUCONAZOLE IV given during pregnancy may increase the risk of a baby being born with birth defects affecting the bones and/or muscles. It also increases the risk of having a miscarriage.

If you are of childbearing age, you must use effective contraceptive measures during your treatment with BIO FLUCONAZOLE IV and for approximately 1 week after the final dose.

Driving and using machines

If you suffer from dizziness, headaches, tiredness or nausea make sure that you are well enough to drive or

operate machinery, as your ability to react may be impaired.

It is not always possible to predict to what extent BIO FLUCONAZOLE IV may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BIO FLUCONAZOLE IV affects you.

BIO FLUCONAZOLE IV contains sodium

BIO FLUCONAZOLE IV contains 354 mg sodium (main component of cooking/table salt) per 100 mL of the solution. This is equivalent to 17,7 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your pharmacist or doctor if you need BIO FLUCONAZOLE IV on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How BIO FLUCONAZOLE IV is used

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself BIO FLUCONAZOLE IV. It will be given to you by a person who is qualified to do so.

BIO FLUCONAZOLE IV will be given by your doctor or nurse as a slow injection (infusion) into your vein that will last several minutes.

For adults the usual dose of BIO FLUCONAZOLE IV is between 50 mg and 400 mg given once a day or as a single dose, depending on the infection you are being treated for.

For children the usual dose of BIO FLUCONAZOLE IV depends on bodyweight, age and the infection being treated.

If you are an elderly person, you will be given the usual adult dose unless you have kidney problems.

If you have kidney problems your doctor may modify your dose, depending on your kidney function and bodyweight.

Your doctor will tell you how long your treatment with BIO FLUCONAZOLE IV will last. If you have the impression that the effect of BIO FLUCONAZOLE IV is too strong or too weak, tell your doctor or pharmacist.

If you receive more BIO FLUCONAZOLE IV than you should

If you are concerned that you may have been given too much BIO FLUCONAZOLE IV, tell your doctor or nurse immediately. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucinations and paranoid behaviour).

Since a healthcare provider will administer BIO FLUCONAZOLE IV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of BIO FLUCONAZOLE IV

Since a healthcare provider will administer BIO FLUCONAZOLE IV, it is unlikely that the dose will be missed. However, tell your doctor or nurse if you think that a dose has been forgotten.

4. Possible side effects

BIO FLUCONAZOLE IV can have side effects.

Not all side effects reported for BIO FLUCONAZOLE IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving BIO FLUCONAZOLE IV, please consult your healthcare provider for advice.

If any of the following happens, stop receiving BIO FLUCONAZOLE IV and tell your doctor **immediately** or go to the casualty department at your nearest hospital:

Signs of an allergic reaction:

- 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
- fever and chills
- severe skin reactions such as a rash that causes blistering, this can affect the mouth and tongue (toxic epidermal necrolysis, or Stevens-Johnson syndrome)
- widespread rash, with high body temperature and enlarged lymph nodes (swollen glands) (DRESS syndrome or drug hypersensitivity syndrome)

Signs of liver problems:

- unusual tiredness or weakness
- dark or amber urine
- loss of appetite
- vomiting
- stomach pain
- pale stools
- yellowing of your skin or the whites of your eyes (jaundice)

These are all very serious side effects. You may need urgent medical attention.

If you are an AIDS patient, you are more likely to get severe skin reactions to medicines including BIO FLUCONAZOLE IV.

Tell your doctor of you notice any of the following:

Frequent side effects

- headache
- stomach discomfort
- vomiting

- diarrhoea
- feeling sick (nausea)
- loss of appetite
- increases in blood tests of liver function
- rash

Less frequent side effects

- lower than normal red blood cells which can make skin pale and cause weakness or breathlessness (anaemia)
- lower than normal white blood cells that help defend against infections (agranulocytosis, leukopenia, neutropenia) and blood platelet that help to stop bleeding (thrombocytopenia)
- red or purple discoloration of the skin which may be caused by low platelet count, or other blood cell changes
- high blood levels of cholesterol or fats (triglycerides)
- low blood potassium levels resulting in convulsions, decreased urine, dry mouth and irregular heartbeat
- inability to sleep (insomnia), feeling drowsy
- seizures (fits)
- dizziness, sensation of spinning (vertigo)
- feeling nervous, tingling or pricking (pins and needles), hyperactive and unable to concentrate, changes in sense of taste
- shaking (tremor)
- changes in vision
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- constipation, indigestion, wind, dry mouth, thirst
- liver damage or failure, higher than normal levels of bilirubin in your blood (seen in blood tests)

- itching, increased sweating, dry skin, abnormal odour, hair loss (alopecia)
- muscle pain, muscle stiffness
- large volumes of dilute urine
- female sexual dysfunction, abnormal vaginal bleeding between periods, abnormally heavy bleeding at menstruation (menorrhagia)
- flow of a whitish, yellowish, or greenish discharge from the vagina that may be normal or that may be a sign of infection
- tiredness, general feeling of being unwell, lack of energy, fever, shivering

If you notice any side effects not mentioned in this leaflet, please inform you doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BIO FLUCONAZOLE IV.

5. How to store BIO FLUCONAZOLE IV

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not freeze.

Discard remaining contents after use.

Do not use after the expiry date stated on the label.

Do not use BIO FLUCONAZOLE IV if the solution is not clear and free of visible particles.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What BIO FLUCONAZOLE IV contains

- The active substance is fluconazole. Each bottle contains 200 mg fluconazole per 100 mL solution (2 mg/mL).
- The other ingredients are sodium chloride and water for injection.

What BIO FLUCONAZOLE IV looks like and contents of the pack

BIO FLUCONAZOLE IV is a clear colourless to pale yellow solution.

BIO FLUCONAZOLE IV is packed in a 100 mL transparent clear LDPE bottle. Each bottle is wrapped with a transparent clear polypropylene wrapper.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd.

Block K West, Central Park

400 16th Road, Halfway House

Midrand, South Africa

1685

Tel. (011) 848 3050

This leaflet was last revised in

To be allocated

Registration number

42/20.2.2/0683