

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

### **BIO METRONIDAZOLE IV 500 mg/100 mL solution for infusion**

#### **Metronidazole**

Sugar free.

**Read all of this leaflet carefully before you are given BIO METRONIDAZOLE 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.
- BIO METRONIDAZOLE IV has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### **What is in this leaflet**

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

#### **1. What BIO METRONIDAZOLE IV is and what it is used for**

BIO METRONIDAZOLE IV contains metronidazole, which is an antibiotic. BIO METRONIDAZOLE IV is used for the treatment of certain bacterial infections and to prevent infection after an operation.

Your doctor or healthcare professional has prescribed this medicine for your specific condition.

## **2. What you need to know before you are given BIO METRONIDAZOLE IV**

### **You should not be given BIO METRONIDAZOLE IV:**

- If you are hypersensitive (allergic) to metronidazole, other imidazoles or any of the other ingredients of BIO METRONIDAZOLE IV (listed in section 6).
- If you are pregnant or breastfeeding.
- If you have end stage liver damage, haematopoietic disorders (blood disorders) and active disease of the central or peripheral nervous systems.

### **Warnings and precautions**

#### ***Tell your doctor or health care provider before being given the injection:***

- If you are taking any alcohol (remember that medicines such as cough syrup also contains alcohol).  
When given with alcohol, BIO METRONIDAZOLE IV may cause reactions such as abdominal cramps, nausea, vomiting, headache or flushing, in some patients.
- If you have any disease affecting your blood or nervous system.
- If you have a severe liver disorder.
- If you have a condition called hepatic encephalopathy (which may cause confusion, fatigue, tremors, memory loss, bad breath due to your liver failing).
- If you have a kidney disorder.
- If you experience pseudomembranous colitis (infection of the colon) which includes abdominal cramps, bloody stools, fever, urge to have a bowel movement, watery diarrhoea during your treatment with BIO METRONIDAZOLE IV.
- If you have been diagnosed with, or you suspect you might have syphilis (a sexually transmitted disease).  
Your doctor may need to screen you for an additional 4 to 8 weeks.
- If you are taking a medicine called busulfan used to treat cancer of the blood cells (leukaemia). Using BIO METRONIDAZOLE IV with busulfan may lead severe busulfan toxicity and death.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with

Cockayne syndrome may occur with BIO METRONIDAZOLE IV.

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with BIO METRONIDAZOLE IV and afterwards.

Tell your doctor immediately and stop using BIO METRONIDAZOLE IV if you develop stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or clay-coloured stools or itching.

#### **Other medicines and BIO METRONIDAZOLE IV**

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

The following medicines may interact with BIO METRONIDAZOLE IV when you use them together. It may either cause additional side effects or the medicines may not work as well:

- Disulfiram (medicines used to treat chronic alcoholism) may result in acute psychoses (sudden and severe disorganisation of the mind, disturbance of the relational abilities, a loss of contact with what is commonly accepted as reality) or confusion.
- Alcohol or alcohol containing medicines.
- Warfarin (a blood thinning medicine).
- Fluorouracil (medicine for the treatment of cancer of the stomach).
- Phenytoin or phenobarbital (anti-epileptic medicines).
- Lithium (medicine for depression).
- Cimetidine (medicine for stomach ulcers or heartburn).
- Ciclosporin, tacrolimus (medicines that suppress the immune system used after organ transplant).
- Vecuronium (muscle relaxant).
- Cholestyramine (bile acid sequestrant).
- Busulfan used to treat leukaemia (cancer of the blood cells).

Not all medicine interactions are described in this leaflet. It is therefore very important that you tell your doctor or health care provider of all the other medicines you are currently taking.

### **BIO METRONIDAZOLE IV with alcohol**

Alcohol beverages and medicines containing alcohol should not be consumed during and at least 1 to 3 days after treatment with BIO METRONIDAZOLE IV.

### **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 using BIO METRONIDAZOLE IV.

BIO METRONIDAZOLE IV should not be administered if you are pregnant or breastfeeding (see Do not use BIO METRONIDAZOLE IV).

### **Driving and using machines**

BIO METRONIDAZOLE IV can cause confusion, dizziness, hallucinations (see or hear things that are not there), fits (convulsions) or temporary eyesight problems (such as blurred or double vision). When you experience these symptoms, you should not drive or operate machines.

It is not always possible to predict to what extent BIO METRONIDAZOLE 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 METRONIDAZOLE IV affects you.

### **3. How to use BIO METRONIDAZOLE IV**

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

BIO METRONIDAZOLE IV is administered as an intravenous infusion (infusion into your vein).

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

Depending on the type of infection and the severity of your infection your doctor will prescribe the exact dosage of BIO METRONIDAZOLE IV for your specific condition and will determine the duration of your therapy.

If you have the impression that the effect of BIO METRONIDAZOLE IV is too strong or too weak, tell your doctor or pharmacist.

#### **If you receive more BIO METRONIDAZOLE IV than you should**

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

#### **If a dose of BIO METRONIDAZOLE IV is missed**

Since a healthcare provider will administer BIO METRONIDAZOLE, it is unlikely that the dose will be missed.

#### **4. Possible side effects**

BIO METRONIDAZOLE IV can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO METRONIDAZOLE IV. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Side effects occurring less frequently:*

- Unexplained bruising or bleeding.
- Peripheral neuropathy (numbness and pain in your hands or feet).
- Lack of voluntary coordination of muscle, tremor.
- Hepatic encephalopathy (confusion, altered level of consciousness, and coma as a result of liver failure).
- Seizures and convulsions (fits).
- Inflammation of the meninges surrounding your brain (fever, chills, headache, body ache, sensitivity to light, vomiting).
- Yellowing of your skin and eyes due to liver problems, including jaundice.
- Severe painful skin rash, causing blistering or peeling of your skin (Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme).

*Side effects which may occur, but the frequency is not known:*

- Changes in the way your heart beats, such as beating faster than normal or skipping a beat.
- Severe or bloody diarrhoea.
- Chest pain.

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

Tell your doctor if you notice any of the following:

*Side effects occurring frequently:*

- Gastrointestinal disturbances such as nausea and vomiting.
- Diarrhoea and constipation.
- Dryness of mouth.
- Altered taste.
- Inflammation of the mouth or tongue (stomatitis and glossitis).
- Swelling and irritation in the mouth (oral mucositis).
- Furred tongue.
- Painful muscles or joints.

*Side effects occurring less frequently:*

- Dizziness or light-headedness.
- Headache.
- Clumsiness or unsteadiness.
- Mood or mental changes such as depression, confusion, irritability or hallucinations.
- Weakness.
- Drowsiness or sleeplessness.
- Difficulty speaking.
- Changes in your balance or way you walk (gait).
- Pain, tenderness, redness or swelling at site of injection.
- Fever or sore throat.
- Pancreatitis.
- Painful, burning urination or discomfort upon urination, increased urination, inability to control urine flow or darkening of the urine.
- Vaginal infection (thrush).
- Visual disturbances such as double vision or blurred vision, pain when moving your eyes or temporary vision loss (optic neuropathy).
- Abnormal liver function.

- Pustular eruptions (breakouts of blisters, containing pus, on the skin), mild erythematous eruptions (mild redness) with fleeting (brief) joint pains resembling serum sickness (allergic reaction to an injection of serum).
- Lack of energy.
- Inflammation in the lining of some organs such as the nose, mouth, lungs and stomach.
- Fever.

*Side effects which may occur, but the frequency is not known:*

- Vertigo (the sensation that you or the environment around you is moving or spinning).
- Burning, tingling or numb sensation of your skin.
- Total or partial loss of sensation in a part of your body.
- Nasal congestion (blocked/stuffy nose), difficulty breathing.
- Swelling of the face.
- Flushing.
- Skin rash, hives and itching.
- Excessive sweating.
- A general feeling of discomfort.
- Swelling in the arms or legs (peripheral oedema).
- Chills.

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

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of BIO METRONIDAZOLE

IV.

#### **5. How to store BIO METRONIDAZOLE IV**

- Store all medicines out of reach of children.
- Store at or below 30 °C. Do not refrigerate.
- For single use only. Discard any remaining contents after use.
- Protect from light.
- Do not use this medicine after the expiry date stated on the container.
- Please return all unused medicine to your pharmacist for safe disposal.

#### **6. Contents of the pack and other information**

##### **What BIO METRONIDAZOLE IV contains**

The active substance in BIO METRONIDAZOLE IV is metronidazole 500 mg per 100 mL of the solution for infusion.

The other ingredients are citric acid monohydrate, dibasic sodium phosphate (anhydrous), sodium chloride and water for injection.

##### **What BIO METRONIDAZOLE IV looks like and contents of the pack**

BIO METRONIDAZOLE IV solution for infusion is a clear, colourless to pale yellow solution. The solution is sterile and free from particulate matter.

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

##### **Holder of the certificate of registration**

Biotech Laboratories (Pty) Ltd

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Biotech Laboratories (Pty) Ltd.  
Bio Metronidazole IV  
Each 100 ml contains 500 mg metronidazole  
(42/20.2/0567- registered)

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**Access to the corresponding Professional Information**

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email [info@biotechlabs.co.za](mailto:info@biotechlabs.co.za).