PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BIO-METRONIDAZOLE 200 tablets

BIO-METRONIDAZOLE 400 tablets

Metronidazole

BIO-METRONIDAZOLE 200 contains sugar (200 mg lactose per tablet).

BIO-METRONIDAZOLE 400 contains sugar (150 mg lactose per tablet).

Read all of this leaflet carefully before you start taking BIO-METRONIDAZOLE tablets

- 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.
- BIO-METRONIDAZOLE 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 is and what it is used for
2. What you need to know before you take BIO-METRONIDAZOLE
3. How to take BIO-METRONIDAZOLE
4. Possible side effects
5. How to store BIO-METRONIDAZOLE
6. Contents of the pack and other information

1. What BIO-METRONIDAZOLE is and what it is used for

BIO-METRONIDAZOLE tablets contain metronidazole, which is an antibiotic. BIO-METRONIDAZOLE tablets are used for the treatment of certain bacterial infections and to prevent

infection after an operation. BIO-METRONIDAZOLE tablets can also be used in combination with other medicines to treat stomach ulcers caused by a certain type of bacteria called *Helicobacter pylori*.

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

2. What you need to know before you take BIO-METRONIDAZOLE

Do not take BIO-METRONIDAZOLE if:

- You are allergic (hypersensitive) to metronidazole, similar medicines called imidazoles or to any of the other ingredients of BIO-METRONIDAZOLE (listed in section 6).
- You have a blood disorder or disease of the central nervous system.
- You are taking a medicine called busulfan (used to treat certain types of cancers).

Do not take BIO-METRONIDAZOLE if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before taking BIO-METRONIDAZOLE.

Warnings and precautions

Tell your doctor or health care provider if:

- You are taking any alcohol (including medicines such as cough syrup which may also contain alcohol). When given with alcohol, BIO-METRONIDAZOLE may cause reactions such as abdominal cramps, nausea, vomiting, headache or flushing, in some patients (see BIO-METRONIDAZOLE with alcohol).
- You have a nervous system disorder called hepatic encephalopathy.
- You are using medication for hypertension.
- You have a severe liver disorder.
- You have kidney dialysis.
- You might have had sexual intercourse with a person with syphilis. Your doctor may need to screen you for an additional 4 to 8 weeks.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome may occur with BIO-METRONIDAZOLE. If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with BIO-METRONIDAZOLE and afterwards.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of BIO-METRONIDAZOLE:

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk (chest, abdomen, pelvis and back). Also, ulcers of the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk, and upper extremities.

The highest risk for occurrence of serious skin reactions is within one week, typically, within 48 hours after start of treatment. **If you develop a serious rash or another of these skin symptoms, stop taking BIO-METRONIDAZOLE and contact your doctor or seek medical attention immediately.**

Other medicines and BIO-METRONIDAZOLE

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

The following medicines may interact with BIO-METRONIDAZOLE tablets when you take them

together and may either cause additional side-effects or may not work as well:

- Warfarin (a blood thinning agent)
- Fluorouracil (medicine for the treatment of cancer of the stomach)
- Phenytoin or phenobarbital (an anti-epileptic medicine)
- Lithium (medicine for depression)
- Cimetidine (medicine for stomach ulcers or heartburn)
- Ciclosporin (medicine that suppress the immune system used after organ transplant)

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

BIO-METRONIDAZOLE 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.

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 BIO-METRONIDAZOLE.

The safety of BIO-METRONIDAZOLE tablets during pregnancy and lactation has not been established. If you are breastfeeding, do not to take BIO-METRONIDAZOLE. This is because small amounts may pass into the mother’s milk.

Driving and using machines

BIO-METRONIDAZOLE tablets can cause confusion, dizziness, unsteadiness and problems with your ability to see. When you experience these symptoms, you should not drive or operate machines.

3. How to take BIO-METRONIDAZOLE

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

Always take BIO-METRONIDAZOLE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe the exact dose of BIO-METRONIDAZOLE tablets required for your condition. Depending on the type of infection and the severity of your infection the doctor will prescribe the dosage for your specific condition and will determine the duration of your therapy.

Tablets should be swallowed without chewing, with adequate water, preferably during or after meals.

The dosage for children over 10 years of age will be determined according to their body weight.

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

If you take more BIO-METRONIDAZOLE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and any remaining tablets with you, so that your doctor knows what you have taken.

If you take too many BIO-METRONIDAZOLE tablets you might experience symptoms such as vomiting, nausea, numbness, tingling, pain or weakness in your hands and feet and seizures.

If you forget to take BIO-METRONIDAZOLE

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and then go on as before. Do not take two dosages at the same time.

4. Possible side effects

BIO-METRONIDAZOLE can have side effects.

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

If any of the following happens, stop taking BIO-METRONIDAZOLE 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. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Vertigo (the sensation that you, or the environment around you, is moving or spinning).
- Gastrointestinal discomfort, nausea (feeling sick) and unpleasant taste; nausea is sometimes accompanied by headache and vomiting (being sick). Diarrhoea, dry mouth, a furred tongue, oral mucositis (sore/red mouth) and stomatitis (sore mouth, mouth ulcers and cold sores).

The following side effects have been reported less frequently:

- Blood disorders with unexpected infections, mouth ulcers, bleeding or bruising more easily than normal.
- A decrease in the number of white blood cells in your body.
- Confusion, irritability and hallucinations (seeing or hearing things that are not there), changes in mood or mental state such as depression.

- Weakness, dizziness, drowsiness, insomnia (sleep disorder).
- Peripheral neuropathy (a disorder of the nerves), usually presenting as numbness, tingling, or a feeling of weakness in the arms or legs and, fits (convulsions).
- Encephalopathy (brain disease, symptoms of which vary but you may get a fever, stiff neck, headache and see or hear things that are not there) and subacute cerebellar syndrome (where you encounter problems with coordination of movement of your arms and legs, problems speaking or feel confused).
- Vision disorders such as diplopia (double vision) and myopia (short sightedness).
- Pseudomembranous colitis (watery and severe diarrhoea, which may also be bloody).
- Pancreatitis (inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting).
- Increase in liver enzymes (liver problem) and inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine).
- 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).
- Skin rashes, fever, flushing (reddening of skin), and pruritus (itching).
- Urethral (bladder) discomfort and darkening of the urine.

The following have also been reported, but the frequency cannot be estimated from the available information:

- Anorexia (loss of appetite).
- Nasal congestion (blocked/stuffy nose).
- Myalgia (pain in the muscles) and arthralgia (pains in the joints).
- Fever.
- Headache, aseptic meningitis (inflammation of the membranes around the brain and spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light).

- Eyesight problems such as blurred vision, decreased in visual acuity (sharpness of vision), changes in colour vision.
- Optic neuritis (pain in your eyes and increasingly blurred vision).
- Epigastric pain (pain in the upper central region of the stomach).
- Mixed hepatitis and hepatocellular liver injury (liver diseases).
- Cases of liver failure requiring liver transplant have been reported in patients treated with BIO-METRONIDAZOLE in combination with other antibiotic medicines.

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 "**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-METRONIDAZOLE.

5. How to store BIO-METRONIDAZOLE

- Store all medicines out of reach of children.
- Store below 25 °C and 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.
- Do not remove the blisters from the outer carton until required for use.

6. Contents of the pack and other information

What BIO-METRONIDAZOLE contains

The active substance in BIO-METRONIDAZOLE 200 tablets is metronidazole 200 mg and in BIO-

METRONIDAZOLE 400 tablets it is metronidazole 400 mg.

The other ingredients are colloidal silicon dioxide, lactose, magnesium stearate, maize starch, pregelatinised starch, povidone.

What BIO-METRONIDAZOLE looks like and contents of the pack

BIO-METRONIDAZOLE 200 is a white coloured, biconvex uncoated tablet, with 'MZL / 200' engraved along with a break line on one side and plain on the other side.

BIO-METRONIDAZOLE 400 is a white coloured, biconvex uncoated tablet, with 'MZL / 400' engraved along with a break line on one side and plain on the other side.

BIO-METRONIDAZOLE 200:

White PP securitainers with 250 tablets or patient ready packs (white LDPE bags) with 21 or 28 tablets.

PVC/PVDC/aluminium blisters containing 7 tablets per blister strip and 1, 2, or 3 blisters per outer carton.

BIO-METRONIDAZOLE 400:

White PP securitainers with 21, 100 or 500 tablets or patient ready packs (white LDPE bags) with 5, 14 or 21 tablets.

PVC/PVDC/aluminium blisters containing 7 tablets per blister strip and 1, 2, or 3 blisters per outer carton.

HDPE containers with caps, containing 100 or 500 tablets.

Not all pack sizes may be marketed.

Holder of the certificate of registration

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark

Halfway House

Midrand 1685

Tel. 011 848 3050

This leaflet was last revised in

Date of registration: 30 November 1988

Date of revision: 10 June 2026

Registration numbers

BIO-METRONIDAZOLE 200: V/20.2.6/0370

BIO-METRONIDAZOLE 400: V/20.2.6/0371