**PATIENT INFORMATION LEAFLET FOR METRONIDAZOLE 500 mg/100 mL LAMAR**

**Patient information leaflet for**

**METRONIDAZOLE 500 mg/100 mL LAMAR**

**SCHEDULING STATUS** S4

**METRONIDAZOLE 500 mg/100 mL LAMAR**

Metronidazole

Solution for infusion

Sugar free

Read all of this leaflet carefully before you are given METRONIDAZOLE 500 mg/100 mL LAMAR:

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

**What is in this leaflet**



**1. What METRONIDAZOLE 500 mg/100 mL LAMAR is and what it is used for:**

METRONIDAZOLE 500 mg/100 mL LAMAR contains metronidazole which

is an antibiotic.

METRONIDAZOLE 500 mg/100 mL LAMAR is used for the treatment of certain bacterial infections and to prevent infection after an operation.

**2. What you need to know before you are given METRONIDAZOLE 500 mg/100 mL LAMAR:**

**METRONIDAZOLE 500 mg/100 mL LAMAR should not be administered to you:**

- If you are hypersensitive (allergic) to metronidazole, other nitroimidazoles or any of the other ingredients of METRONIDAZOLE 500 mg/100 mL LAMAR (listed in section 6).
- If you are pregnant or breastfeeding.
- If you have a blood disorder or active disease of the central nervous system.

**Warnings and precautions**

**Special care should be taken with METRONIDAZOLE 500 mg/100 mL LAMAR:**

- If you have any liver problems,
- If you have been diagnosed with, or you suspect you might have syphilis,
- If you have a blood formation disorder,
- If you have a disease of brain, spinal cord or nerves,
- If convulsive fits or any other nerve affections (e.g., numbness in limbs) become apparent during therapy, your treatment will promptly be revised.

If you have a severe allergic reaction (such as sudden difficulty

breathing, swelling of the face or throat, or a severe rash), treatment with METRONIDAZOLE 500 mg/100 mL LAMAR will be stopped immediately.

Treatment with METRONIDAZOLE 500 mg/100 mL LAMAR should not usually be continued for longer than 10 days.

Treatment must be stopped or revised immediately if you get severe diarrhoea which may be due to a severe large bowel disease called "*Pseudomembranous colitis*" (see section 4.)

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with products containing metronidazole.

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with metronidazole and afterwards.
Tell your doctor immediately and stop taking metronidazole if you develop:

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic-coloured stools or itching.
- As prolonged use of metronidazole may impair blood formation (see section "Possible side effects"), your blood counts will be monitored during treatment.

Alcohol beverages and medicines containing alcohol should not be consumed during therapy with METRONIDAZOLE 500 mg/100 mL LAMAR.

**Other medicines and METRONIDAZOLE 500 mg/100 mL LAMAR**

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Always tell your health care provider if you are taking any other medicine

(this includes all complementary or traditional medicines).

Tell your doctor if you are taking:

- Amiodarone (used to treat irregular heartbeat),
- Barbiturates (the active substance in sleeping pills),
- Contraceptives (birth control pills),
- Busulfan (a medicine used in chemotherapy),
- Carbamazepine (a medicine for the treatment of epilepsy),
- Cimetidine (a medicine for the treatment of stomach disorders),
- Coumarin derivatives (medicine that inhibit blood clotting),
- Cyclosporin (a medicine used to suppress undesirable immune responses),
- Disulfiram (used in alcohol withdrawal therapy),
- Fluorouracil (an anticancer medicine),
- Lithium (used to treat mental illness),
- Mycophenolate mofetil (used for the prevention of rejection reactions after organ transplant),
- Phenytoin (a medicine for the treatment of epilepsy),
- Tacrolimus (used to suppress unwanted immune reactions),
- Alcohol or medicine containing alcohol,
- Vecuronium (a muscle relaxant used during anaesthesia and surgery),
- Cholestyramine (used to treat high cholesterol).

**METRONIDAZOLE 500 mg/100 mL LAMAR with food, drink and alcohol**

***Alcohol***

You must not drink any alcoholic beverages while you are being

given METRONIDAZOLE 500 mg/100 mL LAMAR because this may cause intolerance reactions such as dizziness, nausea, and vomiting.

**Pregnancy, breastfeeding and fertility**

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 receiving this medicine.

**Pregnancy**

Safety in pregnancy has not been established.
METRONIDAZOLE 500 mg/100 mL LAMAR should not be used during pregnancy.

*Contraception in males and females*

If you are taking a birth control pill, please refer to section “Taking or using other medicines”

**Breastfeeding**

You should not breastfeed during treatment with metronidazole and not resume nursing for another 2–3 days thereafter because METRONIDAZOLE 500 mg/100 mL LAMAR passes into breast milk.

**Fertility**

Animal studies only indicate a potential negative influence of METRONIDAZOLE 500 mg/100 mL LAMAR on the male reproductive system if high doses lying well above the maximum recommended dose for humans were administered.

**Driving and using machines**

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You should not drive or use any machines while being treated with METRONIDAZOLE 500 mg/100 mL LAMAR as METRONIDAZOLE 500 mg/100 mL LAMAR may impair alertness.

This is even more the case at the beginning of treatment or when you have drunk alcohol.

METRONIDAZOLE 500 mg/100 mL LAMAR can cause confusion, dizziness, unsteadiness, and problems with your ability to see. Make sure that you are well enough to drive or operate machinery**.**

**METRONIDAZOLE 500 mg/100 mL LAMAR contains sodium**

This product contains 310 mg sodium (main component of cooking/table salt) in each solution for infusion.
This is equivalent to 16 % of the recommended maximum daily dietary intake of sodium for an adult.

**3. How METRONIDAZOLE 500 mg/100 mL LAMAR is given**

You will not be expected to give yourself METRONIDAZOLE 500 mg/100 mL LAMAR.
It will be given to you by a person who is qualified to do so.

**Dosage**

Dosage depends on the nature and severity of your illness, your age and body weight, and your individual response to treatment.
Your doctor will prescribe the dosage for your specific condition and will determine the duration of your therapy.

**The recommended usual dosages are**

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The usual dosage for the treatment of an infection in an adult is 100 mL (500 mg/100 mL metronidazole).

METRONIDAZOLE 500 mg/100 mL LAMAR infused every eight hours.

In children under 12 years of age the dosage will be determined by the body weight of the child.

**If you are given more METRONIDAZOLE 500 mg/100 mL LAMAR than you should:**

Since a health care provider will administer METRONIDAZOLE 500 mg/100 mL LAMAR, it is unlikely that the dose will be missed.

**4. Possible side effects**

**METRONIDAZOLE 500 MG/100 ML LAMAR can have side effects.**

Not all side effects reported for METRONIDAZOLE 500 mg/100 mL LAMAR are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving METRONIDAZOLE 500 mg/100 mL LAMAR, please consult your health care provider for advice.

If any of the following happens, stop receiving METRONIDAZOLE 500 mg/100 mL LAMAR 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 reaction to METRONIDAZOLE 500 mg/100 mL LAMAR.

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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:

- You have hepatic encephalopathy (occurrence of confusion, altered level of consciousness, and coma as a result of liver failure);
- Eating disorder characterised by food restriction, lack of voluntary coordination of muscle, confusion and depression, sleeplessness, drowsiness and fits;
- Signs of recurrent infections, such as fever or sore throat; unexplained bruising or bleeding;
- Jarisch-Herxheimer reaction if you have syphilis (fever, muscle pain, headache, chills, fast heartbeat, increased breathing rate);
- Inflammation of the meninges surrounding your brain (fever, chills, headache, body ache, sensitivity to light, vomiting);
- Peripheral neuropathy (numbness and tingling in your hands or feet;
- Seizures (fits);
- Severe or bloody diarrhoea;
- 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);
- Changes in the way your heart beats, such as beating faster than normal or skipping a beat;
- Shortness of breath;
- Chest pain.

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

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Tell your doctor if you notice any of the following:

*Side effects occurring frequently:*

- Altered taste;
- Gastrointestinal discomfort, diarrhoea and constipation;
- Nausea, vomiting;
- Coated and inflamed tongue;
- Inflammation of mucous lining in the mouth;
- Dryness of the mouth, unpleasant taste, headache;
- Muscle pain.

*Side effects occurring less frequently:*

- Difficulty sleeping (insomnia);
- Changes in your balance or way you walk (gait);
- Difficulty speaking;
- Problems with your eyesight (double vision or near sightedness);
- Pancreatitis (inflammation of your pancreas causing stomach pain radiating to your back, nausea, vomiting);
- Pain of your stomach area;
- Tongue discoloration;
- Darkening of the urine;
- Discomfort when passing urine;
- Tiredness, mucosal inflammation or fever.

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

- Vertigo;
- Paraesthesia (burning, tingling or numb sensation of your skin);
- Loss of feeling;
- Blocked nose;

- Changes in liver enzymes when blood tests are done;
- Flushing, increased sweating;
- Muscle spasms or joint pain;
- Difficulty urinating (pain or discomfort);
- Injection site reaction;
- Swelling of your hands, feet, arms or legs due to water retention.

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

*Emergency management of pseudomembranous enterocolitis*

In the event of severe persistent diarrhoea, you must promptly inform your doctor because this may be due to pseudomembranous colitis, a serious condition that must be treated immediately.

Your doctor will stop metronidazole and provide appropriate treatment.

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, pharmacist or nurse.

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's website.

By reporting side effects, you can help provide more information on the safety of METRONIDAZOLE 500 mg/100 mL LAMAR.

**5. How to store METRONIDAZOLE 500 mg/100 mL LAMAR**

Store all medicines out of reach of children.

Store at or below 30°C.

Do not use after the expiry date stated on the packaging material.

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Return all unused medicines to your pharmacist.

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

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

The active substance in METRONIDAZOLE 500 mg/100 mL LAMAR is metronidazole.

The other ingredients are citric acid monohydrate, disodium phosphate dihydrate, sodium chloride and water for injection.

**What METRONIDAZOLE 500 mg/100 mL LAMAR looks like and contents of the pack**

**What METRONIDAZOLE 500 mg/100 mL LAMAR looks like**

Clear and colourless or pale yellowish aqueous solution, free of visible particles.

**Contents of the pack**

Polypropylene bottle containing 100 mL of solution for infusion.

Pack size: packages with 1, 4, 10, 25, 50 or 100 bottles.

Not all pack sizes may be marketed.

**Holder of certificate of registration**

Lamar International (Pty) Ltd

2 Waterford Mews

Waterford Place

Century City

7441

Cape Town

**PATIENT INFORMATION LEAFLET FOR METRONIDAZOLE 500 mg/100 mL LAMAR**

South Africa

Tel.: +27 21 943 0600

**Registration number**

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