1.5.5 Clean Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

MERCIDE 500 (Injection)

MERCIDE 1 g (Injection)

Meropenem

Sugar free

Read all of this Leaflet carefully before you are given MERCIDE

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

MERCIDE contains meropenem. Meropenem belongs to a group of medicines known as carbapenem antibiotics.

MERCIDE is used for treatment of a variety of infections caused by susceptible bacteria.

MERCIDE is used to treat the following in adults and children aged 3 months and older:

- Infection affecting the lungs (pneumonia)
- Complicated urinary tract infections
- Inflammatory infections affecting the pelvic area
- Skin Infections
- Acute bacterial infection of the brain (meningitis)
- A serious bloodstream infection (Septicaemia)
- Infections in the abdomen
- MERCIDE may be used in the management of neutropenic patients

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE MERCIDE

MERCIDE should not be administered to you if:

- if you have ever had an allergic reaction to meropenem or to any of the ingredient in MERCIDE listed in section 6 of the leaflet (an allergic reaction may include skin rash, itching, swelling of the face, lips, tongue and throat or difficulty breathing). You may also develop allergic reaction to MERCIDE if you have had in the past, an allergic reaction to other carbapenem antibiotics like imipenem, penicillins or other beta lactam class medicines.
- if you are pregnant, think you might be pregnant or you intend to become pregnant
- if you are currently breast feeding.

Warnings and precautions

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

- if you are suffering from problems with your liver or kidneys.
- if you develop offensive-smelling diarrhoea with fever and abdominal pain during the course of therapy.
- if you suffer from seizures.

You may develop a positive test (Coombs test) which indicates the presence of antibodies that may destroy red blood cells. Your doctor will discuss this with you.

Please consult doctor, even if these statements were applicable to you at any time in the past.

Children and adolescents

Meropenem should not be administered to infants below 3 months of age

Other medicines and MERCIDE

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

Take care if you are using any of the following medicines with MERCIDE

- Probenecid: You/ your child should not be given MERCIDE and probenecid (used to treat gout) together. This can increase the levels of meropenem in blood and also prolong it's duration of action.
- Valproic acid: Meropenem can decrease the blood levels of valproic acid (used for treatment of fits/ convulsions) to less than those required for its beneficial effect. MERCIDE should not be used because it may decrease the effect of sodium valproate.
- Oral anti-coagulant agent (used to treat or prevent blood clots).

You should always tell your doctor about other medicines that you are taking with or without prescription.

Do not take any medicine, vitamin supplement, or other health preparation without first checking with your doctor.

Pregnancy, breast-feeding 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 healthcare provider for advice before being administered with MERCIDE.

You should not be administered MERCIDE if you are pregnant or you think you might be pregnant. The safe use of MERCIDE in human pregnancy has not been established.

You should not be administered MERCIDE if you are breast feeding as it is excreted in human breast milk in low concentrations.

Driving and using machines

Some side effects associated with use of MERCIDE may affect the ability to drive and use machines in some patients. Make sure you know how you react to MERCIDE before you drive, use machines, or engage in any other activity that could be dangerous if you are not alert.

MERCIDE contains sodium

MERCIDE 500 and 1 g contains 104 mg and 208 mg sodium respectively (main component of cooking/table salt) in each dosage unit. This is equivalent to 5,2 % and 10,4 % respectively of the recommended maximum daily dietary intake of sodium for an adult

3. HOW TO TAKE MERCIDE

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

Use in adults

The usual dose will depend on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will decide on the dose that you need.

The dose for adults is usually between 500 mg to 1 g by intravenous administration every 8 hours. However you may receive a dose less often if your kidneys do not work very well.

Use in children and adolescents

The dose for children over 3 months old and up to 12 years of age is decided using the age and weight of the child. The usual dose is between 10 mg and 40 mg of MERCIDE for each kilogram (kg) that the child weighs. A dose is usually given every 8 hours. Children who weigh over 50 kg will be given an adult dose.

MERCIDE should not be used in children with kidney problems.

You or your child would be given MERCIDE as an injection into the vein over approximately 5 minutes or by intravenous infusion over a period of 15 to 30 minutes.

Your doctor will tell you how long your treatment with MERCIDE will last. Do not stop treatment early. If you have the impression that the effect of MERCIDE is too strong or too weak, tell your doctor or pharmacist.

How to use MERCIDE

- MERCIDE will be given to you as an injection or infusion into a large vein.
- Your doctor or nurse will normally give MERCIDE to you.
- Your injection should not be mixed with or added to solutions that contain other medicines.

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

If you have been given more MERCIDE than you should

Since a health care provider will administer MERCIDE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you have missed a dose

Since a health care provider will administer MERCIDE, it is unlikely that the dose will be missed.

If you stop taking MERCIDE

Since a health care provider will administer MERCIDE, your doctor will tell you how long your treatment with MERCIDE will last.

4. POSSIBLE SIDE EFFECTS

MERCIDE can have side effects.

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

If any of the following happen, you should not be given MERCIDE and you should 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
- Extremely serious allergic skin reaction (Stevens-Johnson Syndrome)

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to MERCIDE. 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:

- Seizure or fits

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Feeling sick (nausea), being sick (vomiting), diarrhoea or constipation and stomach-ache
- Headache
- Tenderness and pain with redness and/or swelling at the site of injection

Less frequent side effects:

- White, cream coloured or yellow spots in the mouth with pain or burning sensation, difficulty in swallowing (caused due to fungal infection of the mouth)
- Itching, burning, and soreness, irritation of the vagina and/or vulva, and a whitish or whitish-gray discharge(fungal infection of the vagina)
- Low numbers of some types of blood cells causing anaemia, increased risk of bleeding or increased risk of infections. Increased numbers of a type of blood cell called an eosinophils.
- Offensive-smelling diarrhoea with fever and abdominal pain
- Abnormal liver function tests

- Abnormal blood counts
- Inflammation of veins with formation of clots
- Numbness, tingling or pins and needles sensation
- Mental confusion

Frequency unknown side effects:

- Increase blood creatinine and urea

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 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 MERCIDE.

5. HOW TO STORE MERCIDE

Store all medicines out of reach of children.

Before reconstitution dry powder should be stored at below 25 °C. The vial must be stored in the carton until required for use.

Freshly prepared solutions of MERCIDE should be given whenever possible, however, constituted solutions of MERCIDE, as supplied in injection and infusion vials, maintain satisfactory potency at room temperature (up to 25 °C) or under refrigeration (4 °C) as shown in the table below:

Diluent	**Hours stable** **up to 25 °C**	**Hours stable** **up to 4 °C**

Vials constituted with water for injection for bolus injection	**7**	**48**
Infusions (1-20 mg/ml) prepared with 0,9 % sodium chloride	**8**	**48**
5,0 % dextrose **5,0 % dextrose and 0,2 % sodium chloride** **5,0 % dextrose and 0,9 % sodium chloride** **5,0 % dextrose and 0,15 % potassium chloride** **2,5 % or 10 % mannitol** **Normosol-M in 5 % glucose**	**3**	**14**
10 % dextrose **5 % dextrose and 0,02% sodium bicarbonate solution**	**2**	**8**

After reconstitution do not freeze.

Return any unused medicine to your pharmacist.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What MERCIDE contains

The name of your medicine is MERCIDE (also referred to as meropenem in this leaflet)

The active ingredient of MERCIDE is meropenem. Each vial of MERCIDE 500 contains 500 mg of meropenem. Each vial of MERCIDE 1 g contains 1 000 mg of meropenem.

MERCIDE 500 also contains 104 mg of sodium carbonate as buffer.

MERCIDE 1 g also contains 208 mg of sodium carbonate as buffer.

What MERCIDE looks like and the contents of the pack

MERCIDE 500

30 ml clear glass tubular vial with light grey Bromo-Butyl rubber plug and blue coloured flip off seal.

MERCIDE 1 g

40 ml clear glass tubular vial with light grey Bromo-Butyl rubber plug and red coloured flip off seal.

FOR DRY POWDER

White to pale yellow crystalline powder in clear glass vial sealed with grey rubber stopper and flip off seal.

FOR CONSTITUTED SOLUTION

Clear colourless to pale yellow coloured solution.

HOLDER OF CERTIFICATE OF REGISTRATION AND MANUFACTURER

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext. 1,

Roodepoort,

1724

THIS LEAFLET WAS LAST REVISED IN

06 July 2021

REGISTRATION NUMBER(S)

South africa:

Mercide 500: 43/20.1.1/0769

Mercide 1 g: 43/20.1.1/0770

Namibia:

Mercide 500: NS2 Reg.No.: 10/20.1.1/0461

Mercide 1 g: NS2 Reg.No.: 10/20.1.1/0462