PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MSD-ERTAPENEM™ Sterile Powder for Injection

Ertapenem sodium

Read all of this leaflet carefully before you are given MSD-ERTAPENEM.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MSD-ERTAPENEM 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 MSD-ERTAPENEM is and what it is used for
2. What you need to know before you are given MSD-ERTAPENEM
3. How to use MSD-ERTAPENEM
4. Possible side effects
5. How to store MSD-ERTAPENEM
6. Contents of the pack and other information

1. What MSD-ERTAPENEM is and what it is used for

MSD-ERTAPENEM contains ertapenem which is an antibiotic of the beta-lactam group. It has the ability to kill a wide range of bacteria (germs) that cause infections in various parts of the body.

MSD-ERTAPENEM can be given to persons 3 months of age and older.

MSD-ERTAPENEM is available as intramuscular and intravenous route of administration.

Your doctor has prescribed MSD-ERTAPENEM to treat your infections:

- Intra-abdominal Infection
- Skin Infection, including diabetic lower extremity and diabetic foot infections
- Community Acquired Pneumonia
- Urinary Tract Infection, including kidney infection
- Acute Pelvic Infection.

2. What you need to know before you are given MSD-ERTAPENEM

MSD-ERTAPENEM should not be given intravenously:

- if you or your child are allergic to any of its ingredients.
- if you or your child are allergic to beta-lactams, such as penicillins or cephalosporins.
- if you or your child have bacterial meningitis (infection and inflammation of the membranes and cerebrospinal fluid surrounding the brain and spinal cord).

MSD-ERTAPENEM should not be given intramuscularly:

- if you or your child are allergic to any of its ingredients.
- if you or your child are allergic to beta-lactams, such as penicillins or cephalosporins.
- if you or your child are allergic to local anaesthetics of the amide type, particularly lidocaine hydrochloride.
- if you or your child have bacterial meningitis (infection and inflammation of the membranes and cerebrospinal fluid surrounding the brain and spinal cord).

Warning and precautions

Tell your doctor or any other healthcare professional about any medical condition you or your child has now or has had, including:

- kidney disease
- allergies to any drugs, including antibiotics
- inflammation of the large bowel or any other gastrointestinal disease
- epilepsy.

Tell your doctor if you are taking a medicine containing valproic acid (used for epilepsy and depression).

Pregnancy and breastfeeding

MSD-ERTAPENEM has not been studied in pregnant women.

MSD-ERTAPENEM is secreted in human milk. Women who are receiving MSD-ERTAPENEM should not breastfeed their babies.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking MSD-ERTAPENEM.

Use in children

MSD-ERTAPENEM can be given to children 3 months of age and older. MSD-ERTAPENEM is not recommended in children under 3 months of age as no data are available.

Use in the elderly

The recommended dosage of MSD-ERTAPENEM can be administered without regard to age.

Other medicines and MSD-ERTAPENEM

In general, MSD-ERTAPENEM can be used with other medicine. You should tell your doctor about all medicine that you or your child is taking or plan to take, including those obtained without a prescription, as some medicine may affect each other's action.

Tell your doctor if you are taking a medicine containing valproic acid (used to treat epilepsy, bipolar disorder, migraine or schizophrenia). Your doctor will decide whether you should use MSD-ERTAPENEM in combination with this medicine.

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

Driving and using machinery

There is no information to suggest that MSD-ERTAPENEM affects the ability to drive or operate machinery.

3. How to use MSD-ERTAPENEM

MSD-ERTAPENEM may be infused into a vein (intravenous infusion) or injected into a muscle (intramuscular injection). When administered intravenously, MSD-ERTAPENEM should be infused over a period of 30 minutes.

MSD-ERTAPENEM will be given to you or your child by a medical practitioner or another healthcare professional who will determine the most appropriate method and dose.

It is very important that you or your child continues to receive MSD-ERTAPENEM for as long as your doctor prescribes it. Your doctor will let you or your child know when you may stop receiving MSD-ERTAPENEM.

If you are given more MSD-ERTAPENEM than you should

The injection schedule will be set by your doctor, who will monitor your response and condition to determine what treatment is needed. However, if you or your child is concerned that you may have been given too much MSD-ERTAPENEM, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Do not share medicines prescribed for you with others.

If you forget to use MSD-ERTAPENEM

The injection schedule will be set by your doctor, who will monitor your response and condition to determine what treatment is needed. However, if you or your child is concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MSD-ERTAPENEM may have side effects.

Not all side effects reported for MSD-ERTAPENEM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MSD-ERTAPENEM, please inform your doctor, pharmacist or other healthcare professional.

The common (more than 1 in 100) side effects in adults are:

- diarrhoea
- inflammation of the vein
- nausea

- headache.

Other side effects in adults include:

- irritation of the vein at the infusion site
- vomiting
- rash
- vaginitis
- dizziness
- sleepiness
- sleeplessness
- seizure
- confusion
- altered mental status (including agitation, aggression, delirium, disorientation, mental status changes)
- abnormal movements
- swelling at injection site
- low blood pressure
- shortness of breath
- oral thrush, constipation
- acid regurgitation
- dry mouth
- teeth staining
- indigestion
- loss of appetite

- skin redness
- itching
- hives
- severe allergic reactions (anaphylaxis)
- abdominal pain
- fungal infections
- abnormal taste
- fatigue
- swelling of the lower limbs
- feeling unwell
- fever
- pain
- chest pain
- vaginal itching
- alterations in some laboratory blood tests, and a combination of high fever, feeling unwell and skin rash.

Side effects in children are generally similar to those in adults. The most common side effects in children are diarrhoea, pain and redness at the infusion site.

Other side effects in children include:

- inflammation of the vein at the infusion site
- vomiting
- rash

- swelling
- formation of a lump itching and warmth at the infusion site
- inflammation of the vein and alterations in some laboratory blood tests.

If you experience raised or fluid-filled skin spots over a large area of your body, tell your doctor or nurse straight away.

Your doctor or healthcare professional has a more complete list. Tell your doctor or healthcare professional promptly about these or any other unusual symptoms.

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

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 MSD-ERTAPENEM.

5. How to store MSD-ERTAPENEM

Store the dry powder at or below 25 °C.

Please consult the professional information for information on storage periods for reconstituted solutions. Any unused portion of solutions of MSD-ERTAPENEM should be discarded.

Store all medicines out of reach of children.

Do not use this medicine after the month and year following EXP.: on the container.

Return all 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 MSD-ERTAPENEM contains

Each vial contains ertapenem sodium equivalent to 1 g of ertapenem free acid.

The other ingredients are sodium bicarbonate and sodium hydroxide.

What MSD-ERTAPENEM looks like and contents of the pack

MSD-ERTAPENEM is supplied in 15 mL glass vials fitted with grey stoppers and aluminium seals with caps. The labelled glass vials, embossed with the batch number and expiry date, are packed with leaflets into paperboard cartons. The cartons are also marked with both the batch number and expiry date.

MSD-ERTAPENEM Sterile Powder for Injection: solid, white to off-white essentially uniform cake.

MSD-ERTAPENEM Reconstituted Solution: the reconstituted solution ranges from colourless to pale yellow and is essentially free of visual foreign matter particles.

Holder of certificate of registration

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