PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CARPOREM 500 mg (Meropenem powder for injection)

CARPOREM 1000 mg

(Meropenem powder for injection)

Sugar free

Read all of this leaflet carefully before you are given CARPOREM.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **CARPOREM** 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 CARPOREM IS AND WHAT IS USED FOR

CARPOREM contains the active substance meropenem and belongs to a group of medicines called carbapenem antibiotics.

CARPOREM is indicated for single or multiple susceptible bacterial infections. **CARPOREM** is majorly used prior to determine the causative organisms of several infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CARPOREM

Do not take CARPOREM:

- If you have ever had an allergic reaction to **CARPOREM** or any ingredient of the **CARPOREM**.
- If you are hypersensitive to any beta-lactam antibiotics, carbapenems, penicillins or cephalosporins.
- If you are already taking probenecid (used to treat gout) because **CARPOREM** and probenecid are contraindicated.
- Oral anti-coagulant agent (used to treat or prevent blood clots).
- If you are taking valproates (used to treat epilepsy).
- If your baby's age is below 3 months.
- If you are breastfeeding to your baby.

Warnings and precautions

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

If you are suffering from kidney or liver problems.

If you have previously had severe diarrhoea after taking other antibiotics.

If you have any disorders like epilepsy (seizures).

If you have a condition which requires you to monitor your sodium intake, please inform your doctor or nurse.

Other medicines with CARPOREM:

CARPOREM may have an effect on other medicines or other medicines may have an effect on **CARPOREM**.

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

Pregnancy and breastfeeding:

CARPOREM is not recommended during pregnancy or breastfeeding.

If your pregnant or breast feeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **CARPOREM**.

Driving and using machinery:

No studies on the effect on the ability to drive and use machines have been performed. However, when driving or operating machines, it should be taken into account that headache, tingling or pricing skin (paraesthesia) and convulsions that are usually accompanied with a loss of consciousness, and any of these could affect your ability to drive or operate machines.

CARPOREM contains sodium:

This medicinal product contains 104 mg and 208 mg sodium per dose in the 500 mg and 1000 mg respectively, equivalent to 5.2 % and 10.4 % respectively of the recommended maximum daily intake of 2 g sodium for an adult. If you have a condition which requires you to monitor your sodium intake please inform your doctor or healthcare professional.

HOW TO BE GIVEN CARPOREM

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

Use in Adults

• The dose depends 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 (milligrams) and 2000 mg (milligram). You will usually receive a dose 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 **CARPOREM** 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.

3. How to use CARPOREM

• **CARPOREM** will be given to you as an injection or infusion into a large vein.

• Your doctor or nurse will normally give **CARPOREM** to you.

Your doctor will tell you how long your treatment with **CARPOREM** will last. Do not stop treatment early because this may reoccurrence of your condition. If you have the impression that the effect of **CARPOREM** is too strong or too weak, tell your doctor or pharmacist.

If you take more CARPOREM than you should:

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

If you forget to take CARPOREM:

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

4. POSSIBILE SIDE EFFECTS

CARPOREM can have side effects:

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

- inflammation at site of injection,
- Skin rash and itching or hives on the skin,
- Shortness of breath, wheezing or trouble breathing.

These all are very serious side effects. If you have them, you may have had a serious allergic reaction to **CARPOREM**. You may need urgent medical attention or hospitalization.

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

- swelling of the face, lips, tongue or other parts of the body (angioedema).

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

The following side effects occur frequently:

- anemia (deficiency of red blood cells),
- gastrointestinal disturbances,
- Pain.

The following side effects occur less frequently:

- sepsis (presence of pus-forming bacteria or their toxins in the blood or tissues),
- thrombophlebitis (conjunction with the formation of a blood clot in the vein),
- bleeding events,
- hemoperitoneum (presence of blood in the peritoneal cavity),
- hypoglycaemia (abnormally low blood sugar),
- pruritus (an intense itching sensation),
- skin discolouration,
- Skin ulceration.

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

Tell your doctor if you notice any of the following:

The following side effects occur frequently:

- thrombocytopenia (abnormally small number of platelets in the blood),
- headache
- diarrhoea (frequent and watery bowel movements) moderate or severe,
- vomiting
- nausea
- rash,
- pain,
- itching skin
- inflammation of the skin,
- Increased blood alkaline phosphate
- hives,
- a condition called Stevens Johnson syndrome or toxic epidermal necrolysis

The following side effects occur less frequently:

- lymphopenia (an abnormally small number of lymphocytes in the circulating blood),
- neutropenia (decrease is primarily in number of neutrophils),
- oral fungal infection
- paresthesia (abnormal skin sensations),

- phlebitis (inflammation of a vein (usually in the legs)),
- infection
- hyperbilirubinemia (high amounts of bile pigment (bilirubin) in the blood),
- blood creatinine and urea levels increased
- thrombophlebitis (conjunction with the formation of a blood clot),

The following side effects frequency cannot be determined:

- eosinophilia (increase in number of eosinophils-type of white blood cells)
- seizers

Not all side effects reported for **CARPOREM** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: http:///www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CARPOREM.**

5. HOW TO STORE CARPOREM

Store at or below 25 °C.

Keep the vial in the carton until required for use.

Store the vials out of reach of children.

Do not use **CARPOREM** if you observe any discolouration upon storage.

Do not freeze the reconstituted solution.

Do not use **CARPOREM** after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 CARPOREM contains

The other ingredients of **CARPOREM** are sodium carbonate as a solubilizer and buffering agent.

What CARPOREM looks like and contents of the pack

CARPOREM 500 mg:

Powder for injection is filled in 30 ml clear glass tubular vial type-I stoppered with grey rubber stoppers and sealed with aluminium seal having taxim blue colour PP disc.

Pack size: 1's: Printed cardboard carton containing one vial only.

CARPOREM 1000 mg:

Powder for injection is filled in 40 ml clear glass tubular vial type-I stoppered with grey rubber stoppers and sealed with aluminium seal having white colour PP disc.

Pack size: 1's: Printed cardboard carton containing one vial only.

Holder of Registration

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Access to the corresponding Professional Information

The professional information will be printed and supplied with the vial.