Adcock Ingram Critical Care (Pty) Ltd.
Email: Aicc.RegulatoryAffairs@adcock.com
18 June 2025

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ADCO MEROPENEM 500 mg IV (powder for solution for Intravenous injection)

ADCO MEROPENEM 1 000 mg IV (powder for solution for Intravenous injection)

(Meropenem)

Sugar free

Read all of this leaflet carefully before you are given ADCO MEROPENEM

- **Keep this leaflet. You may need to read it again.**
- **If you have further question, please ask your doctor or your pharmacist.**

What is in this leaflet

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

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1. What ADCO MEROPENEM is and what it is used for

ADCO MEROPENEM is used for the treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem and as therapy prior to the identification of the causative organism.

- Intra-abdominal infections
- Meningitis
- Respiratory tract infections (including cystic fibrosis patients)
- Septicaemia
- Skin infections
- Urinary tract infections

2. What you need to know before you use ADCO MEROPENEM

ADCO MEROPENEM should not be administered to you:

- If you are hypersensitive (allergic) to **meropenem,** or any of the other ingredients of ADCO MEROPENEM (listed in section 6)
- If you are hypersensitive (allergic) to any antibiotics related to meropenem

Therefore, you should tell your doctor if you have ever had any unusual or allergic reaction to carbepenems, penicillins, or other beta-lactam antibiotics.

Hypersensitivity (allergic) reactions have been reported with **ADCO MEROPENEM**. Also tell your healthcare professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

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Warnings and precautions:

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

- 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.

Children: Efficacy and tolerability in infants under 3 months old have not been established, therefore **ADCO MEROPENEM** is not recommended for use below this age.

Other medicines and ADCO MEROPENEM

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Certain medicines should not be used together. In these cases, your doctor may want to change the dose, or other precautions may be necessary. It is important that your healthcare professional knows if you are taking any other medications.

Tell your healthcare professional if you are taking any of the following:

- If you are already taking Probenecid (used to treat gout) because meropenem and probenecid are contraindicated.
- Oral anti-coagulant medicines (used to treat or prevent blood clots).
- If you are taking valproates (used to treat epilepsy).

Pregnancy and breastfeeding:

The safety of **ADCO MEROPENEM** in human pregnancy has not been established. **ADCO MEROPENEM** is detectable at very low concentrations in animal breast milk. It is not known whether **ADCO MEROPENEM** is distributed into human breast milk and therefore should not be used in breast-feeding.

If you are pregnant or breast feeding your baby please consult your health care provider for advice before taking this medicine

Geriatrics: Elderly patients are more likely to have an age-related decrease in renal function, which may require a reduction in dosage in these patients.

Driving and using machinery:

ADCO MEROPENEM is not known to interfere with your ability to drive and operate machinery.

ADCO MEROPENEM contains sodium

ADCO MEROPENEM 500 mg IV contains 45 mg sodium (main component of cooking/table salt) in each 500 mg dose. This is equivalent to 2,25 % of the recommended maximum daily dietary intake of sodium for an adult.

ADCO MEROPENEM 1 000 mg IV contains 90 mg sodium (main component of cooking/table salt) in each 1 000 mg dose. This is equivalent to 4,5 % of the recommended maximum daily dietary intake of sodium for an adult.

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3. How ADCO MEROPENEM is administered

You will not be expected to give yourself ADCO MEROPENEM. It will given to you by a person who is qualified to do so, by intravenous injection or infusion. The dose will be decided by your doctor depending on the severity of your condition.

If you receive more ADCO MEROPENEM than you should:

Since a healthcare professional will administer **ADCO MEROPENEM** he/she will control the dosage. However, in the event of an overdosage, your doctor will manage the overdosage.

4. Possible side effects

ADCO MEROPENEM can have side effects.

Not all side effects reported for **ADCO MEROPENEM** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ADCO MEROPENEM,** please consult your healthcare provider for advice.

If you experience any of the following side effects, consult with your doctor or healthcare professional immediately:

- Swelling of the face, lips, tongue and other parts of the body
- Shortness of breath and/or difficulty breathing
- Severe headaches and fits
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

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

The following side effects occur frequently:

- anaemia (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
- haemoperitoneum (presence of blood in the peritoneal cavity)
- hypoglycaemia (abnormally low blood sugar)
- pruritus (an intense itching sensation)
- skin discolouration
- skin ulceration.

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:

- 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, rash
- inflammation of the skin
- increased blood alkaline phosphate
- hives
- a condition called Stevens Johnson syndrome or toxic epidermal necrolysis
- phlebitis (inflammation of a vein (usually in the legs))
- infection
- hyperbilirubinaemia (high amounts of bile pigment (bilirubin) in the blood),
- blood creatinine and urea levels increased
- thrombophlebitis (conjunction with the formation of a blood clot).

Tell your doctor if you notice any of the following:

- feeling weak, trembling and headache (feeling hungry)
- redness, swelling and pain at the site of injection
- severe, bloody, black or watery stools and/or diarrhoea
- constipation, abdominal or stomach cramps and pain
- nausea and vomiting and/or black vomit

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- severe skin rash and itching
- nose bleeds
- red or brown urine
- increase in blood platelets (shown by blood tests)

The following side effects frequency cannot be determined:

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

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
- paraesthesia (abnormal skin sensations).

Consult with your doctor or healthcare professional, should you experience any side-effects even if they are not listed above.

Reporting of side effects

If you get side effects, talk to your doctor. You also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **ADCO MEROPENEM.**

5. How to store ADCO MEROPENEM

Store all medicines out of reach of children.

ADCO MEROPENEM powder vials should be stored in a cool dry place at or below 25 °C

Do not use ADCO MEROPENEM if you noticed any discolouration.

6. Contents of the pack and other information

What ADCO MEROPENEM contains:

ADCO MEROPENEM 500 mg IV:

Each vial contains meropenem trihydrate equivalent to 500 mg meropenem.

Excipient: Sodium carbonate

ADCO MEROPENEM 1 000 mg IV:

Each vial contains meropenem trihydrate equivalent to 1 000 mg meropenem.

Excipient: Sodium carbonate

What ADCO MEROPENEM looks like and contents of the pack

ADCO MEROPENEM 500 mg IV: White to light yellow powder for injection. A 20 ml uncoloured, type III glass vial, sealed with a rubber stopper and packed in a printed carbon box.

ADCO MEROPENEM 1000 mg IV: White to light yellow powder for injection. A 20 ml uncoloured, type III glass vial, sealed with a rubber stopper and packed in a printed carbon box.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd

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Johannesburg

2013

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Registration numbers:

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ADCO MEROPENEM 1000 mg IV: 44/20.1.1/0303

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