

Patient Information Leaflet

MERONIA®500 IV

Meropenem 500 mg, Powder for solution for injection or for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. If you have questions or you notice side effects not mentioned in this leaflet, contact your doctor or your healthcare professional. Do not pass this medicine on to others.

1. What Meronia® is and what it is used for

Meronia® (meropenem) is an antibiotic belonging to the group of carbapenems. It works by killing bacteria which can cause serious infections and is used to treat adults and children aged 3 months and older.

- Infections of the lungs
- Lung and bronchial infections when suffering from cystic fibrosis
- Complicated urinary tract infections
- Complicated infections of the abdomen
- Infections that you can catch during or after the delivery
- Complicated skin and soft tissues infections
- Acute bacterial infection of the brain

Meronia can also be used in the management of certain blood diseases that suspected to be due to bacterial infection.

2. What you need to know before you use Meronia®

Meronia® should not be given to you if you are

- allergic (hypersensitive) to meropenem or to any other ingredient of this medicine listed in section 6.
- Allergic (hypersensitive) to other antibiotics such as penicillins, cephalosporins, or carbapenems

Warnings and precautions

Before receiving Meronia®

Your doctor must be well informed and take into account your medical history and your health condition .

During treatment with Meronia®

If you experience signs and symptoms of a severe skin reaction, talk to your doctor or nurse immediately so they can treat the symptoms.

Other medicines and Meronia®

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines without a prescription.

In particular:

- Probenecid (to treat gout)
- Valproic acid/sodium valproate/valpromide (tot treat epilepsy)
- Oral anti-coagulants (to treat or prevent blood clots)

Pregnancy and breast-feeding

If you think you might be pregnant, or are planning to get pregnant or if you are breast-feeding, you must tell your doctor that you are taking medicines.

Your doctor will decide whether or not you should be given this medicine.

Driving and using machines

Meropenem has been associated with headache and tingling and pricking skin. Any of these side effects could affect your ability to drive or use machines.

Important information about some ingredients of Meronia® 500 IV

Meronia 500 mg powder contains 45 mg of sodium. If you have a condition which requires you to monitor your sodium intake, inform your doctor or nurse.

3. How to use Meronia® 500 IV

Always use this medicine exactly as your doctor or health care provider has told you.

Your doctor will decide on the dose that you need.

The usual dose for adults is 500 mg to 2000 mg. Usually you will receive a dose every 8 hours.

The solution of Meronia will be prepared and administered by your doctor or nurse as an injection or an infusion into a large vein. The injection may take about 5 minutes (injection) or 15 to 30 minutes (infusion).

Use in children

The usual dose in 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 meropenem for each kilogram that the child weighs and is given every 8 hours.

Children weighing above 50 kg will be given an adult dose.

If you have kidney problems

You may receive your dose less often.

If you stop taking Meronia®

Your doctor will advise you how long you should receive this medicine.

If you have any further question on the use of this medicine, ask your doctor, pharmacist, health care provider.

4. Possible side effects

Like all medicines, Meronia can cause side effects, although not everybody gets them.

Severe allergic reactions

If you experience any of the following symptoms, **tell your doctor or nurse immediately**. You may need urgent medical treatment.

- Severe rash, itching or hives on the skin
- Swelling of the face, lips, tongue or other parts of the body
- Wheezing or troubles breathing
- A serious life-threatening skin rash, in form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals (Stevens-Johnson syndrome or Lyell syndrome)
- A drug reaction called DRESS (rash, fever, inflammation internal organs, blood abnormalities)

Other side effects by frequency of appearing

- **Common** : abdominal pain, feeling sick, vomiting ,diarrhoea, headache, shin rash, itchy skin, pain and inflammation, increased number of blood platelets
- **Uncommon**: Changes in blood parameters, tingling feeling, infection of the mouth or the vagina, inflammation of the bowl with diarrhoea, sore vein on the injection site.
- **Rare**: convulsions, acute disorientation and confusion
- **Not known**: damage to red blood cells (being unexpectedly breathless; red or brown urine)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or health care provider.

5. How to store Meronia® 500 IV

Keep out of the reach and sight of children.

Store below 30°C .

Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

The reconstituted solutions for intravenous use by injection or for infusion should be used immediately. If not used immediately in-use storage times and conditions are the responsibility of the user.

Do not freeze the reconstituted solution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and further information

What Meronia® 500 IV contains

The active substance is meropenem (meropenem trihydrate equivalent to 500 mg meropenem).

The other ingredient is sodium carbonate.

What Meronia® 500 IV looks like and content of the pack

White to light yellow powder.

Meronia 500 IV powder is packed in transparent glass vial (sterile product).

Bow with one vial.

Meronia® 500 IV is a prescription medicine.

Manufacturer

Anfarm Hellas S.A

61st km. Nat. Rd. Athens, Lamia, Schimatari Viotias, 32009, Greece

Marketing Authorisation Holder

Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

Date of revision of the leaflet

06/2021