

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

TIENAM® 500 Sterile Powder for Injection

TIENAM® MONO 500 Sterile Powder for Injection (Dose Not Marketed)

(imipenem and cilastatin sodium, MSD)

Read all of this leaflet carefully before you start receiving TIENAM.

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

TIENAM 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

1. WHAT TIENAM CONTAINS

TIENAM is an antibiotic, in the form of a dry powder blend to be mixed with a suitable diluent for injection into a vein. It contains imipenem and cilastatin sodium as the active ingredients in a 1:1 ratio by weight.

In addition, TIENAM contains the following inactive ingredients: Sterile Sodium Bicarbonate and Nitrogen.

2. WHAT TIENAM IS USED FOR

TIENAM belongs to a class of antibiotics, the thienamycins, and has the ability to kill a broad spectrum of bacteria that cause infections.

TIENAM may be administered for the treatment of the following infections:

Intra-abdominal infections

Lower respiratory tract infections

Gynaecological infections

Septicemia (bacterial infection of the blood)

Genitourinary tract infections

Bone and joint infections

Skin and soft tissue infections

Endocarditis (bacterial infection of the lining of the heart cavity and valves)

Prevention of certain post-operative infections

TIENAM is indicated for the treatment of mixed infections caused by susceptible strains of bacteria. The majority of these mixed infections are associated with contamination by faecal flora or flora originating

from the vagina, skin, or mouth. TIENAM also has demonstrated efficacy against many infections caused by bacteria resistant to some other antibiotics.

You may obtain further information from your doctor or other healthcare professionals who have more detailed information about TIENAM and your condition.

3. BEFORE YOU RECEIVE TIENAM

Do not receive TIENAM:

if you are allergic to imipenem and cilastatin sodium or any of the other ingredients in TIENAM

if you have meningitis

if you are pregnant or breastfeeding

Take special care with TIENAM:

Tell your doctor or other healthcare professional about any medical condition you have or have had including:

allergies to any drugs, including antibiotics

colitis or any other gastro-intestinal disease

suspected pregnancy

any central nervous system disorders, such as localised tremors, or seizures

kidney or urinary problems

Tell your doctor if you are taking a medicine containing valproic acid.

Use in children:

TIENAM is not recommended for the treatment of meningitis.

TIENAM should not be used in infants less than 3 months of age or paediatric patients with kidney problems.

Pregnancy and Breast-feeding:

Use in Pregnancy

TIENAM should not be used in pregnant women. You should tell your doctor if you think you are pregnant or plan to become pregnant (see **Do not receive TIENAM** and **Take special care with TIENAM**)

Use in Breast-feeding

TIENAM is secreted in human milk. As the breast-fed baby may be affected, women who are receiving TIENAM should not breast-feed. If you intend to breast-feed, talk to your doctor.

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Use in patients with kidney disease:

To prescribe the correct dose of TIENAM, your doctor needs to know if you have kidney disease.

Driving and using machinery:

There are some side effects associated with this product that may affect your ability to drive a car or operate machinery (see **POSSIBLE SIDE-EFFECTS**)

Taking other medicines with TIENAM:

You should always tell your doctor about all the medicines that you are taking or plan to take, including those obtained without a prescription.

Tell your doctor if you are taking ganciclovir which is used to treat some viral infections.

Also, 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 TIENAM in combination with these medicines.

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

4. HOW TIENAM IS GIVEN

TIENAM may be injected into a vein (intravenous injection). TIENAM must not be taken by mouth.

How much TIENAM should I receive?

TIENAM will be given to you by a physician or another healthcare professional who will determine the most appropriate method and dose. The number, type of injection and amount in each injection that you require will depend upon your condition and the severity of your infection.

How long do I need to receive TIENAM?

It is very important that you continue to receive TIENAM for as long as your doctor prescribes it.

Your doctor will let you know when you may stop receiving TIENAM.

If you receive more TIENAM 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 are concerned that you may have been given too much TIENAM, contact your doctor or another healthcare professional immediately.

If you missed a dose of TIENAM:

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 are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

5. POSSIBLE SIDE EFFECTS

Any medicine may have unintended or undesirable effects, so-called side effects, some of which may be serious. The most common side effects are pain, skin redness and tenderness at the injection site or along a blood vessel in the area.

Other side effects include: nausea, vomiting, diarrhoea, rash, itching, fever, hearing loss, taste perversion, jaundice (yellowing of the skin and eyes), hepatitis (inflammation of the liver) and kidney dysfunction; blood disorders affecting the components of the blood and usually detected by blood tests (symptoms may be tiredness, paleness of skin, and prolonged bruising after injury).

Additional side effects such as, psychic disturbances (such as mood swings and impaired judgment), hallucinations, confusional states, encephalopathy (irritation to the brain), abnormal movements and agitation. Seizures have been reported.

A few people may be allergic to TIENAM, and may have some of the following symptoms: swelling of the face, lips, tongue and/or throat (with difficulty in breathing or swallowing); hives; or severe skin reactions (rare reports). If these side effects occur while receiving or after receiving TIENAM, the medicine must be stopped and your doctor contacted immediately.

Other side effects may also occur rarely and as with any prescription medicine, some side effects may be serious. Ask your doctor or other healthcare professional for more information. Both have a more complete list of side effects.

Tell your doctor or another healthcare professional promptly about these or any other unusual symptoms.

Not all side-effects reported for this medicine 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 health care professional for advice.

6. STORING AND DISPOSING OF TIENAM

Store the dry powder below 25°C and protect from light. Protect from freezing.

Please consult the package insert for information on storage periods for reconstituted solutions.

Keep all medicines out of reach and sight of children

Do not use after the expiry date stated on the container.

Do not dispose of unused medicines in the drains or sewage systems (e.g. toilets)

7. PRESENTATION OF TIENAM

TIENAM 500 is supplied in 20 ml glass vials, packed in 1's.

TIENAM MONO 500 is supplied in 22 ml glass vials with attached needle transfer sets. **(Dose not marketed)**

8. IDENTIFICATION OF TIENAM

TIENAM 500:	A white to light yellow powder.
TIENAM 500 reconstituted solution:	A clear, colourless pale to yellow solution.
TIENAM MONO 500:	White to light yellow powder (Dose Not Marketed)
TIENAM MONO 500 reconstituted solution:	A clear, colourless pale to yellow solution (Dose Not Marketed)

9. REGISTRATION NUMBER

TIENAM 500	:	S/20.1.1/175
TIENAM MONO 500	:	31/20.1.1/0693 (Dose Not Marketed)

10. NAME AND ADDRESS OF REGISTRATION HOLDER

MSD (PTY) LTD
16th Road
Halfway House
1685
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11. DATE OF PUBLICATION

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