PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using Cefazolin Oethmaan powder for injection.

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

Scheduling status: **S4**

Proprietary name, strength and pharmaceutical form:

Cefazolin Oethmaan 500 mg Powder for injection (each 500 mg vial contains cefazolin sodium equivalent to 500 mg cefazolin).

Cefazolin Oethmaan 1 g Powder for injection (each 1 g vial contains cefazolin sodium equivalent to 1 g cefazolin).

The sodium content is 48,3 mg/g of cefazolin sodium. The pH of the reconstituted solution is between 4,0 and 6,0.

1. What Cefazolin Oethmaan contains:

Active ingredient: Cefazolin

Inactive ingredients: None

2. What Cefazolin Oethmaan is used for:

The active ingredient, cefazolin, is a cephalosporin antibiotic. It destroys bacteria of many different species by disrupting their cell wall structure.

CEFAZOLIN OETHMAAN is indicated in the treatment of the following infections:

- Respiratory tract infections.
- Urinary tract and genital infections.
- Skin and skin structure infections.
- Bone and joint infections.
- Septicaemia (infection characterised by bacteria and toxins in the blood)
- Endocarditis (bacterial infection affecting the heart)

CEFAZOLIN OETHMAAN may also help to prevent wound infections after an abdominal hysterectomy.

3. Before you use Cefazolin Oethmaan:

Do not use Cefazolin Oethmaan:

- If you are hypersensitive (allergic) to cefazolin or to the cephalosporin group of antibiotics or other beta-lactam group of antibiotics, e.g. penicillins.

Take special care with Cefazolin Oethmaan:

Tell your doctor:

- If you are allergic to penicillin antibiotic or previously had a hypersensitivity (allergy) reaction to a cephalosporin or penicillin antibiotic. If you are allergic to penicillin, you may also be allergic to CEFAZOLIN OETHMAAN.
- If you develop severe, persistent diarrhoea while on CEFAZOLIN OETHMAAN treatment. Your doctor may decide to discontinue the treatment.
- If you have existing medical diseases including kidney or liver problems and gastrointestinal diseases.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice. The safety of CEFAZOLIN OETHMAAN in pregnant and breastfeeding women has not yet been established.

Driving and using machinery:

You should refrain from driving or using machinery until you know how this medicine affects your ability to concentrate.

Using other medicines with Cefazolin Oethmaan:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CEFAZOLIN OETHMAAN with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Co-administration of CEFAZOLIN OETHMAAN and probenecid may increase the plasma levels of CEFAZOLIN OETHMAAN.

Concomitant use of alcohol may result in disulfiram-like effects such as stomach cramps, facial flushing, headache, hypotension, nausea, irregular or fast heartbeat, shortness of breath, sweating, or vomiting.

CEFAZOLIN OETHMAAN may possibly enhance the effects of warfarin and increase the risk of bleeding.

4. How to use Cefazolin Oethmaan:

CEFAZOLIN OETHMAAN is an injection which will be administered to you by your doctor. This injection can be administered directly into your vein or muscle. Your doctor may also mix CEFAZOLIN OETHMAAN with other intravenous solutions and administer it as an intravenous infusion.

If you have the impression that the effect of CEFAZOLIN OETHMAAN is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will decide on the appropriate dose based on:

- the bacteria that caused the infection;

- the seriousness of the infection;
- your weight (children);
- whether or not you have impairment of your kidney function.

If you take more Cefazolin Oethmaan than you should:

Since your doctor will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will treat the side effects symptomatically.

5. Side effects:

CEFAZOLIN OETHMAAN can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor or pharmacist for advice.

You may experience headache, dizziness, stomach cramps, diarrhoea, nausea, vomiting and indigestion. Some patients may also experience skin rashes, itchy skin or hives, and pain at the injection site.

The use of CEFAZOLIN OETHMAAN may lead to the overgrowth of organisms that are not susceptible to cefazolin. These organisms may cause vaginal infections, oral thrush, and itchiness around the anus area.

Notify your doctor immediately if you experience any of the following side effects:

- Skin rashes, skin itching and redness, hives, fever, swelling of the face and tongue, difficulty in breathing, sore throat, sores on your lips and mouth.
- Severe stomach pain, watery and severe diarrhoea.

6. Storing and disposing of Cefazolin Oethmaan:

- Store the dry powder below 25 °C.

- Reconstituted CEFAZOLIN OETHMAAN is stable for 24 hours when stored at 2 to 8 °C. Any unused solution should be discarded.
- KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.
- Do not use the product after the expiry date printed on the vials.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. Presentation of Cefazolin Oethmaan:

Cefazolin Oethmaan 500 mg and 1 g Powder for injection vials are supplied in cartons containing 10 vials.

8. Identification of Cefazolin Oethmaan:

Cefazolin Oethmaan 500 mg Powder for injection vial is sealed with a rubber stopper and an aluminium cap. It contains sterile powder for injection.

Cefazolin Oethmaan 1 g Powder for injection vial is sealed with a rubber stopper and an aluminium cap. It contains sterile powder for injection.

9. Registration number:

Cefazolin 500 mg Oethmaan Powder for injection: 31/20.1.1/0675

Cefazolin 1 g Oethmaan Powder for injection: 31/20.1.1/0676

10. Name and address of registration holder:

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2195

11. Date of publication

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