CEFTAZIM® 0,5 g & 1 g

Ceftazidime

PRESENTATION:

- Powder for injection for children (IM, IV) containing 500 mg ceftazidime: vials of powder, unitary packaging.
- Powder for injection (IM, IV) containing 1g ceftazidime: vials of powder, unitary packaging.

COMPOSTION:

CEFTAZIM 0.5 g:

Ceftazidime ……500 mg
Sodium Carbonate …… 9 %

CEFTAZIM 1g:

Ceftazidime ……1 g
Sodium Carbonate ……9 %

PHARMACOLOGY:

Ceftazidime is a bacterial cephalosporin antibiotic third generation.

INDICATIONS:

They are limited to severe infections due to germs sensitive to ceftazidime including meningitis particularly due to pseudomonas, but excluding those due to Listeria monocytogenes.

CONTRAINDICATIONS:

Hypersensitivity to beta lactamin antibiotics (penicillins cephalosporins).

PRECAUTION OF USE:

- During meningitis treatment, it is necessary to control the product activity by dosage in the cephalo-rachidien liquid, to compare the results with MIC range of the isolated germ and to study the bactericide power of the cephalo-rachidian fluid.
- In case of renal impairment, adapt the posology in function of the creatinine clearance (see Posology & administration) to avoid clinical repercussions due to elevated rates of antibiotics, for exemple: convulsions.
- Ceftazidime does not induce antabuse effect.
- It is advisable to supervise the renal function in case of association with potentially nephrotoxic antibiotics (particularly aminosides) or with diuretics such as furosemide.
-Take into account the content of sodium for patients following a strict hyponatraemic diet. The amount of sodium is equal to 53 mg/g of ceftazidime

WARNINGS:

- The occurring of any allergic manifestations imposes the interruption of treatment.
- The prescription of cephalosporin necessitates a previous questionning.
- The selection of resistant germs during treatment has been noted, particularly for Pseudomonas aeruginosa or certain enterobaters such as Enterobacter cloacae.

SIDE EFFECTS

- Hypersensitivity: maculopapular or urticarial rash, fever, pruritus.
- Gastsrointestinal: nausea, vomiting, diarrhoea, colitis.
- Transient Haematological manifestations: hypereosinophilia.
- Urinary and hepatic manifestations: moderate and transient elevation of hepatic enzymes, LDH, GGT, alkaline phosphatases.
- Nephrotoxicity: especially when treatment is associated to aminosides and strong diuretics.
- Other manifestation: candidiasis, vaginitis, headache, dizziness.
- Local: pain and/or inflammation after IM injection.
- Report to your physician or pharmacist any side effect not mentioned in this insert.

PREGNANCY & LACTATION:

The use of CEFTAZIM should be considered during pregnancy only if necessary.
Ceftazidime is excreted in human milk; consequently caution should be exercised when ceftazidime is administered to a nursing mother.

POSOLOGY & ADMINSTRATION:

Posology:

• Adult:

3g / day on average (1 g every 8 hours) by intermittent administration. This posology can be increased in function of the severity of the infection.

• Infants & children:

50 mg / kg / day on average by intermittent administration.

• Neonates:

25 to 50 mg / kg / day by intermittent administration.
This posology has to reach 100 mg to 200 mg /kg /day in case of meningitis, respiratory infections due to pseudomonas and in case of medular aplasia in intermittent administration.

• Renal impairment:

For patients with renal failure, the dosage by intermittent administration should be adapted following the clearance of creatinine.

Administration:

IM or IV route (500 mg, 1 g vials): it is recommended to dilute CEFTAZIM with water for injection :
2 ml by vial of 500 mg;
3 ml by vial of 1g.
IV infusion:
25 ml for 1 g of ceftazidime;

**** Modality of manipulation:***

Reconstitution:

During the dissolution of the powder, a gaz emission is produced. For a good utilization, it is adviced to adopt the following technic of reconstitution :
1- Drive in the needle of the syringe in the stopper of the bottle and inject the recommended of volume solvent. The vacuum can facilitate the entrance of the solvent. Let the needle and the syringe in position until feeling an ascent of the piston.
2- Withdraw the needle of the stopper.
3- Shake well to dissolve until obtaining a clear solution (1 to 2 minutes).
4- Reverse the bottle. Be sure that the piston of the syringe is to tip of race, then insert the needle through the stopper of the bottle.
5- Check that the needle is immersed in the solution and not in the empty space. Suckup the total volume of the solution in the syringe according to the classic diagram and maintaining the piston. The pressure in the bottle should help the prelevment.
6- Solution can contain small bubbles of carbon dioxide, do not take into account of it.
Compatibilitis : this medicine is compatible with solutions for the following IV administration :

- sodium chloride at 0,9 %,
- glucose solution 5 %,
- glucose solution 10 %,
- solution of chloride sodium 0,9 %+glucose solution 5 %,
- ringer solution,
- ringer-lactate solution,
- solution of intrapéritoneale dialysis (lactate) 1,36 %.

No incompatibility has been observed with the following molecules and solutions :

- fluoroquinolones (ciprofloxacine, ofloxacine) ;
- amphotéricine B ;
- fluconazole ;
- foscarnet ;
- lipidic solution ;
- glucose solution at 30 % ;
- amino-acid solutions ;
- chloride of potassium, chloride of calcium ;
- gluconate of calcium.

For continuous administration, when associating with anticancerous chemotherapy, use a different way of administration than the one used for the ceftazidime because of the risk of formation of insoluble compounds.

INTERACTIONS:

To avoid possible interactions with other drugs, report systematically to your physician any concomitant treatment.

STORAGE CONDITIONS:

Store below 25°C and protect from light.
The reconstituted solution may be conserved 24 hours at a temperature below 25°C.

List I

MA: 909 356 1H (CEFTAZIM® 0,5 g)
909 356 2H (CEFTAZIM® 1 g)

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption to instruction is dangerous for you.
- Follow strictly the doctor's prescription, method of use and the instructions of pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period treatment prescribed of you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children.

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