CEFTAZIDIME NORMON 500 mg POWDER AND SOLVENT FOR INJECTABLE SOLUTION

CEFTAZIDIME NORMON 1 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION

CEFTAZIDIME NORMON 1 g POWDER FOR PERFUSION

CEFTAZIDIME NORMON 2 g POWDER FOR PERFUSION

The drug substance in ceftazidime.

CEFTAZIDIME NORMON 500 mg POWDER AND SOLVENT FOR INJECTABLE SOLUTION: Each package contains 1 vial with 500 mg of ceftazidime (pentahydrate) buffered with sodium carbonate and an ampoule with 5 ml of water for injection.

CEFTAZIDIME NORMON 1 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION: Each package contains 1 vial with 1 gram of ceftazidime (pentahydrate) buffered with sodium carbonate and an ampoule with 10 ml of water for injection.

CEFTAZIDIME NORMON 1 g POWDER FOR PERFUSION: Each package contains 1 vial with 1 gram of ceftazidime (pentahydrate) buffered with sodium carbonate.

CEFTAZIDIME NORMON 2 g POWDER FOR PERFUSION: Each package contains 1 vial with 2 gram of ceftazidime (pentahydrate) buffered with sodium carbonate.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER
LABORATORIOS NORMON, S.A.
Ronda de Valdecarrizo, 6 - 28760 MADRID, (SPAIN)

1. WHAT CEFTAZIDIME NORMON IS AND WHAT IT IS USED FOR

CEFTAZIDIME NORMON contains the drug substance ceftazidime (pentahydrate) buffered with sodium carbonate. It is an antibiotic of the cephalosporin group.

This drug is for diagnostic use only. Always under medical prescription, this drug is indicated for the treatment of severe, simple or mixed bacterial infections, caused by sensitive organisms.

The indications include:

- Severe infections, e.g. septicaemia, infections in immunodepressed patients.
- Infections of the lower airways.
- Infections of the urinary tracts.
- Intra-abdominal infections, including peritonitis and infections of the bile duct.
- Gynaecological infections.
- Skin and soft tissue infections.
- Bone and joint infections.

2. BEFORE USING CEFTAZIDIME NORMON

- **Do not use CEFTAZIDIME NORMON** if you are allergic to cephalosporins.
- **Take special care with CEFTAZIDIME NORMON:**

- If you are allergic to cephalosporins, you should not use CEFTAZIDIME NORMON. Tell your doctor if you are allergic or have had a reaction to penicillin, other antibiotics or other drugs.
- If an allergic reaction occurs, stop treatment immediately and consult your doctor.
- When there is alteration to kidney function; in this case, the dose should be adjusted in accordance with the degree of kidney alteration.
- If CEFTAZIDIME NORMON is to be used for prolonged periods of time, over-infections by non-susceptible organisms (*Candida, Enterococcus*) may occur and it may be necessary to stop treatment.

- **Pregnancy:** consult your doctor or pharmacist before using any medicinal product.
- **Breastfeeding:** consult your doctor or pharmacist before using any medicinal product.
- **Driving and operating machinery:** None have been described.
- **Important information about some of the ingredients of CEFTAZIDIME NORMON:**

CEFTAZIDIME NORMON 500 mg POWDER AND SOLVENT FOR INJECTABLE SOLUTION, CEFTAZIDIME NORMON 1 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION, CEFTAZIDIME NORMON 1 g POWDER FOR PERFUSION and CEFTAZIDIME NORMON 2 g POWDER FOR PERFUSION contain, respectively, 25, 50, 50 and 100 mg of sodium per vial, which could be harmful with patients on low sodium diets.

- **Taking or using other medicine:**

Inform your doctor or pharmacist if you are taking, or have recently taken, any other medicinal product, including products not subject to medical prescription.

Some drugs (such as aminoglycoside antibiotics or diuretics, such as furosemide) may harm your kidneys when administered with high doses of cephalosporins. This problem is unlikely to occur with ceftazidime if your doctor prescribes the appropriate doses.

CEFTAZIDIME NORMON should not be mixed in the same syringe as aminoglycoside antibiotics.

If a blood or urine analysis is required, tell your doctor, pharmacist or nurse if you are using this drug, as positive reactions in sugar urine analyses may occur with certain analytical techniques.

3. HOW TO USE CEFTAZIDIME NORMON

This drug will always be administered by qualified persons. Never self-administer this drug. The dose received will depend on the type of infection to be treated and kidney function.

4. POSSIBLE ADVERSE EFFECTS

As with all drugs, CEFTAZIDIME NORMON may have adverse effects.

If you experience any of the adverse effects described below, inform your doctor immediately. Do not use more of the drug unless told to do so by your doctor. The doctor may decide to stop treatment.

The following adverse effects are very rare and may occur with less than 1 in 10,000 people who use CEFTAZIDIME NORMON:

- Difficulty in breathing, wheezing and oppression on the chest.
- Swelling of the eyelids, face or lips, or swelling of the skin.
- Feeling of pins and needles.
- Bad taste in the mouth.
- Skin reaction with the appearance of burns.
- Jaundice (yellow colouring to the skin and/or eyes, dark urine). These symptoms may be accompanied by itching, fever, nausea, loss of appetite and general malaise.

The following effects are frequent and may occur in more than 1 in every 100 and less than 1 in 10 persons who use CEFTAZIDIME NORMON:

- Urticaria of the skin or rash (red marks).
- Diarrhoea.

The following effects are infrequent and may occur in more than 1 in every 1,000 and less than 1 in 100 persons who use CEFTAZIDIME NORMON:

- Vaginitis (inflammation of the vagina), mouth ulcers.
- Headache, dizziness.

Abdominal discomfort, nausea or vomiting, colitis (inflammation of the intestine).

If you do not feel well or if you do not improve once the established treatment has finished, inform your doctor as soon as possible.

If you observe any other adverse reaction not described in this package leaflet, consult your doctor or pharmacist.

5. STORE OF CEFTAZIDIME NORMON

Keep CEFTAZIDIME NORMON out of the reach and sight of children.

Protect the un-reconstituted vials from the light.

Store at a temperature below 25 °C.

Expiry: do not use CEFTAZIDIME NORMON after the expiry date shown on the packaging.

6. INSTRUCTIONS FOR USE AND HANDLING FOR HEALTH PROFESSIONALS

CEFTAZIDIME NORMON should only be administered by a nurse or doctor.

Intramuscular administration:

CEFTAZIDIME NORMON 500 mg POWDER AND SOLVENT FOR INJECTABLE SOLUTION and CEFTAZIDIME NORMON 1 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION may be administered intramuscularly or intravenously.

The volumes of diluent to be added to reconstitute the contents of the vial of CEFTAZIDIME NORMON 500 mg POWDER AND SOLVENT FOR INJECTABLE SOLUTION are shown in the following table:

Route of administration	Volume of diluent to be added
Intramuscular	1.5 ml
Direct intravenous	5 ml

The volumes of diluent to be added to reconstitute the contents of the vial of CEFTAZIDIME NORMON 1 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION are shown in the following table:

Route of administration	Volume of diluent to be added
Intramuscular	3 ml
Direct intravenous	10 ml

Intravenous administration:

CEFTAZIDIME NORMON 1 g POWDER FOR PERFUSION and CEFTAZIDIME NORMON 2 g POWDER FOR PERFUSION must be administered intravenously.

The volume of diluent to be added to reconstitute the contents of the vial of CEFTAZIDIME NORMON 1 g POWDER FOR PERFUSION and the vial of CEFTAZIDIME NORMON 2 g POWDER FOR PERFUSION is 50 ml.

PREPARATION OF THE SOLUTIONS FOR INTRAMUSCULAR AND INTRAVENOUS ADMINISTRATION

The vials are supplied under reduced pressure. When the product dissolves, it releases carbon dioxide and a positive pressure develops. To facilitate use, the following reconstitution technique is recommended:

1. Insert the syringe needle through the vial stopper and inject the recommended diluent volume. The vacuum may help the diluent to enter.
2. Remove the needle from the syringe. Stir, preferably in a rotational direction, until dissolved: the carbon dioxide is released and a clear solution is obtained in 1-2 minutes.
3. Turn the vial upside down. With the syringe plunger fully pressed, insert the needle through the vial stopper and extract the total volume of solution (the pressure created in the vial helps to extract the volume). Ensure that the needle is inside the solution, not the air chamber. The extracted solution may contain bubbles of carbon dioxide which can be ignored.

The maximum shelf-life once the injectable is reconstituted with the indicated volume of diluent is 8 hours at a temperature of 25 °C and 24 hours at a temperature between 2 °C to 8 °C.

For intramuscular use, it may be reconstituted with 0.5% to 1% injectable lidocaine hydrochloride, and stored for 6 hours at 25 °C.