

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FORTUM 500 MG POWDER FOR INJECTION/INFUSION

FORTUM 1 G POWDER FOR INJECTION/INFUSION

CEFTAZIDIME

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Fortum is and what it is used for
2. Before you use Fortum
3. How to use Fortum
4. Possible side effects
5. How to store Fortum
6. Further information

1. WHAT FORTUM IS AND WHAT IT IS USED FOR

Fortum contains a medicine called ceftazidime and belongs to a group of medicines called antibiotics. Antibiotics such as ceftazidime are used to treat infections in different parts of the body caused by bacteria.

Fortum is given by a doctor or nurse as an injection or infusion (drip) into a vein or an injection into a muscle. Fortum can be used in adults or in children (including new born babies).

2. BEFORE YOU USE FORTUM

Do not use Fortum

- if you are allergic to antibiotics such as **cephalosporins or penicillins** (beta-lactams).
- If you think this applies to you, **don't use Fortum** until you have checked with your doctor

Take special care with Fortum

Before you are given Fortum your doctor needs to know:

- if you have **kidney disease** your doctor may lower your dose of <Tradenam>
- if you need a **low salt intake**
- Check with your doctor if you think this may apply to you.

Look out for important symptoms

Fortum can cause serious side effects, such as allergic reactions including serious skin rashes, nervous system disorders and severe diarrhoea (pseudomembranous colitis). You must look out for certain symptoms while you are receiving Fortum, to help reduce the risk of any problems.

While you are taking Fortum

If you need a blood or urine test

Fortum can affect the results of a blood test known as the Coombs test or urine tests for sugar for example Benedict's or Fehling's tests. If you need a blood or urine test:

- Tell the person taking the sample that you have been given Fortum.

Using other medicines

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes other medicines bought without a prescription. The following medication can affect how Fortum works, or make it more likely that you'll have side effects:

- antibiotics such as chloramphenicol or aminoglycosides
- a type of water tablets known as loop diuretics (for example furosemide)
- **Tell your doctor** if you are taking any of these.

Oral contraception

Fortum may reduce how well the contraceptive pill works. If you are taking the **contraceptive pill** while you are being treated with Fortum you also need to use a **barrier method of contraception** (such as condoms). Ask your doctor for advice.

Pregnancy and breast-feeding

If you are pregnant, or think you could be, or if you are planning to become pregnant, your doctor will consider the benefit to you against the risk to your baby of taking Fortum while you're pregnant.

The ingredients in Fortum can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Fortum.

Fortum contains sodium

Each 1 g of Fortum contains 52 mg sodium; this should be considered if you need a low salt intake.

- Check with your doctor that Fortum is suitable for you.

3. HOW TO USE FORTUM

Fortum will usually be given by a doctor or nurse either directly into a vein (intravenously) or into a muscle (intramuscularly) or it can be given as a **drip** (intravenous infusion). Your doctor will decide on the correct dose of Fortum depending on:

- the severity and type of your infection

- your age
- how well your kidneys are working.

→ If you have any questions about your dose of Fortum or how Fortum is given **ask your doctor or nurse**.

4. POSSIBLE SIDE EFFECTS

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

Look out for important symptoms

Severe allergic reactions

These occur very rarely (up to 1 in 10,000 people). Signs include:

- raised and itchy rash
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse
- low blood pressure that can cause light-headedness on standing up (hypotension).

→ Contact a doctor immediately if you get any of these symptoms and stop treatment with Fortum.

Serious skin reactions

Serious skin reactions are very rare in people taking Fortum (occur in up to 1 in 10,000 people). Signs include:

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) called erythema multiforme
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis).
- Contact a doctor immediately if you get any of these symptoms and stop treatment with Fortum.

Nervous system disorders

These occur very rarely (up to 1 in 10,000 people), particularly in people with kidney disease. Signs include: tremors, fits and sometimes coma.

→ Contact a doctor immediately if you get any of these symptoms and stop treatment with Fortum.

Severe diarrhoea (Pseudomembranous colitis)

While taking Fortum you may develop inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain and fever (pseudomembranous colitis). This effect can occur after stopping treatment with Fortum.

→ Contact a doctor immediately if you get any of these symptoms.

Other side effects that have occurred in people taking Fortum are:

Common side effects

These may affect up to 1 in 10 people:

- diarrhoea
- red raised or itchy skin rash
- swelling and redness along a vein when Fortum is injected into a vein
- pain and swelling when Fortum is injected into a muscle

Common side effects that may show up in blood tests:

- an increase in a type of white blood cell (eosinophilia)
- an increase in the number of blood platelets (cells that help blood to clot) (thrombocytosis)
- an increase in enzymes produced by the liver
- positive Coombs test (see section 2)

Uncommon side effects

These may affect up to 1 in 100 people:

- inflammation of the gut which can cause pain or diarrhoea which may contain blood (colitis)
- thrush - fungal infections in the mouth or vagina
- headache
- dizziness
- feeling sick (nausea) or being sick (vomiting)
- stomach ache
- fever
- itching

Uncommon side effects that may show up in blood tests:

- decrease in the number of white blood cells (leucopenia or neutropenia)
- decrease in number of blood platelets (cells that help blood to clot) (thrombocytopenia)
- an increase in the level of urea, urea nitrogen or serum creatinine in the blood

Very rare side effects

These may affect up to 1 in 10,000 people:

- yellowing of the whites of the eyes or skin (jaundice)
- tingling or numbness of the hands or feet
- unpleasant taste in the mouth

Very rare side effects that may show up in blood tests:

- an increase in a certain type of white blood cell in the blood (lymphocytosis)
- red blood cells destroyed too quickly (haemolytic anaemia)
- severe decrease in number of white blood cells (agranulocytosis)

If you get side effects

→ Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE FORTUM

Keep out of the reach and sight of children.

Do not use Fortum after the expiry date shown on the pack.

Protect from light.

Do not store above 25 °C.

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. FURTHER INFORMATION

What Fortum contains:

- The active pharmaceutical ingredient is ceftazidime.
- The other ingredient is Sodium carbonate (anhydrous).

What Fortum looks like and contents of the pack:

Fortum has a glass vial containing powder for injection.

Manufacturer

GlaxoSmithKline Manufacturing S.P.A, Via Fleming 237 135, Verona Italy.

This leaflet was last approved on:

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