Consumer Medicine Information

FORTUM INJECTION
Ceftazidime pentahydrate, 500 mg, 1 g and 2 g injection

What is in this leaflet

Please read this leaflet carefully.

This leaflet answers some common questions about FORTUM injection. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being administered Fortum Injection against the benefits this medicine is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What FORTUM is used for

FORTUM Injection contains an antibiotic called ceftazidime, which treats infections caused by bacteria, in different parts of the body.

FORTUM injection belongs to a group of antibiotics called cephalosporins. These antibiotics work by either killing the bacteria that cause the infections or stopping their growth.

FORTUM will not work against infection cased by viruses such as colds or the flu (influenza).

Ask your doctor if you have any questions or if you aren't sure why FORTUM injection has been prescribed for you.

FORTUM is only available with a doctor's prescription.

FORTUM is not addictive.

Before you are given FORTUM

When you must not be given it

Do not use FORTUM if you have ever had an allergic reaction to FORTUM, other cephalosporins or any of the ingredients listed at the end of this leaflet.

Before you start using FORTUM

You must tell your doctor if:

- you have had an allergic reaction to penicillin or cephalosporin antibiotics
- You may have an increased chance of being allergic to FORTUM if you are allergic to penicillins.
- you have had or have kidney problems
- you need a low salt intake
- you are pregnant, trying to become pregnant or breastfeeding
you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using FORTUM with other medicines such as chloramphenicol and aminoglycoside antibiotics.

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**How FORTUM is given**

FORTUM can be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle

Fortum is generally administered by a doctor or a nurse in a hospital.

Your doctor will decide on the dose and the length of time that you will receive FORTUM. This depends on the severity of your infection and other factors such as your weight. FORTUM is generally given twice a day.

**If too much FORTUM is given (overdose)**

You may experience symptoms such as convulsions and coma. Tell your doctor if you are feeling unwell.

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**While you are using FORTUM**

**Things you must do**

Tell your doctor if your infection symptoms don't improve or they become worse.
Tell your doctor if you get a sore, white mouth or tongue while using or soon after stopping FORTUM.
Tell your doctor if you get vaginal itching or discharge.
This may mean that you have a fungal infection called thrush. The use of FORTUM sometimes allows fungi to grow, causing the above symptoms. FORTUM does not work against fungi.
Tell your doctor if you become pregnant or you are breastfeeding.
If you have any urine tests while taking FORTUM, tell your doctor. FORTUM may affect the results of some urine tests.

**Things you must not do**

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

**Things to be careful of**

FORTUM can cause side effects that affect your ability to drive, such as dizziness. Don’t drive or use machines unless you are sure you’re not affected.

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**Side-Effects**

Tell your doctor or pharmacist as soon as possible if you have any problems while using FORTUM even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, FORTUM can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Some reported side effects are:

- White, furry, sore tongue and mouth (oral thrush)
- Sore, itchy vagina and/or discharge (vaginal thrush)
Swelling, pain or tenderness at the injection site
Diarrhoea, feeling sick (nausea), vomiting, stomach pain
Bad taste in the mouth
Headache
Dizziness
Tingling sensations
These are more common side effects. If any of these side effects persist, or are troublesome, see your doctor or pharmacist.

If you have any of the following, contact your doctor promptly:

- fits (seizures)
- tremor
- confusion
- jaundice – yellowing of the skin possibly with nausea and vomiting and low energy.
- Severe chills, sore throat or mouth ulcers
- Tendency to bruise or bleed easily

These may be more serious side effects. They are rare.

If you think you are having an allergic (hypersensitivity) reaction to FORTUM, TELL YOUR DOCTOR IMMEDIATELY or go to the emergency department at your nearest hospital. Symptoms include:

- Severe skin rash, itching or hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing and swallowing
- Fever
- Low blood pressure

This is a rare but serious side effect and needs immediate medical attention.

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with FORTUM:

- severe abdominal/stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

Ask your doctor or pharmacist to answer any questions you may have.

This is not a complete list of all possible side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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After using FORTUM

Storage

FORTUM powder vials should be stored in a cool, dry place, below 25°C.

Protect the vial from direct sunlight.
Do not put the vial in the freezer.

Do not store the medicine, in a bathroom or near a sink.

Keep your product in its pack until it is time to use it.

If you take the product out of its packaging it may not keep well.

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**Product description**

*What FORTUM looks like*

FORTUM is a white to faintly yellow powder. When water is added, FORTUM dissolves with effervescence (fizzing) and becomes a clear solution.

The powder comes in a vial packed into a box. Each vial contains either 500 mg, 1 g or 2 g ceftazidime pentahydrate.

*Ingredients*

Each 1 g of FORTUM contains 52 mg of sodium (118 mg sodium carbonate per gram of ceftazidime).

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**Supplier**

Your FORTUM Injection is supplied by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
NEW ZEALAND

Phone: (09) 367 2900
Fax: (09) 367 2910

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**Further Information**

This is not all the information that is available on FORTUM. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away. You may need to read it again.

The information provided applies only to: FORTUM

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