

PipTaz Sandoz[®]

piperacillin/tazobactam powder for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PipTaz Sandoz.

It does not contain all 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 having this medicine against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What PipTaz Sandoz is used for

This medicine is used to treat serious bacterial infections such as:

- chest infections
- urine infections
- stomach infections
- skin infections
- gynaecological infections
- septicaemia (blood poisoning).

It is also used to treat many other infections.

In hospitalised children aged 2 to 12 years, PipTaz Sandoz is used to treat serious infections in the abdomen. It is not recommended to treat abdominal infections in children under 2 years.

It contains the active ingredients piperacillin and tazobactam.

Piperacillin and tazobactam belong to a group of medicines called penicillins.

Piperacillin works by killing many types of bacteria. Tazobactam does not have activity against bacteria, but helps piperacillin to overcome bacteria which have become resistant to piperacillin.

PipTaz Sandoz will not work against infections caused by viruses such as colds or flu.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you are given PipTaz Sandoz

When you must not receive it

Do not have this medicine if you have an allergy to:

- piperacillin or tazobactam the active ingredients
- any other similar medicines such as antibiotics in the penicillin, cephalosporin or beta-lactamase inhibitor groups.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

PipTaz Sandoz should not be given to children under 2 years of age unless directed by the child's doctor.

Do not have this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start having this medicine, talk to your doctor.

Before you start to receive it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- cystic fibrosis
- kidney disease
- liver disease
- are on a low salt diet
- are being treated for gonorrhoea, as your doctor should test you for syphilis as well.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits of using this medicine if you are pregnant. This medicine passes into breast milk. Therefore if you are breastfeeding, you should discuss with your doctor whether to stop breastfeeding while having or to stop having PipTaz Sandoz.

If you have not told your doctor about any of the above, tell

him/her before you start having PipTaz Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PipTaz Sandoz may interfere with each other. These include:

- probenecid, a medicine used for gout
- aminoglycoside antibiotics such as tobramycin
- vancomycin, an antibiotic
- anticoagulants such as warfarin or heparin
- methotrexate, used to treat cancer, rheumatoid arthritis and other inflammatory conditions
- vecuronium, a muscle relaxant used in surgery.

These medicines may be affected by PipTaz Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while having this medicine.

How PipTaz Sandoz will be given

How much you will be given

The dose is generally 4.5 g every eight hours. The dose may vary between 2.25 g and 4.5 g and may also be given every six hours.

For children aged 2 to 12 years, weighing up to 40 kg, and with normal kidney function, the recommended dosage is 112.5 mg/kg (100 mg piperacillin/12.5 mg tazobactam) every 8 hours. For

children aged 2 to 12 years, weighing over 40 kg, and with normal kidney function, the recommended dose is 4.5 g (4 g piperacillin/0.5 g tazobactam) every 8 hours.

Your doctor may change these dosages.

If you have kidney problems, the dose will be adjusted to suit you.

How it will be given

A doctor or nurse in hospital will always give PipTaz Sandoz to you. It will usually be given to you as a slow injection into a vein over 20 to 30 minutes.

How long you will receive PipTaz Sandoz

The length of time you will be given this medicine depends on the type and severity of your infection. It should be given for at least five days, and for 48 hours after all signs of illness and fever have gone.

If you receive too much (overdose)

It is unlikely that you will ever receive an overdose of this medicine because it will be given by a trained nurse or doctor. However, if you are:

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have received too much PipTaz Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, diarrhoea or convulsions.

While you are receiving PipTaz Sandoz

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having PipTaz Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are receiving this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are receiving this medicine.

It may affect other medicines used during surgery.

If you become pregnant while having this medicine, tell your doctor immediately.

If you receive PipTaz Sandoz for a prolonged time, your doctor may wish to do some blood tests. Sometimes blood disorders can occur if you take PipTaz Sandoz.

If you are asked to provide a urine sample, tell your doctor that you are receiving this medicine.

Antibiotics in the penicillin family, including PipTaz Sandoz, can cause interference in some tests for glucose in urine. Penicillins that are excreted in urine can cause a false-positive result. The doctor will request a test, which is not affected by penicillins.

If you develop severe diarrhoea, tell your doctor immediately. Do this even if it occurs several weeks after stopping PipTaz Sandoz.

This may be a sign of a serious side effect that affects the bowel. You may need urgent medical care. Do not take any medicines to treat this diarrhoea without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving PipTaz Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea or indigestion
- vomiting
- diarrhoea or constipation
- rash, itchy or red skin
- allergic reactions such as hives (urticaria)
- a new infection caused by bacteria that are resistant to PipTaz Sandoz (superinfection)
- difficulty sleeping
- headache, dizziness or light-headedness.

These are the more common side effects of the medicine, and are usually mild and short-lived.

Rare side effects include:

- increased sweating
- eczema, severe skin reactions
- flaky or peeling of the skin
- inflammation of the mouth, dry mouth
- weakness and tiredness
- hallucinations or severe confusion
- muscle or joint pain or prolonged muscle relaxation
- fever
- hot flushes

- swelling of the hands, feet and ankles
- swelling or redness along a vein which is extremely tender when touched
- changes in liver function including jaundice (yellowing of skin and eyes) or hepatitis
- injection site pain or inflammation
- severe diarrhoea caused by a certain superinfection in the gut
- convulsions ('fits') if given in high doses
- short-term changes in kidney function
- cough, fever, chills, shortness of breath and chest pain
- thrush, especially with prolonged treatment.

Tell your doctor immediately if you notice any of the following:

- severe blisters and bleeding in the lips, eyes, mouth, nose or genitals
- itchy spots accompanied by fever and feeling unwell
- tiredness, being short of breath and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor if you have severe diarrhoea in the next few weeks after PipTaz Sandoz treatment. Do not try to treat yourself with medicines that you can buy without a prescription.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After having PipTaz Sandoz

Storage

It is unlikely that you will be asked to store this medication. If you are:

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store PipTaz Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop having this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

PipTaz Sandoz comes in one strength:

PipTaz Sandoz 4.5 g – white to off-white powder for injection, contained in 50 or 100 mL glass infusion bottles.

Pack size of one and ten infusion bottles.

Not all presentations may be marketed.

Ingredients

Active ingredients:

- PipTaz Sandoz 4.5 g – 4 g piperacillin (as sodium) and 0.5 g tazobactam (as sodium).

There are no inactive ingredients.

Supplier

PipTaz Sandoz is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket, Auckland 1149

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Tel: 0800 354 335

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