

TAZOPIP POWDER FOR INJECTION

Piperacillin (as sodium) and Tazobactam (as sodium)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TAZOPIP.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TAZOPIP against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What TAZOPIP is used for

TAZOPIP contains the active ingredients piperacillin and tazobactam. This medicine belongs to a group of medicines called antibiotics called penicillins. It works by killing bacteria.

Piperacillin is an antibiotic that kills many types of bacteria. Tazobactam belongs in the penicillin group but does not have activity against bacteria. It helps piperacillin to overcome bacteria which have become resistant to piperacillin.

This medicine is active against bacteria which cause serious infections such as:

- Chest infections
- Urine infections
- Stomach infections
- Skin infections
- Gynaecological infections
- Septicaemia (blood poisoning).

TAZOPIP is also used to treat many other infections.

In hospitalised children aged 2 to 12 years, TAZOPIP is used to treat serious infections in the abdomen.

TAZOPIP is not recommended to treat abdominal infections in children under 2 years.

TAZOPIP will not work against infections caused by viruses such as cold 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 available only with a doctor's prescription.

This medicine is not addictive.

Before you are given TAZOPIP

When you must not receive TAZOPIP

Do not receive TAZOPIP if you have an allergy to:

- any medicine containing piperacillin, tazobactam, or any other penicillin antibiotics.
- any antibiotic in the cephalosporin group.
- any medicines called beta-lactamase inhibitors.

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.

This medicine must not be given to a child under the age of 2 years unless directed by the child's doctor.

Safety and effectiveness in children younger than 2 years have not been established.

If you are not sure whether you should be receiving this medicine, talk to your doctor.

Before you start to receive TAZOPIP

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 other health problems, including kidney or liver disease.

The dose of TAZOPIP will be altered, depending on the blood tests.

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

Your doctor can discuss with you the risks and benefits involved if you are pregnant.

Tell your doctor if you are breastfeeding. TAZOPIP passes into breastmilk. Therefore, if you are breastfeeding, you should discuss with your doctor whether to stop breastfeeding while or stop using TAZOPIP.

Tell your doctor if you are on a low salt diet.

Your doctor can discuss with you the risks and benefits involved if you are pregnant.

Tell your doctor if you are being treated with TAZOPIP for gonorrhoea, your doctor should test you for syphilis as well. TAZOPIP in high doses may hide early symptoms of syphilis without curing it long-term.

If you have not told your doctor about any of the above, tell them before you start taking TAZOPIP.

If you are not sure whether you should be taking TAZOPIP, talk to your doctor.

Taking other medicines

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

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

- medicines used to treat gout such as probenecid
- aminoglycoside antibiotics, medicines including tobramycin
- vancomycin, an antibiotic
- preparations used for thinning blood (warfarin, 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 TAZOPIP 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 taking this medicine.

If you have not told your doctor about any of the above, tell them before you start taking TAZOPIP.

How TAZOPIP will be given to you

How much you will be given

The usual dosage for adults and children is 4 g piperacillin/0.5 g tazobactam (TAZOPIP) given every eight hours. The dose can vary from 2g piperacillin/0.25g tazobactam to 4g piperacillin /0.5g tazobactam administered every six or eight hours.

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

For children aged 2 to 12 years weighing over 40 kg and with normal kidney function, follow the adult dose guidance, i.e. 4g piperacillin/0.5g tazobactam every 8 hours.

Your doctor may change these dosages.

If you have kidney disease your doctor will adjust the dose to suit you.

How TAZOPIP will be given to you

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

How long TAZOPIP will be given to you

The length of time you will be given TAZOPIP 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 take too much (overdose)

It is unlikely that you will ever receive an overdose of TAZOPIP because it will be given by a trained nurse or doctor.

Symptoms of an overdose are the same as side effects but may be more severe. The symptoms of a side effect are listed under Side Effects below.

Immediately contact your doctor or go to Accident and Emergency department at the nearest hospital, if you notice the symptoms of an overdose. Contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.

While you are receiving TAZOPIP

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may wish to do some blood tests if you receive TAZOPIP for a prolonged time to make sure the medicine is working and to prevent unwanted side effects. Sometimes blood disorders can occur if you take TAZOPIP.

If you are asked by a doctor for a urine sample, tell them that you are receiving TAZOPIP.

Antibiotics in the penicillin family, including TAZOPIP, 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.

Things you must do

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

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 the diarrhoea without first checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TAZOPIP.

This medicine is effective in most people but it may have unwanted side effects in some people.

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.

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

More common side effects are:

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

Rare side effects are:

- increased sweating
- eczema
- flaking 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
- severe diarrhoea caused by a certain superinfection in the gut
- convulsions ('fits') if TAZOPIP is given in high doses
- short-term changes in kidney function
- cough, fever, chills, shortness of breath and chest pain
- thrush, especially with prolonged treatment.

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

side effects occur less often in people taking TAZOPIP.

Tell your doctor as soon as possible if you notice any of the following:

- 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
- moderate or severe skin rash or blisters often with flu-like symptoms

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

This is not a complete list of side effects. Other side effects not listed above may also occur in some people; there may be some side effects not yet known.

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

Importantly, tell your doctor if you have severe diarrhoea in the next few weeks after TAZOPIP treatment.

Do not be alarmed by the list of side effects.

You may not experience any of them.

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

Do not try to treat yourself with medicines that you can purchase without a prescription.

After using TAZOPIP

Storage

TAZOPIP will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place protected from light where the temperature stays below 25 °C.

It is unlikely that you will be asked to store this medicine. However, if you are:

Keep this medicine where young children cannot reach it.

A locked cupboard at least 1 and a half metres above the ground is a good place to store medicines.

Keep it in a cool dry place where it stays below 25°C. Do not store it in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking TAZOPIP, or it has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

TAZOPIP is a white to off-white powder packaged in glass containers (vials).

Ingredients

TAZOPIP contains 2g/0.25g of piperacillin and 4g/0.5g of tazobactam as the active ingredients mixed with sterile liquid to give a solution for injection by your doctor.

This medicine does not contain any excipients or preservatives.

Supplier

TAZOPIP is supplied in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

TAZOPIP piperacillin and tazobactam powder for injection

2g/0.25g: AUST R 144969

TAZOPIP piperacillin and tazobactam powder for injection

4g/0.5g : AUST R 144970

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