Dimension：180*580mm

成品线(Keyline)

文字图案区域（Text area）

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

TAZOPIP, 4,5 g, Lyophilized Powder for Solution for Infusion
Piperacillin sodium and Tazobactam sodium
Sugar free

Read all of this leaflet carefully before you are given TAZOPIP
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What TAZOPIP is and what it is used for
TAZOPIP belongs to a group of medicines called antibacterials for systemic use and is a combination of penicillin and tazobactam (a beta-lactamase inhibitor).

Piperacillin belongs to the group of medicines known as "broad-spectrum penicillin antibiotics". Tazobactam can prevent some resistant bacteria from surviving the effects of piperacillin. When given together, more types of bacteria are killed.

TAZOPIP is used to treat bacterial infections of the chest, abdomen, skin, uterus and blood.

It may be given together with another medicine called an aminoglycoside in patients who have very low levels of white blood cells and are therefore not able to fight infections.

2. What you need to know before you are given TAZOPIP
TAZOPIP should not be administered to you:
- if you are hypersensitive (allergic) to piperacillin / tazobactam or to any of the other ingredients of TAZOPIP (listed in section 6)
- if you have a history of allergic reactions to any of the penicillins and/or cephalosporins or ß-lactamase inhibitors.

Warnings and precautions
Special care should be taken with TAZOPIP:
- if you have previously had an allergic reaction to penicillins, other beta-lactam agents such as cephalosporin, monobactam or carbapenem, because you are more likely to be allergic to TAZOPIP.
- It may cause serious and occasionally fatal allergic reactions
- TAZOPIP may cause severe cutaneous adverse skin reactions. Tell your doctor if you develop a skin rash.
- if you develop a fever, stomach pains, rash, yellowing of the skin and eyes, as you may have developed a condition where your immune system does not work properly.
- If you experience severe and continuous diarrhoea. Tell your doctor immediately and do not take any medicine to stop the diarrhoea.
- if you experience excessive or unexplained bleeding or bruising
- if you experience seizures
- if you have any kidney problems

Children
TAZOPIP should not be given to children 0-2 years old because safety has not been established.

TAZOPIP should only be given to children under the age of 12 if they experience a decrease in neutrophils (a specific type of white blood cell; a main defender of bacteria) and are more prone to infection.

Other medicines and TAZOPIP
Always tell your health care provider if you are taking any other medicine.
(This includes complementary or traditional medicines.)

If you are taking any of the following medicines, please inform your doctor before taking TAZOPIP:
- Medicine that helps prevent blood clots (blood thinners) as the blood clotting function may be affected and you may require more frequent blood tests.
- An antibiotic that is an aminoglycoside (a class of antibiotics such as tobramycin and gentamicin) as TAZOPIP may weaken the effects of these antibiotics, if you have kidney problems.
- Methotrexate (a medicine that slows down your body's immune system and helps reduce inflammation) as piperacillin may reduce the rate at which methotrexate is removed from your body.
- Muscle relaxants such as vecuronium because piperacillin may prolong its effects.
- Probenecid (a medicine that is used in the treatment of chronic gout or gouty arthritis; these conditions are caused by too much uric acid in the blood) because it prolongs the amount of time that both piperacillin and tazobactam stay in your system.
- Vancomycin (an antibiotic) because being given both TAZOPIP and vancomycin could lead to kidney injury.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
Safety in pregnancy and breastfeeding has not been established.

Driving and using machines
It is not always possible to predict to what extent TAZOPIP may interfere with your daily activities. You should ensure that they do not engage in the above activities until you are aware of the measure to which TAZOPIP affects you.

TAZOPIP contains sodium
Talk to your doctor or other health care provider if you are on a strict sodium diet because TAZOPIP contains 216 mg of sodium per vial, which may increase your overall sodium intake.

3. How TAZOPIP will be given to you
You will not be expected to give yourself TAZOPIP. It will be given to you by a person who is qualified to do so.

Your doctor will decide on the dose that you require and for how long your treatment will last. TAZOPIP will be given to you as an infusion into your vein the infusion will take about 30 minutes to complete.

If you are given more TAZOPIP than you should
Since a health care provider will administer TAZOPIP, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take TAZOPIP
Since a health care provider will administer TAZOPIP, it is unlikely that the dose will be missed.

4. Possible side effects
TAZOPIP can have side effects.

Not all side effects reported for TAZOPIP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TAZOPIP, please consult your health care provider for advice.
If any of the following happen tell your doctor to stop TAZOPIP immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to TAZOPIP.
You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- severe watery diarrhoea which may also be bloody
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you, swelling of feet and ankles, nausea, vomiting, tiredness or shortness of breath – these may indicate a kidney problem
- yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- nausea (feeling sick),
- abdominal pains,
- Abnormal blood test results showing decreased of red blood cells,
- constipation,
- Diarrhoea
- Skin rashes
- Abnormal laboratory test results (positive direct Coombs).
- Pain, swelling, warmth or redness around the site of injection.

Less frequent side effects:
- stomach cramps and discomfort
- twitching
- muscle pain or weakness
- fever
- yeast infection,
- headache,
- difficulty sleeping,
- increased sweating,
- tiredness,
- dry, sore mouth,
- mouth ulcers,
- agitation (being nervously excited and anxious),
- confusion,
- anxiety,
- hallucination (seeing, hearing or feeling things that does not exist),
- depression,
- a feeling of being cold (chills)

Side effects with frequency unknown:
- Acute disorientation and confusion (delirium).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of TAZOPIP.

5. How to store TAZOPIP
Store all medicines out of reach of children. Stored at or below 25 °C
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What TAZOPIP contains
The active substances are piperacillin and tazobactam

What TAZOPIP looks like and contents of the pack
Off-white to white cake or powder.

TAZOPIP is packaged in a 50 ml clear, borosilicate, type I glass vial, with a type I, halogenated bromobutyl rubber stopper and a blue aluminium plastic combined cap.

The vials are packed in a carton containing 1 or 10 vials.

Holder of Certificate of Registration
Encha Health (Pty) Ltd
Building 3, Magwa Crescent West Maxwell Office Park
Waterfall City 1662
Tel: +27 11 312 2223

Marketed by:
AFT Pharmaceuticals SA (Pty) Ltd
Suite A, Rubenstein Ridge
617 Rubenstein Drive
Moreleta Park
0181

This leaflet was last revised in
18 March 2025

Application number
57/20.1.1/0266

PASIëNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

TAZOPIP, 4,5 g, poeier vir oplossing vir infusie
Piperasillien en tasobaktaam
Suikervry

Lees hierdie hele blad noukeurig deur voordat TAZOPIP aan u gegee word.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.

Wat in hierdie blad is

1. Wat TAZOPIP is en waarvoor dit gebruik word
TAZOPIP behoort aan 'n groep medisyne wat antibakteriële middels vir sistemiese gebruik genoem word en is 'n kombinasie van 'n penisillien met tasobaktaam ('n beta-laktamaseremmer).

Piperasillien behoort aan 'n groep medisyne bekend as breëspektrum penisillien-antibiotika. Tasobaktaam kan voorkom dat sekere weerstandige bakterieë die effekte van piperasillien oorleef. Wanneer dit saam gegee word, word meer soorte bakterieë doodgemaak.

TAZOPIP word gebruik om bakteriële infeksies van die bors, buik, vel, baarmoeder en bloed te behandel.
Dit kan saam met 'n ander middel genaamd 'n aminoglikosied gegee word aan pasiënte wat baie lae vlakke witbloedselle het en dus nie in staat is om infeksies te beveg nie.

2. Wat u moet weet voordat u TAZOPIP kry
TAZOPIP moet nie aan u gegee word nie:
- as u hipersensitief (allergies) vir piperasillien of vir tasobaktaam of vir enige van die ander bestanddele van TAZOPIP (gelys in afdeling 6) is.
- as u 'n geskiedenis van allergiese reaksies op enige van die penisilliene en/of sefalosporiene of β-laktamaseremmers het.

Waarskuwings en voorsorgmaatreëls
Wees besonder versigtig met TAZOPIP:
- as u voorheen 'n allergiese reaksie op penisilliene, ander beta-laktaammedisyne soos sefalosporiene, monobaktame of karbapenems gehad het, omdat u meer geneig is om allergies te wees vir TAZOPIP. Dit kan ernstige en soms dodelike allergiese reaksies veroorsaak.
- TAZOPIP kan erge velreaksies veroorsaak. Sê vir u dokter as u 'n veluitslag ontwikkel.
- as u koors, maagpyn, uitslag en geel verkleuring van die vel en oë ontwikkel, aangesien u dalk 'n toestand ontwikkel het waar u immuunstelsel nie behoorlik werk nie.
- as u erge of aanhoudende diarree ervaar. Sê dadelik vir u dokter en moenie enige medisyne gebruik om die diarree te stop nie.
- as u oormatige of onverklaarbare bloeding of kneusing ervaar.
- as u stuiptrekkings kry.
- as u enige nierprobleme het.

Kinders
TAZOPIP moet nie aan kinders van 0 - 2 jaar oud gegee word nie omdat veiligheid nie bepaal is nie.
TAZOPIP moet slegs aan kinders onder die ouderdom van 12 gegee word as hulle 'n daling in neutrofiele ervaar ('n spesifieke tipe witbloedsel; 'n hoofverdediger teen bakterieë) en meer geneig tot infeksie is.

Ander medisyne en TAZOPIP
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).
As u enige van die volgende medisyne gebruik, moet u dit vir u dokter sê voordat u TAZOPIP kry:
- Medisyne wat help om bloedklonte te voorkom (bloedverdunners), aangesien die bloedstolfunksie aangetas kan word en u meer gereelde bloedtoetse nodig mag hê.
- 'n Antibiotikum wat 'n aminoglikosied is ('n klas antibiotika soos tobramisien en gentamisien) aangesien TAZOPIP die effekte van hierdie antibiotika kan verswak as u nierprobleme het.
- Metotreksaat ('n middel wat u liggaam se immuunstelsel vertraag en help om inflammasie te verminder), aangesien piperasillien die tempo waarteen metotreksaat uit u liggaam verwyder word, kan vertraag.
- Spierverslappers soos vekuronium omdat piperasillien die effekte daarvan kan verleng.
- Probenesied ('n middel wat gebruik word vir die behandeling van chroniese jig of jigartritis; hierdie toestande word veroorsaak deur te veel uriensuur in die bloed) omdat dit die tyd wat beide piperasillien en tasobaktaam in u stelsel bly, verleng.
- Vankomisien ('n antibiotikum) omdat die toediening van TAZOPIP saam met vankomisien tot nierbesering kan lei.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg voordat u hierdie medisyne gebruik.
Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

Motorbestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel tot watter mate TAZOPIP met u daaglikse aktiwiteite kan inmeng nie. Totdat u weet tot watter mate TAZOPIP u beïnvloed, moet nie by bogenoemde aktiwiteite betrokke raak nie.

TAZOPIP bevat natrium
Elke flessie TAZOPIP bevat 216 mg natrium, wat jou algehele natrium inname mag verhoog. Raadpleeg u dokter of ander gesondheidspraktisyn indien u op 'n beheerdenatriumdieet is.

3. Hoe TAZOPIP aan u gegee sal word
Daar sal nie van u verwag word om TAZOPIP aan uself te gee nie. Dit sal aan u gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.
U dokter sal besluit oor die dosis wat u nodig het en vir hoe lank u behandeling sal duur. TAZOPIP sal as 'n infusie in u aar aan u gegee word. Die infusie neem ongeveer 30 minute om te voltooi.

As u meer TAZOPIP gekry het as wat u moes
Omdat 'n gesondheidsorgverskaffer TAZOPIP sal gee, sal hy/sy die dosis beheer. In geval van oordosering, sal u dokter die oordosering egter bestuur.

As u vergeet om TAZOPIP te neem
Aangesien 'n gesondheidsorgverskaffer TAZOPIP sal gee, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte
TAZOPIP kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir TAZOPIP aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar terwyl u TAZOPIP kry, moet u u gesondheidsorgverskaffer asseblief om advies raadpleeg.

As enige van die volgende voorkom, moet u dadelik vir u dokter sê om TAZOPIP te stop of na die ongevalle-afdeling van u naaste hospitaal gaan:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floutes

Hierdie is almal baie ernstige newe-effekte. As u dit het, kan dit wees dat u 'n ernstige reaksie op TAZOPIP gehad het. U mag dringende mediese aandag of hospitalisasie nodig hê.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:
- erge waterige diarree wat ook bloederig kan wees.
- tekens van herhaalde infeksies soos koors of seer keel.
- minder urien as wat normaal vir u is, swelling van die voete en enkels, naarheid, braking, moegheid of kortasemheid – dit kan op 'n nierprobleem dui.
- geel verkleuring van die vel en oë, donker urien en moegheid wat simptome van lewerprobleme kan wees.

Dit is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:
Algemene newe-effekte
- naarheid (voel mislik)
- buikkrampe of maagpyn
- abnormale bloedtoets resultate wat dui op verminderde rooibloed selle,
- konstipasie
- diarree
- vel uitslae
- abnormale laboratorium toets resultate (positiewe direkte Coombs).
- Pyn, swelling, warmte of rooiheid rondom die inspuitings area.

Minder algemene newe-effekte
- maagkrampe en ongemaklikheid
- rukkings
- spierpyn of -swakheid
- koors
- swam infeksie
- hoofpyn
- verminderde slaap
- verhoogde sweet
- moegheid
- droë, seer mond
- mondswere
- geagiteerd (gevoel van senuweeagtig opgewonde en angstig)
- verwardheid
- angs
- hallusinasies (sien, hoor of voel dinge wat nie bestaan nie)
- depressie
- kouekoors

Newe-effekte met onbekende frekwensie
- Akute disorientasie en delirium.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte ervaar. U kan newe-effekte ook by SAHPRA aanmeld via die Med Safety-toep (Medsafety X SAHPRA) en eReporting-platform (who-umc.org) wat op SAHPRA se webwerf gekry kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van TAZOPIP te gee.

5. Hoe om TAZOPIP te bêre
Hou alle medisyne buite bereik van kinders.
Bêre die flessie, by of onder 25 °C.
Handig alle ongebruikte medisyne oor aan jou apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting
Wat TAZOPIP bevat
Die aktiewe bestanddele is piperasillien en tasobaktaam.

Hoe TAZOPIP lyk en die inhoud van die pak
'n Wit tot afwit koek of poeier.
TAZOPIP is verpak in 'n flessie van 50 ml van deursigtige tipe I-boorsilikaatglas, met 'n tipe I gehalogeneerde broombutielrubber-prop en 'n blou aluminium-plastiekdop.

Die flessies word verpak in karton dosies wat 1 of 10 flessies bevat.

Houer van die registrasiesertifikaat
Encha Health (Pty) Ltd
Building 3, Magwa Crescent West
Maxwell Office Park
Waterfall City
1662
Tel: +27 11 312 2223
Bemark deur:

AFT Pharmaceuticals SA (Pty) Ltd
Suite A, Rubenstein Rif
617 Rubenstein Rylaan
Moreleta Park
0181

Hierdie blad is laas hersien in
18 Maart 2025

Registrasienommer
57/20.1.1/0266