PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TAPRANEM

4 g piperacillin (as sodium salt) and 0,5 g tazobactam (as sodium salt) Powder for solution for infusion

Sugar free.

Read all of this leaflet carefully before you are given TAPRANEM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.

What is in this leaflet

1. What TAPRANEM is and what it is used for

Piperacillin belongs to the group of medicines known as “broad-spectrum penicillin antibiotics”. It can kill many kinds of bacteria. Tazobactam can prevent some resistant bacteria from surviving the effects of piperacillin. This means that when piperacillin and tazobactam are given together, more types of bacteria are killed.

TAPRANEM is used in adults and adolescents to treat bacterial infections, such as those affecting the lower respiratory tract (lungs), urinary tract (kidneys and bladder), abdomen, women reproductive system, or skin.

TAPRANEM may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

TAPRANEM is used in children aged 2-12 years to treat infections of the abdomen such as appendicitis, peritonitis (infection of the fluid and lining of the abdominal organs), and gallbladder (biliary) infections. TAPRANEM may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

2. What you need to know before you use TAPRANEM

TAPRANEM should not be administered to you:

- if you are hypersensitive (allergic) to piperacillin, tazobactam, any penicillins and/or cephalosporins or ß-lactamase inhibitors, or any of the other ingredients of TAPRANEM (listed in section 6).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you have allergies.
- if you develop a skin rash during treatment. If you develop skin lesions, your doctor will discontinue your treatment.
- if you are suffering from diarrhoea before, or if you develop diarrhoea during or after your treatment. Do not take any medicine for the diarrhoea without first checking with your doctor.
- Your doctor will perform periodic assessment of your organ system functions, as well as your blood composition.
- if you are taking certain medicines (called anticoagulants) to avoid an excess of blood clotting (see also Other medicines and TAPRANEM in this leaflet) or any unexpected bleeding occurs during the treatment.
- if you think you developed a new or worsening infection.
- if you develop convulsions during the treatment.
- if you have low levels of potassium in your blood. Your doctor may want to check your kidneys before you take this medicine and may perform regular blood tests during treatment.

- if you have kidney or liver problems or are receiving haemodialysis. Your doctor may want to check your kidneys before you take this medicine and may perform regular blood tests during treatment.

Children

TAPRANEM has not been evaluated in this indication for children below the age of 2 years.

Other medicines and TAPRANEM

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may interact with TAPRANEM. These include:

- medicine for gout (probenecid). This can increase the time it takes for piperacillin and tazobactam to leave your body
- medicines containing the other antibiotics tobramycin, gentamicin or vancomycin. Tell your doctor if you have kidney problems
- medicines to treat blood clots or prevent blood clots (e.g., heparin, warfarin, or aspirin)
- medicines used to relax your muscles during surgery. Tell your doctor if you are going to have a general anaesthetic
- methotrexate (medicine used to treat cancer, arthritis, or psoriasis). Piperacillin and tazobactam can increase the time it takes for methotrexate to leave your body
- medicines that reduce the level of potassium in your blood (e.g. tablets enhancing urination or some medicines for cancer)

Effect on laboratory tests

Tell the doctor or laboratory staff that you are taking TAPRANEM if you have to provide a blood or urine sample.

Pregnancy and breastfeeding

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 healthcare provider for advice before using this medicine.

You should not receive TAPRANEM if you are breastfeeding your baby.

Safety and efficacy during pregnancy and breastfeeding has not been established.

Driving and using machines

It is not always possible to predict to what extent TAPRANEM may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which TAPRANEM affects you.

The use of TAPRANEM is not expected to affect the ability to drive or use machines.

TAPRANEM contains sodium

TAPRANEM contains 207 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 10 % of the recommended maximum daily dietary intake of sodium for an adult. This should be taken into consideration if you are on a controlled-sodium diet.

3. How to use TAPRANEM

Do not share medicines prescribed for you with any other person.

Your doctor or other healthcare provider will give you this medicine through an infusion (a drip for 30 minutes) into one of your veins.

The dose of TAPRANEM given to you depends on what you are being treated for, your age, and whether or not you have kidney problems.

Adults and adolescents above 12 years of age

The usual dose is 4 g/0,5 g TAPRANEM every 6-8 hours, which is given into one of your veins (directly into the blood stream).

Children aged 2 to 12 years

Your doctor will calculate the dose depending on your child's weight but each individual dose will not exceed 4 g/0,5 g of TAPRANEM.

You will be given TAPRANEM until the sign of infection has gone completely (7 to 10 days).

Patients with kidney problems

Your doctor may need to reduce the dose of TAPRANEM or how often you are given it. Your doctor may also want to test your blood to make sure that your treatment is at the right dose, especially if you have to take this medicine for a long time.

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

If you receive more TAPRANEM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Since a healthcare provider will administer TAPRANEM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of TAPRANEM

Since a healthcare provider will administer TAPRANEM, it is unlikely that the dose will be missed.

4. Possible side effects

TAPRANEM can have side effects.

Not all side effects reported for TAPRANEM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TAPRANEM, please consult your healthcare provider for advice.

If any of the following happens, stop using TAPRANEM and tell your doctor immediately:

- 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 TAPRANEM. You may need urgent medical attention or hospitalisation.

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

- diarrhoea

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- yeast infection
- decrease in platelets, decrease of red blood cells, or blood pigment / haemoglobin, abnormal lab test (positive direct Coombs), prolonged blood clotting time (activated partial thromboplastin time prolonged)
- headache
- abdominal pain, vomiting, nausea, constipation, upset stomach
- fever, injection site reaction

Less frequent side effects:

- decrease in white blood cells (leukopenia), prolonged blood clotting time (prothrombin time prolonged)
- decreased blood potassium, decreased blood sugar
- fits (convulsions)
- low blood pressure, inflammation of the veins (felt as tenderness or redness in the affected area), reddening of skin
- severe decrease in white blood cells (agranulocytosis), nose bleeds
- inflammation of the mucous lining of the mouth
- severe decrease of red blood cells, white blood cells and platelets (pancytopenia), decrease in white blood cells (neutropenia), decrease of red blood cells due to premature breakdown or degradation, small spot bruising, bleeding time prolonged, increase of platelets, increase of a specific type of white blood cells (eosinophilia)
- inflammation of the liver, yellow staining of the skin or whites of the eyes
- poor kidney functions and kidney problems
- a form of lung disease where eosinophils (a form of white blood cell) appear in the lung in increased numbers
- 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 the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TAPRANEM.

5. How to store TAPRANEM

Store all medicines out of reach of children.

Dry powder: Do not store above 30 °C and protect from moisture.

For storage conditions of the reconstituted and diluted medicine, see Professional Information.

Single use only. Discard any unused solution.

6. Contents of the pack and other information

What TAPRANEM contains

- The active substance is piperacillin and tazobactam. Each vial contains 4 g piperacillin (as sodium salt) and 0,5 g tazobactam (as sodium salt). Powder for solution for infusion.
- There are no other ingredients.

What TAPRANEM looks like and contents of the pack

A white or almost white powder or loose mass.

TAPRANEM is filled in a 50 ml Type II glass vial with grey bromobutyl rubber stopper and blue aluminium flip-off caps. The vials are packed into a cardboard carton - 1, 5, 10, 12, 25 or 50 vials per carton.

Holder of Certificate of Registration

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