# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:**

S4

**PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM:**

**TAZIJECT 0,5 g (Powder for Injection)**

**TAZIJECT 1,0 g (Powder for Injection)**

**TAZIJECT 2,0 g (Powder for Injection)**

**Read all of this leaflet carefully before you are given TAZIJECT**

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

If you have further questions, please ask your doctor or your pharmacist.

**TAZIJECT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## WHAT TAZIJECTCONTAINS

The active ingredient per vial of **TAZIJECT** is ceftazidime pentahydrate equivalent to 0,5 g, 1 g or 2 g of ceftazidime.

**TAZIJECT** contains the following inactive ingredient: Sodium carbonate.

## WHAT TAZIJECT IS USED FOR

**TAZIJECT** is an antibiotic effective against a wide range of bacteria. It is used to treat the following infections caused by bacteria:

- Severe infections such as: blood poisoning, abscess or skin eruption caused by bacterial infection, inflammation of the lining of the abdominal cavity, and severe infections in patients who's immune response is weakened by the administration of immunosuppressive medicines, by irradiation, by malnutrition, or by certain disease processes (for example, cancer).
- Respiratory tract infections such as lung infection, inflammation or infection of the air passages of the lung and also lung infections in patients with cystic fibrosis.
- Ear, nose and throat infections.

- Kidney or bladder infections.
- Skin and soft tissue infections.
- Stomach, intestine and liver infections.

## BEFORE YOU ARE ADMINISTERED TAZIJECT

### You must not be administered TAZIJECT if:

- you are allergic to cephalosporin antibiotics
- you are pregnant or breastfeeding

### Special care should be taken with TAZIJECT

You must tell your doctor if:

- you are allergic to penicillins or if you have a history of allergies to medicines
- you suffer from any medical problems such as kidney problems

Blood tests and kidney functioning tests will be necessary if you are given high doses of **TAZIJECT** or if your treatment is continued for a long time.

### Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving **TAZIJECT.**

### Using other medicines with TAZIJECT

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).[5]

**TAZIJECT** may interact with any of the following medicines and it should therefore not be used together with: (please refer to the scientific package insert for further information)

- nephrotoxic medicines such as the aminoglycoside gentamicin;
- furosemide;
- probenecid;
- bateriostatic antibacterials.

## HOW TAZIJECT WILL BE ADMINISTERED TO YOU

**TAZIJECT** is given by deep intramuscular injection, slow intravenous injection over 3 to 5 minutes, or intravenous infusion over up to 30 minutes by your doctor or other healthcare professional.

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

For specific dosage recommendations and instruction for reconstitution, please refer to the scientific package insert.

The dosage will be reduced in very young or very old patients, as well as in patients with kidney problems.

Do not share medicine prescribed for you with others.

If you have the impression that the effect of **TAZIJECT** is too strong or too weak, tell your doctor or pharmacist.

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

## POSSIBLE SIDE EFFECTS

**TAZIJECT** can have side effects**.**

Not all side effects reported for TAZIJECT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving **TAZIJECT**, please consult your doctor, pharmacist or other healthcare professional for advice.

The most common side effects are allergic reactions, such as skin reactions, increased number of a certain type of white blood cells in blood, fever, reactions resembling serum sickness, or a sudden, life threatening severe allergic reaction.

Digestive system side effects such as queasiness, vomiting, and frequent or loose watery stools may occur.

There may be pain around the skin area where the injection was given, and inflammation of a vein with formation of a clot has occurred after intravenous infusion.

Other blood related side effects that may occur include: lack of red blood cells, too few white blood cells, too few platelets and bleeding complications.

Damage to the kidneys has also been reported, especially in older patients or patients who already have kidney function problems. Diseases of the liver have also been reported.

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

## STORAGE AND DISPOSING OF TAZIJECT

The dry powder in vials should be stored at or below 25 °C and kept in carton until required for use. The scientific package insert for **TAZIJECT** will give more information on how the vials should be reconstituted before it will be ready for administration by your doctor or other healthcare professional.

**Store all medicine out of reach of children.**

## PRESENTATION OF TAZIJECT

Packs for I.M., I.V. or for I.V. infusion containing:

Single dose clear glass vial with dry substance equivalent to 0,5 g ceftazidime in packs with 1 or 10 vials.

Single dose clear glass vial with dry substance equivalent to 1 g ceftazidime in packs with 1 or 10 vials.

Single dose clear glass vial with dry substance equivalent to 2 g ceftazidime in packs with 1 or 10 vials.

Vials of **TAZIJECT** for injection do not contain any preservatives and should be used as single-dose preparations.

## IDENTIFICATION OF TAZIJECT

**TAZIJECT** is a white to off-white powder.

Reconstituted product: Clear yellow solution.

## REGISTRATION NUMBERS:

0,5 g Injection : A39/20.1.1/0125

1,0 g Injection : A39/20.1.1/0126

2,0 g Injection : A39/20.1.1/0127

## NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

Acino Pharma (Pty) Ltd

106 16th Road

Midrand

South Africa

## DATE OF PUBLICATION

3 June 2005

**Namibia only:**

Scheduling Status: NS2

Taziject 0,5 g: Reg No 06/20.1.1/0249

Taziject 1,0 g: Reg No 06/20.1.1/0248

Taziject 2,0 g: Reg No 06/20.1.1/0247