Package leaflet: Information for the patient

Azactam™ 1g or 2g

Powder for Solution for Injection or Infusion

Aztreonam

Please read this leaflet carefully before you start taking your medicine because it contains important information for you.

- **Please keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor.**

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Azactam is and what it is used for
2. What you need to know before you are given your medicine
3. How you will be given your medicine
4. Possible side effects
5. How to store your medicine
6. Contents of the pack and other information

1. What Azactam is and what it is used for

The name of this medicine is Azactam. The active ingredient in Azactam is aztreonam. Azactam is available in two strengths and each vial contains either 1g or 2g aztreonam as a powder for solution for injection or infusion. Aztreonam is an antibiotic and a member of the family of medicines called monobactams. Azactam also contains L-arginine.

Azactam is for the treatment of serious infections caused by bacteria which require an antibiotic injection.

2. What you need to know before you are given your medicine

Do not take Azactam if:

- You are allergic to aztreonam or L-arginine or any of the ingredients of this medicine (listed in Section 6)
- You are pregnant or planning to become pregnant

Warnings and precautions

Talk to your doctor before taking Azactam.

Take special care with Azactam if

- You have ever had an allergic reaction to any antibiotics
- You have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using Azactam tell your doctor as soon as possible since it may be necessary to interrupt the treatment.
- You have any Liver problems
- You have any Kidney problems or are using a certain antibiotics (aminoglycosides)

- You are taking a medicine for blood clots (anticoagulants)
- You have any blood disorders, e.g. severe reduction in blood cells which can cause weakness, bruising or make infections more likely (pancytopenia)
- You have skin disorders, including serious illness with blistering of the skin (toxic epidermal necrolysis)
- You have fits (convulsions or seizures)
- You develop any bacterial or fungal infections
- You test positive in a Coombs' test (a test for some blood problems)

You must tell your doctor if you experience unexplained confusion, altered mental function, coma, seizure, or weakness.

Other medicine and Azactam
Always tell your doctor or pharmacist about other medicines you may be taking or have recently taken including those obtained without a prescription. Some medicines can have an effect on each other's actions.

Pregnancy and breastfeeding
If you are pregnant or may become pregnant, you should speak to your doctor before being treated with Azactam. Breast-feeding is not recommended while taking Azactam. Tell your doctor if you are breast-feeding.

Driving and using machinery
This medicine could affect your ability to drive or use machinery (see sections 2 and 4). Azactam has also been shown to cause dizziness, confusion, and blurred vision (please see Section 4 below).

Azactam contains aztreonam.

3. How you will be given your medicine

Azactam will be given to you under the supervision of an experienced doctor.
How it will be given, either as an infusion (a drip) and/or into a vein (intravenously) will be determined by your doctor.

Adults:
The adult dose range is 1 to 8g daily. This dose can be split equally over the day meaning you may be given between one to four doses a day. Maximum recommended dose is 8 g per day.

Children:
The usual daily dose in children older than one week is 30 mg per kg of body weight given every 6 to 8 hours, but in severe infections in patients two years of age or older, this will be increased to 50 mg per kg of body weight every 6 to 8 hours. The maximum daily dose in children should not exceed the maximum recommended dose for adults.

Elderly:
Kidney function is a major determinant of the dose of Azactam given to the elderly. The doctor will assess kidney function by measuring a chemical called creatinine in the blood and also in the urine. If this level is above a certain limit (30 mL/min), the normal

recommended adult dose will be given. However, if this level is below the limit (30 mL/min), the dose will be adjusted accordingly by the doctor.

Liver and Kidney
The dose of Azactam given will also be adjusted by the doctor for anyone with severe kidney disease, for example kidney failure.

If you are given more Azactam than you should
It is unlikely that you will receive more Azactam than you should as it will be administered by injection into a muscle or vein by a doctor, nurse or other suitably trained person. If this does happen you will be closely monitored.

You must tell your doctor if you experience unexplained confusion, altered mental function, coma, seizure, or weakness.

If you have any further questions on the use of this medicines, ask your doctor.

4. Possible side effects

Like all medicines, Azactam can cause unwanted side effects, although not everybody gets them.

Tell your doctor immediately if you get any of the following symptoms:
- **swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. These may be signs of an allergic reaction.**
- **severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is rare side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation.**

Patients treated with Azactam have reported the following side effects:

Uncommon: may affect less than 1 in 10 people
- Temporary increases in the levels of some chemicals in your blood (creatinine)

Rare: may affect up to 1 in 1000 people
- Pins and needles
- Inflammation of the liver
- Spinning sensation
- Muscle pain
- Changes to blood count
- Positive results in a Coombs' test (a test for some blood problems)
- Difficulty sleeping
- Changes in your heart beat (measured by electrocardiogram-ECG)
- Feeling of being unwell
- Dizziness
- Ringing in the ears
- Double vision
- Gastrointestinal bleeding
- Diarrhoea with blood or mucous or inflammation

- Bad breath
- Chest pain
- Fever
- Weakness
- Yellowing of the skin
- Thrush or other vaginal irritation
- Fits
- Headache
- Wheezing
- Breast tenderness
- Shortness of breath
- Sneezing
- Nasal congestion
- Fall in blood pressure
- Confusion
- Bleeding
- Lengthening of the time it takes for a cut to stop bleeding
- Decrease in blood cells
- Increase or decrease in the number of infection fighting blood cells

Not known: frequency cannot be estimated from available data

- Narrowing of the airways in the lungs
- Inflammation of the veins
- Tender or painful veins
- Increase in some liver enzymes
- Increase in blood alkaline phosphatise (certain substance in the blood)
- Sweating
- Excessive sweating
- Swelling of eyes, lips and throat
- Abdominal cramps
- Mouth ulcers
- Nausea and/or vomiting
- Diarrhoea
- Altered taste
- Discomfort at the injection site
- Weakness
- Severe allergic reaction
- Skin conditions including
- Serious skin rashes
- Swelling of the skin that resembles severe burns
- Inflammation and peeling of the skin
- Rash
- Itching
- Red or purple discolouration of the skin
- Pin point bleeding under the skin
- Confusion, altered mental function, coma, seizure, or weakness

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL-Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your medicine

Keep this medicine out of the sight and reach of children.

This medicine will be stored in the pharmacy at not more than 25°C and prepared in a special area before the doctor or nurse gives it to you. This product is for single use only. Do not use this medicines after the expiry date which is stated on the vial label and on the carton. The expiry date refers to the last day of that month. .

6. Further Information

What Azactam contains
The active substance is aztreonam. Each vial contains either 1g or 2g aztreonam. The other ingredients are: L-arginine (780 mg per 1 g of aztreonam or 1.54 g per 2 g of aztreonam).

What Azactam looks like and the contents of the pack
Azactam comes in clear glass vials, closed with siliconed grey butyl rubber closure, sealed with aluminium seal with a plastic flip off button, in packs of 1 x 15 mL.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Athlone Pharmaceuticals Limited, Connaught House, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland.

Manufacturer:
CATALENT ANAGNI S.R.L.
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Dublin 15, D15 T867
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PLEASE DETACH BEFORE HANDING ABOVE SECTION TO PATIENT

INFORMATION FOR HEALTH PROFESSIONALS

Below is a summary of the dosage and administration for Azactam. Reference should be made to the Summary of Product characteristics (SmPC) for full prescribing information.

ADMINISTRATION:
Intramuscular or intravenous injection, or intravenous infusion.

Adults:
The dose range of Azactam is 1 to 8g daily in equally divided doses. The usual dose is 3 to 4g daily. The maximum recommended dose is 8g daily. The dosage and route of administration should be determined by the susceptibility of the causative organisms, severity of infection, and the condition of the patient.

Type of Infection[1]	Dosage	Frequency (hours)	Route
Urinary tract infections	500 mg or 1 g	8 or 12	IM or IV
Gonorrhoea/cystitis	1 g	single dose	IM
Cystic Fibrosis	2 g	6 - 8	IV
Moderately severe systemic infections	1 g or 2 g	8 or 12	IM or IV
Severe systemic or life-threatening infections	2 g	6 or 8	IM or IV
Other infections either	1 g	8	IM or IV
or	2 g	12	IV

(1) Because of the serious nature of infections due to Pseudomonas aeruginosa, a dose of 2g every 6 or 8 hours is recommended, at least for initial therapy in systemic infections caused by this organism.

The intravenous route is recommended for patients requiring single doses greater than 1g, or those with bacterial septicaemia, localised parenchymal abscess (e.g. intra-abdominal abscess), peritonitis, meningitis or other severe systemic or life-threatening infections.

Paediatric: The usual dose for patients older than one week is 30mg/kg/dose every 6 or 8 hours. For severe infections in patients 2 years of age or older, 50mg/kg/dose every 6 or 8 hours is recommended. The recommended dose for all patients in the treatment of infections due to *P. aeruginosa* is 50 mg/kg every six to eight hours. The maximum daily paediatric dose should not exceed the maximum recommended dose for adults. Dosage information is not yet available for new-borns less than 1 week old.

Elderly: Renal status is a major determinant of dosage in the elderly; these patients in particular may have diminished renal function. Serum creatinine may not be an accurate determinant of renal status. Therefore, as with all antibiotics eliminated by the kidneys, estimates of creatinine clearance should be obtained, and appropriate dosage modifications made if necessary.

Elderly patients normally have a creatinine clearance in excess of 30mL/min and therefore would receive the normal recommended dose. If renal function is below this level, the dosage schedule should be adjusted (see Renal Impairment).

Renal Impairment:
Prolonged serum levels of aztreonam may occur in patients with transient or persistent renal insufficiency. Therefore, after an initial usual dose, the dosage of aztreonam should be halved in patients with estimated creatinine clearances between 10 and 30 mL/min/1.73 m^2.

In patients with severe renal failure (creatinine clearance less than 10 mL/min/1.73 m^2), such as those supported by hemodialysis, the usual dose should be given initially. The maintenance dose should be one-fourth of the usual initial dose given at the usual fixed interval of 6, 8 or 12 hours. For serious or life-threatening infections, in addition to the maintenance doses, one-eighth of the initial dose should be given after each hemodialysis session.

Hepatic impairment:

A dose reduction of 20-25% is recommended for long-term treatment of patients with chronic liver disease with cirrhosis, especially in cases of alcoholic cirrhosis and when renal function is also impaired.

RECONSTITUTION:
Azactam Powder for Solution for Injection or Infusion is supplied in 15mL vials. Upon the addition of the diluent the contents should be shaken immediately and vigorously. Vials of reconstituted Azactam are not intended for multi-dose use, and any unused solution from a single dose must be discarded. Depending on the type and amount of diluent, the pH ranges from 4.5 to 7.5, and the colour may vary from colourless to light straw-yellow, which may develop a slight pink tint on standing; however this does not affect the potency.

For intramuscular injections: For each gram of aztreonam add at least 3mL Water for Injections Ph Eur or 0.9% Sodium Chloride BP and shake well.

Single-Dose Vial Size	Volume of Diluent to be added
0.5g	1.5mL
1.0g	3.0mL

Azactam is given by deep injection into a large muscle mass, such as the upper outer quadrant of the gluteus maximus or the lateral part of the thigh.

For intravenous injection: To the contents of the vial add 6 to 10mL of Water for Injections Ph Eur, and shake well. Slowly inject directly into the vein over a period of 3 to 5 minutes.

For intravenous infusion: For each gram of aztreonam, add at least 3mL of Water for Injections Ph Eur and shake well. Dilute this initial solution with an appropriate infusion

solution to a final concentration less than 2% w/v (at least 50mL solution per gram of aztreonam). The infusion should be administered over 20-60 minutes.

Appropriate infusion solutions include: 0.9% Sodium Chloride Injection BP
5% Glucose Intravenous Infusion BP, 5% or 10% Mannitol Intravenous Infusion BP, Sodium Lactate Intravenous Infusion BP, 0.9%, 0.45% or 0.2% Sodium Chloride & 5% Glucose I.V. Infusion BP, Compound Sodium Chloride Injection BPC 1959 (Ringer's Solution for Injection), Compound Sodium Lactate Intravenous Infusion BP (Hartmann's Solution for Injection).

A volume control administration set may be used to deliver the initial solution of Azactam into a compatible infusion solution being administered. With use of a Y-tube administration set, careful attention should be given to the calculated volume of Azactam solution required so that the entire dose will be infused. With intermittent infusion of Azactam and another drug via a common delivery tube, the tube should be flushed before and after delivery of Azactam with any appropriate infusion solution compatible with both drug solutions. Except for the antibiotics described below, the drugs should not be delivered simultaneously.

Reconstitution: Intravenous infusion solution of Azactam for Injection prepared with 0.9% Sodium Chloride Injection BP or 5% Glucose Intravenous Infusion BP, in PVC or glass containers, to which clindamycin phosphate, gentamicin sulphate, tobramycin sulphate, or cephazolin sodium have been added at concentrations usually used clinically, are stable for up to 24 hours in a refrigerator (2-8°C). Ampicillin sodium admixtures with aztreonam in 0.9% sodium chloride injection BP are stable for 24 hours in a refrigerator (2-8°C); stability in 5% Glucose Intravenous Infusion BP is eight hours under refrigeration. Store the reconstituted solution at 2°C-8°C (under refrigeration) for not more than 24 hours. Discard any unused solution.
If aztreonam and metronidazole are to be used together, they should be administered separately as a cherry red colour has been observed after storage of solutions containing combinations of the two products.
Any unused medicinal product or waste mat
erial should be disposed of in accordance with local requirements.

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