FRONT SIZE L75 X H 150MM

Breast feeding. In a study in 12 healthy women given aztreonam, peak concentrations in breast milk were found to be less than 1% of those in serum and this was considered suggestive of a low risk of adverse effects in breast-fed infants. The American Academy of Pediatrics states that no adverse effects have been seen in breast-fed infants whose mothers received aztreonam and considers it to be usually compatible with breast feeding, 2 although UK licensed product information recommends that mothers should refrain from breast feeding while receiving aztreonam.

Uses and Administration:

Aztreonam is a monobactam or monocyclic betalactam antibacterial used parenterally as an alternative to aminoglycosides or third-generation cephalosporins for the treatment of infections caused by susceptible Gram-negative aerobic organisms. These have included bone and joint infections, gonorrhoea, intra-abdominal and pelvic infections, lower respiratory-tract infections including pseudomonal infections in patients with cystic fibrosis, meningitis, septicaemia, skin and soft-tissue infections, and urinary-tract infections. For details of these infections and their treatment, see under Choice of Antibacterial. To broaden the spectrum of activity for empirical treatment of infections, aztreonam should be used with other antibacterials. Use with an aminoglycoside may be of benefit in serious *Pseudomonas aeruginosa* infections. Aztreonam is usually given parenterally by deep intramuscular injection, by slow intravenous injection over 3 to 5 minutes, or by intravenous infusion over 20 to 60 minutes. It is given to adults, in usual doses ranging from 1 to 8 g daily, in divided doses every 6 to 12 hours, according to the severity of the infection. Single doses over 1 g should be given by the intravenous route. UK licensed product information recommends that infants older than one week and children be given aztreonam 30 mg/kg every 6 or 8 hours. For severe infections, children of 2 years or older may be given 50 mg/kg every 6 or 8 hours up to a maximum total daily dose of 8 g. Although not licensed in the UK for neonates less than one week old, the *BNFC* suggests a dose of 30 mg/kg every 12 hours. In the USA the dose for children from 9 months of age is 30 mg/kg every 8 hours for mild to moderate infection, or every 6 to 8 hours in moderate to severe infection up to a maxhnum **total daily** dose of **120** mg/kg. For details of dosage in patients with renal impairment, see below. A single intramuscular dose of 1 g has been recommended for the treatment of gonorrhoea or cystitis.

Urinary Tract Infections (complicated and uncomplicated), including pyelonephritis and cystitis (initial and recurrent) caused by *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter cloacae, Klebsiella oxytoca•, Citrobacter* species*, and *Serratia marcescens**.

Lower Respiratory Tract Infections, including pneumonia and bronchitis caused by *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Haemophilus influenzae, Proteus mirabilis, Enterobacter* species, and *Serratia marcescens**.

Skin and Skin-Structure Infections, including those associated with postoperative wounds, ulcers, and burns, caused by *Escherichia coli, Proteus mirabilis, Serratia marcescens, Enterobacter* species, *Pseudomonas aeruginosa, Klebsiella pneumoniae,* and *Citrobacter* species*.

Intra-abdominal **Infections,** including peritonitis caused by *Escherichia coli, Klebsiella* species including *K. pneumoniae, Enterobacter* species including *E. cloacae**, *Pseudomonas aeruginosa, Citrobacter* species* including *C. freundii**, and *Serratia* species* including *S. marcescens•*.

Pregnancy :

Pregnancy Category B '

In pregnant women, aztreonam crosses the placenta and enters the fetal circulation.

Developmental toxicity studies in pregnant rats and rabbits with daily doses of aztreonam upto 1800 and 1200 mg/kg, respectively, revealed no evidence of embryotoxicity or fetotoxicity or teratogenicity. These doses, based on body surface area, are 2.2-and 2.9fold greater than the **MRHD** for adults of 8 g per day. A pert/postnatal study in rats revealed no drug-induced changes in any maternal, fetal, or neonatal parameters. The highest dose used in this study, 1800 mg/kg/day, is 2.2 thnes the MRHD based on body surface area.

There are no adequate and well-controlled studies of aztreonam on human pregnancy outcomes. Because animal reproduction studies are not always predictive of human response, aztreonam should be used during pregnancy only if clearly needed.

OVERDOSAGE '

If necessary, aztreonam may cleared from the serum by hemodialysis and/or peritoneal dialysis.

Storage:- Store Below 25'C tilt reconstitution. Avoid from excessive heat & Protected from Light and moisture.

Improper Storage may deteriorate the product

Medicine:- Keep out of reach of children.

Mfd. by : **Oscar Remedies Pvt. Ltd.**
(An ISO-GMP & GLP Certified Co.)
Tirath Nagar, Badi Majra,
Yamuna Nagar – 135001 (HR)

BACK SIZE L75 X H 150MM

For the use of only of a Registered Medical Practitioner of a Hospital or a Laboratory

Aztreonam for Injection USP

OZAM

For IM /IV use only

Each vial contains :		Each vial contains :
Aztreonam (Sterile)	500 mg.	Aztreonam (Sterile) USP 1000 mg.
(As Dry Mixture of Sterile		(As Dry Mixture of Sterile
Aztreonam USP 8L-Arginine USP)		Aztreonam USP & L-Arginine USP)

Description :

Aztreonam for Injection USP is a totally synthetic monocyclic beta lactam belonging to a new class of antibiotics, the monobactams. Chemically, Aztreonam is designated as:
(Z)-2-((((2-amino-4-thiazolyl)-(((2S, 3S)-2-methyl-4-oxo-1-sulfo-3-azetidinyl) carbamoyl) methylene)-amino) oxy)-2-methylpropionic acid.
The structural formula is:

Aztreonam Injection contains a sulphonic acid substituent in the 1-position of the beta-lactam nuclear ring, which activates the beta-lactam moiety. It also contains an aminothiazolyloxime side chain in the 3-position and a methyl group in the 4-position which confer the specific anti-bacterial spectrum and beta-lactamase stability.

Aztreonam for Injection is a white to off-white, free flowing sterile non-pyrogenic powder blend of Aztreonam and L-arginine which upon reconstitution is intended for intravenous or intramuscular administration. Aztreonam for Injection is sodium free and contains approximately 45 % of anhydrous Arginine. The pH of Aztreonam for Injection solution, depending on the type and amount of diluent used ranges between 4.5 and 7.5.

PHARMACOLOGY :

Pharmacokinetics :

Aztreonam for Injection is not intended for oral administration as it is not absorbed from the gastrointestinal tract. Single 30-minute intravenous infusions of 0.5, 1 gm doses of Aztreonam for injection in healthy volunteers produced serum levels of 54, 90 and 204mcg/mL, respectively, immediately after administration. Single 3-minute intravenous injections of the same doses resulted in peak serum levels of 58, 125 and 242mcg/mL. Serum levels of aztreonam 8 hours after 3 or 30 minute infusions were 1, 3 and 6mcg/mL.

Aztreonam is poorly absorbed from the gastrointestinal tract and is therefore given parenterally. Absorption after intramuscular injection is good; peak plasma concentrations of about 46 micrograms/mL have been achieved within 1 hour of a 1-g dose. Aztreonam has a plasma half-life of about 1.7 hours. The half-life may be prolonged in neonates, in the elderly, in patients with renal impairment, and to some extent in those with hepatic impairment. Aztreonam is about 56% bound to plasma proteins. It is widely distributed in body tissues and fluids, including bile. Diffusion into the CSF is poor unless the meninges are inflamed. It crosses the placenta and enters the fetal circulation; small amounts are distributed into breast milk.

Aztreonam is not extensively metabolised. The principal metabolite, SQ-26992, is inactive and is formed by opening of the beta-lactam ring; it has a much longer half-life than the parent compound. Aztreoium is excreted mainly in the urine, by renal tubular secretion and glomerular filtration; about 60 to 70% of a dose appears within 8 hours as unchanged drug with only small quantities of metabolites. Only small amounts of unchanged drug and metabolites are excreted in the faeces. Aztreonam is removed by haemodialysis and to a lesser extent by peritoneal dialysis.

Antimicrobiat Action :

Aztreonam is bactericidal and acts similarly to the penicillins by inhibiting synthesis of the bacterial cell wall; it has a high affinity for the penicillin-binding protein 3 (PBP-3) of Gram-negative bacteria. The activity of aztreonam is restricted to Gram-negative aerobic organisms, including beta-1actamase-producing strains, with poor or no activity against Crram-positive aerobes or anaerobic organisms. It is active against most Enterobacteriaceae including *Escherichia coli, Klebsiella, Proteus, Providencia, Salmonella, Serratia, Shigella,* and *Yersinia* spp. Some strains *oY Enterobacter* and *Citrobacter* spp. are resistant. Aztreonam has some activity against *Pseudomonas aeruginosa,* although most strains of *other Pseudomonas* spp. are insensitive. Aztreonam has good activity against *Haemophilus influenza* and *Neisseria* spp. Synergy has been reported in vifro between aztreonam and aminoglycosides against *Ps. aeruginosa* and some *Enterobacteriaceae.* Aztreonam is stable to hydrolysis by many beta-lactamases and appears to be a poor inducer of beta-lactamase production. Acquired resistance has occasionally been reported.

Precautions :

Aztreonam should not be given to patients who are hypersensitive to it and should be used with caution in those known to be hypersensitive to other beta lactams, although the incidence of cross-sensitivity appears to be low (but see below).

Aztreonam should be used with caution in patients with renal or hepatic impairment.

Allegato

AL MINISTERO DELLA SALUTE
USMAF-SASN ……
UNITA' TERRITORIALE……

Richiesta di importazione di medicinali ai sensi del D.M. 11/02/1997.

Il sottoscritto Dr. ……..……..……..……

Residente in …… via ……..

Tel. ……

Iscritto nell'Albo dell'Ordine dei Medici-Chirurghi di …..…….

al n. …… cod. regionale ……

chiede di importare il medicinale (contenente il seguente/i principio/i attivo/i):

AZTREONAM ……..

nome commerciale: **OZAM**

forma farmaceutica: **1 GR**

nella quantità di numero ……..…..…….confezioni contenenti **1 FIALA** di farmaco cadauno.

Prodotto dalla ditta: **Oscar Remedies Pvt. Ltd.** (specificare il nome dell'azienda).

Precisa che tale medicinale è regolarmente registrato nel Paese di provenienza: **INDIA**

Per il trattamento di ……

Tale medicinale è indispensabile per la cura del Sig. (iniziali o codice) ……

affetto da: ……

Dichiara altresì che il farmaco:

- Non ha valida alternativa terapeutica con altri medicinali registrati in Italia;
- Non contiene sostanze stupefacenti o psicotrope;
- Non è un emoderivato;
- Verrà impiegato sotto la propria responsabilità, dopo aver ottenuto il consenso informato scritto dal paziente;
- Che le generalità del paziente ed i documenti relativi al consenso informato sono custoditi presso il medico curante per la durata prevista dalla normativa vigente.

Particolari condizioni di conservazione del medicinale:
Temperatura (es. -20°C, da 2 a 8°C, <25°C, <30°C, nessuna indicazione): ……
Altro: ……

Luogo e data _____

_____

Timbro e firma leggibile del medico