ASPIN
An OBS Group Company

M-Span®
(Cefixime)

Capsule / Suspension / DS Suspension

ایم۔اسپان
(سیفکزائم)
کیپسول/سسپنشن/ڈی ایس سسپنشن

M-Span capsules 400 mg:
Each capsule contains Cefixime as Trihydrate .....400 mg

M-Span dry suspension 100 mg/5 ml:
Each 5 ml of reconstituted suspension contains Cefixime as Trihydrate .....100 mg

M-Span DS dry suspension 200 mg/5 ml:
Each 5 ml of reconstituted suspension contains Cefixime as Trihydrate.....200 mg

DESCRIPTION:
M-Span (Cefixime) is a semisynthetic third generation cephalosporin antibiotic for oral administration.

CLINICAL PHARMACOLOGY:
A single 400 mg capsule produces an average peak concentration of approximately 3.7 mcg/ml (range 1.3 to 7.7 mcg/ml). Peak serum concentration occurs between 2 to 4 hours following oral administration of a single 400 mg capsule or 100 mg / 200 mg of M-Span Suspension / M-Span DS suspension.

INDICATIONS:
M-Span (Cefixime) is an orally active cephalosporin antibiotic, which has marked in vitro bactericidal actively against wide range of Gram positive and Gram negative organisms. It is indicated for the treatment of the following acute infections caused by susceptible micro-organisms:

- Otitis Media
- Respiratory Infection

Upper Respiratory Tract Infection (URTI):
- Sinusitis
- Upper Scarlet fever
- Pharyngitis and Tonsillitis

Lower Respiratory Tract Infection (LRTI):
- Acute bronchitis and Acute Exacerbations of Chronic Bronchitis
- Secondary infections in chronic respiratory
- Bronchiectasis
- Community-acquired Pneumonia

Uncomplicated Urinary Tract Infections:
- Cystourethritis
- Cystitis
- Pyelonephritis

- Uncomplicated Gonorrhea (cervical/urethral):

Others:
- Cholangitis
- Cholecystitis
- Typhoid fever (Enteric fever) including multi-drug resistant typhoid fever

ANTIMICROBIAL ACTIVITY:
As with other cephalosporin, bactericidal action of Cefixime results from inhibition of cell-wall synthesis. Cefixime is highly stable in the presence of beta-lactamase enzymes. As a result many organisms resistant to penicillins due to presence of beta-lactamase may be susceptible to Cefixime. Cefixime (M-Span) has shown to be active against most strains of the following organisms:

GRAM POSITIVE ORGANISMS:

- Streptococcus pneumoniae
- Streptococcus pyogenes
- Streptococcus agalactiae

GRAM NEGETIVE ORGANISMS:

- Escherichia coli
- Proteus mirabilis
- Neisseria gonorrhoeae
- Haemo philus parainfluenzae (β-lactamase positive and negative strains)
- Haemophilus influenzae (β-lactamase positive and negative strains)
- Moraxella (Branhamella) catarrhalis (most of are beta lactamase strains)
- Proteus vulgaris
- Klebsiella pneumonia
- Klebsiella oxytoca
- Pasteurella multocida
- Providencia species
- Salmonella species
- Shigella species
- Citrobacter amalonaticus
- Citrobacter diversus
- Serratia marcescens

Note

Pseudomonas species, strain of group "D" streptococci (including enterococci) Listeria monocytogenes, most strains of Staphylococci (including methicillin resistant strains), most strains of Enterobacter, most strains of Bacteroides fragilis, and Clostridia are resistant to Cefixime.

POSOLOGY AND ADMINISTRATION:

The usual course of treatment is 5 – 14 days depending upon the severity of infection.

Adults & children over 12 years:

The recommended adult dosage is 400 mg daily administered as single dose.

Children under 12 years (Use Oral Suspension):

The recommended dosage for children is 8mg/kg/day. This may be administered as a single daily dose or may be given in two divided doses, as 4mg/kg every 12 hours. As a general guide for prescribing in children, the following daily doses are suggested.

Pediatric Dosage Chart		
Age	**100mg/5ml Suspension**	**200mg/5ml Suspension**
Infants 6 months to 1 year	3.37ml daily	1.87ml daily
Children 1-4 years	5ml daily	2.5ml daily
Children 5-9 years	10ml daily	5ml daily
Children 10-12 years	15ml daily	7.5ml daily
Adults & children over 12 years	-	10ml daily

Infants:

The dosage in children aged 6 months to one year should be calculated on mg/kg basis. The safety and efficacy of Cefixime has not been established in children aged less than 6 months.

In elderly:

In elderly patients with normal renal function the same recommended dose may be given.

Patient with renal impairment

Normal dose may be given to patients with creatinine clearance of 60ml/min. or greater. In patients whose creatinine clearance is less than 20ml/min, it is recommended that a dose of 300mg once daily should not be exceeded.

CONTRA-INDICATION

Patients with known hypersensitivity to cephalosporin.

PRECAUTIONS AND WARNING

As other cephalosporin Cefixime should be given with caution to penicillin sensitive patients, as there is some evidence of partial cross-allergicity between penicillin and cephalosporin patients who had severe reaction including (anaphylaxis) to both classes of drugs. If an allergic effect occurs with M-Span drug should be discontinued and patient treated with appropriate agent if necessary.

The use of broad spectrum antibiotic alter the normal flora of the colon and may permit overgrowth of clostridia; studies indicate that a toxin produced by Clostridium difficile is a primary cause of antibiotic associated diarrhea and pseudomembranous colitis so it is important to consider its diagnosis on patient who developed dairrhoea in association with the use of antibiotics. Seizures have been reported with several cephalosporins (e.g., cefuroxime, ceftazidime), particularly in patients with renal impairment in whom dosage of the drug was not reduced. If seizures occur during treatment with a cephalosporin, the drug should be discontinued and anticonvulsant therapy initiated as clinically indicated. The dose of Cefixime should be adjusted in patient with severe renal impairment as well as those undergoing Continuous Ambulatory Peritoneal Dialysis (CAPD) and Haemodialysis (HD) patients on dialysis should be monitored carefully. Special caution should be taken in patient with pre-existing renal impairment when M-Span combine with aminoglycoside antibiotic, polymixin B, colistin or high dosed loop diuretics.

USE IN PREGNANCY AND BREAST-FEEDING

Studies have been performed in mice and rats at doses up to 40 times higher to human dose and resulted in no evidence of impaired fertility or harm to the fetus due to Cefixime. There are no adequate and well controlled studies in pregnant woman and nursing mother available. M-Span should not be used in pregnancy or in nursing mother, unless considered essential by the physician.

DRUG INTERACTION

- Carbamazepine
  Elevated carbamazepine levels have been reported in post marketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.
- Warfarin and Anticoagulants
  Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

OVERDOSE

There is no experience with overdoses of Cefixime and adverse reaction seen at the dose 2 gm which did not differ from profile seen in patients treated with normal doses. Gastric lavage may be initiated in over dosage.

SIDE EFFECTS

Cefixime is generally well tolerated; the undesired effects observed in clinical trials were mild and self limiting in nature.

Gastrointestinal

The most frequent side effect seen with Cefixime is diarrhea and stool change. In some cases severe diarrhoea has been reported. Cefixime should be discontinued if marked diarrhea occurs. Other G.I. side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting and flatulence.

Central nervous system

Headache, dizziness and risk of seizures / neurotoxicity.

Hypersensitivity reaction

Allergy in the form of rashes, pruritis, urticaria and drug fever have been observed. These reactions are infrequent and reversible.

Haematological and clinical changes

Thrombocytopenia, leukopenia and eosinophilia have been observed. These reations are infrequent and reversible. Mild transient change in liver and renal function test have been observed.

RECONSTITUTED DIRECTIONS FOR ORAL SUSPENSION

To reconstitute, add (previously boiled and cooled) water in a bottle upto the given mark. Invert and shake well to make suspension. Reconstituted suspension should be used within 7 days.

DOSAGE

As prescribed by the physician.

INSTRUCTIONS

- For M-Span capsules 400 mg: Do not store above 30°C.
- For M-Span dry suspensions: Prior to reconstituition do no store above 25°C.
- After reconstitution store at room temperature.
- Protect from light and moisture.
- Keep out of the reach of children.
- Shake the bottle well before use.
- Use reconstituted suspension within seven days.

PRESENTATION

M-Span Capsule 400mg: Pack of 05 Capsules.
M-Span Dry Suspension 100mg/5ml in HDPE Bottle of 30ml.
M-Span-DS Dry Suspension 200mg/5ml in HDPE Bottle of 30ml.

ہدایات

ایم-اسپان کیپسول ۴۰۰ ملی گرام: ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجۂ حرارت پر نہ رکھیں۔
ایم-اسپان سسپینشن : سسپینشن بنانے سے پہلے ۲۵ ڈگری سینٹی گریڈ سے زیادہ درجۂ حرارت پر نہ رکھیں۔
تیارشدہ سسپنشن کو کمرے کے درجہ حرارت پر رکھیں۔
دوا کو روشنی اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
استعمال سے قبل بوتل کو اچھی طرح ہلالیں ۔
تیارشدہ سسپنشن کو سات دن کے اندر استعمال کرلیں۔

دوا تیار کرنے کا طریقہ:

سسپنشن بنانے کے لئے پہلے سے ابال کر ٹھنڈا کیا ہوا پانی بوتل پر دیئے گئے نشان تک ڈالیں اور اچھی طرح ہلائیں۔
تاکہ تمام پاؤڈر پانی میں یکساں طور پر حل ہوجائے۔ تیارشدہ سسپنشن کو سات دن کے اندر استعمال کرلیں۔

خوراک اور طریقہ استعمال:

بالغان اور بارہ سال سے بڑے بچوں کے لئے: ایک کیپسول (۴۰۰ ملی گرام) روزانہ ۔
۱۲ سال سے کم عمر کے بچوں کے لئے: ۸ ملی گرام فی کلوگرام ۲۴ گھنٹے بطور ایک خوراک ۔

عمومی خوراک برائے ۱۰۰ ملی گرام /۵ ملی لیٹر سسپنشن

عمر	روزانہ بطور ایک خوراک
۱ سے ۴ سال	۵ ملی لیٹر
۵ سے ۹ سال	۱۰ ملی لیٹر
۱۰ سے ۱۲ سال	۱۵ ملی لیٹر

عمومی خوراک برائے ۲۰۰ ملی گرام / ۵ ملی لیٹر سسپنشن

عمر	روزانہ بطور ایک خوراک
۱ سے ۴ سال	۲٫۵ ملی لیٹر
۵ سے ۹ سال	۵ ملی لیٹر
۱۰ سے ۱۲ سال	۷٫۵ ملی لیٹر
بالغ اور ۱۲ سال سے بڑے	۱۰ ملی لیٹر

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MANUFACTURED BY:
AGP Limited
D-109, S.I.T.E., Karachi-Pakistan.

MANUFACTURED FOR:
ASPIN
An OBS Group Company
Aspin Pharma (Pvt.) Ltd.
Plot No. 10 & 25, Sector 20,
Korangi Industrial Area,
Karachi - 74900, Pakistan.
www.aspin.com.pk