Bosch

For Medical Professional only

DROMAX

(C e f a d r o x i l)

CAPSULES / TABLETS / SUSPENSION / DROPS

ڈرومیکس

کیپسولز/ٹیبلیٹس/سسپنشن/ڈراپس

(سیفاڈروکسِل)

DESCRIPTION:
DROMAX (Cefadroxil) is a semi-synthetic cephalosporin antibiotic intended for oral administration. It is a white to off-white crystalline powder. It is slightly soluble in water and it is acid-stable. It is chemically designated as 5-Thia-l-azabicyclo[4.2.0]oct-2-ene-2 carboxylic acid, -[[amino(4-hydroxyphenyl) acetyl]amino]-3 -methyl-8-oxo- monohydrate[6R- [6α, 7β (R*)]]-. It has the formula $C_{16}H_{17}N_3O_5S \cdot H_2O$ and the molecular weight of 381.40.

COMPOSITION:
DROMAX Tablets 1000mg:
Each film coated tablet contains:
Cefadroxil U.S.P. .... 1000mg as Cefadroxil Monohydrate
(Product Specs.: U.S.P.)
"Product contains lactose"

DROMAX Capsules 500mg:
Each capsule contains:
Cefadroxil U.S.P. ..... 500mg as Cefadroxil Monohydrate
(Product Specs.: U.S.P.)

DROMAX 125mg/5ml Suspension:
Each 5ml contains: Cefadroxil U.S.P. .....125mg as Cefadroxil Monohydrate
(Product Specs. U.S.P.)

DROMAX 250mg/5ml Suspension:
Each 5ml contains: Cefadroxil U.S.P. ..... 250mg as Cefadroxil Monohydrate
(Product Specs. U.S.P.)

DROMAX 100mg/ml Drops:
Each ml contains : Cefadroxil U.S.P. ... 100mg as Cefadroxil Monohydrate
(Product Specs. U.S.P.)

CLINICAL PHARMACOLOGY:
Pharmacodynamic Properties:
Mechanism of Action:
Cefadroxil is a first-generation cephalosporin antibiotic. It is bactericidal, and acts by inhibiting synthesis of the bacterial cell wall. Bacterial cell wall is held rigid and protected against osmotic rupture by peptidoglycan. Cefadroxil inhibits the final cross linking stage of peptidoglycan production by binding to and inactivating transpeptidase, which is a penicillin binding protein on the inner surface of the bacterial cell membrane.

Microbiology:
- Beta-hemolytic streptococci
- Staphylococci, including penicillinase-producing strains
- Streptococcus (Diplococcus) pneumoniae
- Escherichia coli
- Proteus mirabilis
- Klebsiella species
- Moraxella (Branhamella) catarrhalis

Pharmacokinetic Properties
DROMAX is rapidly absorbed after oral administration. Following single dose of 500 mg, average peak serum concentrations were approximately 16 µg/ml. Measurable levels were present 12 hours after administration. The major of the drug is excreted unchanged in the urine within 24 hours. Peak urine concentrations are approximately 1800 µg/mL during the period following a single 500 mg oral dose. Increases in dosage generally produce a proportionate increase in DROMAX urinary concentration.

DROMAX is substantially excreted by the kidney, and dosage adjustment is indicated for patients with renal impairment. Because elderly patients are more likely to have decreased renal function care should be taken in dose selection, and it may be useful to monitor renal function.

THERAPEUTIC INDICATIONS:
DROMAX is indicated in the treatment of mild to moderate infections of the respiratory tract (Pharyngitis & tonsillitis), urinary tract, skin and skin structure infections and bone caused by susceptible organisms and as an alternative to penicillin in patients with a history of hypersensitivity reactions.

DOSAGE AND ADMINISTRATION:
Adults:
Urinary tract infections: For uncomplicated lower urinary tract infections (i.e. cystitis) the usual dosage is 1 to 2g daily in single (q.d.) or divided doses (b.i.d). For all other urinary tract infections the usual dosage is 2 g per day in divided doses (b.i.d).

Skin and skin structure infections: For skin and skin structure infections the usual dosage is 1 g per day in single (q.d.) or divided doses (b.i.d.).

Respiratory tract infections: Treatment of group A beta-hemolytic streptococcal pharyngitis and tonsillitis 1g per day in single (q.d.) or divided doses (b.i.d.) for 10 days.

Children:
The recommended daily dosage for children is 25-50mg/kg/day in two equally divided doses (every 12 hours). For pharyngitis, tonsillitis and Impetigo, the recommended daily dose may be administrated as single dose or in two equally divided doses (every 12 hours).

Child's Weight (Kg)	Drops 100mg/mL	125mg/5mL (25 mg/mL)	250mg/5ml (50 mg/mL)
4	0.5 - 1 dropperful	-	-
5	-	2.5 - 5 mL	-
10	-	5 - 10 mL	2.5 - 5 mL
15	-	7.5 - 15 mL	3.75 - 7.5 mL
20	-	10 - 20 mL	5 - 10 mL
25	-	12.5 - 25 mL	6.25 - 12.5 mL

Patients with Renal Impairment:
In patients with renal impairment, the dosage of cefadroxil monohydrate should be adjusted according to creatinine clearance rates to prevent drug accumulation. The following schedule is suggested. In adults, the initial dose is 1000 mg of DROMAX and the maintenance dose (based on the creatinine clearance rate [mL/min 1.73 M^2] is 500 mg at the time intervals listed below.

Creatinine Clearance	Dosage Interval
0 - 10mL/min	36 hours
10 - 25mL/min	24 hours
25 - 50mL/min	12 hours

Patients with creatinine clearance rates over 50 mL/min may be treated as if they were patients having normal renal function.

CONTRAINDICATIONS:
Contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS AND PRECAUTIONS:
Before starting therapy, check the hypersensitivity reaction to DROMAX, cephalosporins and penicillins. If an allergic reaction occurs, discontinue the drug. Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including DROMAX and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.

CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed ongoing antibiotic use not directed against difficile may need to be discontinued. Appropriate fluid and electrolyte management protein supplementation antibiotic treatment of difficile, and surgical evaluation should.be instituted as clinically indicated.

In patients with known or suspected renal impairment careful clinical observation and appropriate laboratory studies should be made prior to and during therapy. Prescribing DROMAX in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Prolonged use of DROMAX may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. DROMAX should be prescribed with caution in individuals with history of gastrointestinal disease particularly colitis.

Skipping doses or not completing the course of therapy may decrease the effectiveness of the immediate treatment and increase the likelihood that bacteria will develop resistance and will not be treatable by DROMAX or other antibacterial drugs in the future.
Positive direct Coombs tests have been reported during treatment with the cephalosporin antibiotics.

ADVERSE EFFECTS:
DROMAX is generally well-tolerated. The common side effects are gastrointestinal disturbances (diarrhoea), hypersensitivity reactions (skin rashes). Other side effects are nausea and vomiting. Other reactions reported rarely are genital pruritus, genital moniliasis, vaginitis. Sometimes it causes anaphylaxis, erythema multiforme, toxic epidermal necrolysis, fever, abdominal pain, super infection, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, and hemorrhage. Several cephalosporins have been implicated triggering seizures, particularly in patients with renal impairment.

USE IN PREGNANCY AND LACTATION:
Pregnancy:
Pregnancy Category B.
DROMAX should be used during pregnancy only if clearly needed.

Lactation:
Treatment should only be given if clearly needed.

OVERDOSE:
Ingestion of less than 250 mg/kg of cephalosporins is not associated with significant outcomes. No action is required other than general support and observation. For amounts greater than 250 mg/kg, induce gastric emptying. An average of 63% of a 1 g oral dose is extracted from the body during a 6-8 hours hemodialysis session.

METHOD OF RECONSTITUTION:
Suspension and Drops: Add a small quantity of pre boiled cool water in the bottle and shake well, then add more water upto the mark given on the bottle and shake well to make suspension.

SHELF LIFE: 3 Years

STORAGE & INSTRUCTIONS:
Tablets & Capsules:
Protect from heat, sunlight & moisture, store at room temperature (15°C-30°C)

Suspension & Drops:
Before reconstitution protect from heat, sunlight & moisture, store at room temperature (15°C-30°C).
Precautions: Once reconstituted the suspension should be used within 7 days if stored at room temperature (15°C-30°C) or 14 days if stored in a refrigerator (2°C-8°C).
Do not take open seal bottle.
Keep out of the reach of the children.
Close the bottle properly after use.
Shake well before use.
The expiration date refer to the product correctly stored at the required condition.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

PRESENTATION:
DROMAX (Cefadroxil) is supplied in:
DROMAX 500mg Capsule: Pack of 2x6's Capsule in cold form & cold seal (Alu Alu) Blister Pack.
DROMAX 1000mg Tablet: Pack of 2x6's Tablet in cold form & cold seal (Alu Alu) Blister Pack.
DROMAX Suspension 125mg/5ml (60ml): Pack Contains dry powder for 60ml suspension (After reconstitution).
DROMAX Suspension 250mg/5ml (60ml): Pack Contains dry powder for 60ml suspension (After reconstitution).
DROMAX 100mg/ml Drops: Pack Contains dry powder for 10ml drops (After reconstitution).

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

ٹیبلیٹس / کیپسولز:
دھوپ، گرمی اور نمی سے محفوظ کمرے کے درجہ حرارت ۱۵ - ۳۰ ڈگری سینٹی گریڈ پر رکھیں۔
سسپنشن / ڈراپس:
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تیار شدہ سسپنشن ریفریجریٹر (۲-۸ ڈگری سینٹی گریڈ) میں رکھنے کی
صورت میں ۱۴ دن اور کمرے کے درجہ حرارت (۱۵-۳۰ ڈگری سینٹی گریڈ) میں
۷ دن کے اندر استعمال کریں۔ کھلی سیل والی بوتل نہ لیں۔
بچوں کی پہنچ سے دور رکھیں۔ استعمال کے بعد ڈھکن کو اچھی طرح بند رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

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ISO 9001:2015 Certified Company