STABILITY
See expiry on the pack

Presentation:
Velora (Cephradine) Capsules 250mg are available in pack of 12's.
Velora (Cephradine) Capsules 500mg are available in pack of 12's.
Velora (Cephradine) Powder for Oral Suspension 125mg/5mL is available in 60mL.
Velora (Cephradine) Powder for Oral Suspension 250mg/5mL is available in 60mL.

INSTRUCTIONS:
Keep out of reach of children.
Avoid exposure to heat,light and humidity.
Store between 15 to 30C.
Improper storage may deteriorate the medicine.
The reconstituted suspension should be kept at 8-15"C, so that potency of the product remains stable and be used within 14 days.

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

Manufactured by:
Platinum
Pharmaceuticals (Pvt.) Ltd.
A-20, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

QAR NO. AW19 - 0456

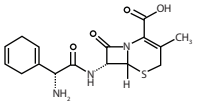
Velora
(Cephradine)

Capsules 250mg & 500mg
Powder for Oral Suspension 125mg/5mL & 250mg/5mL

ویلورا
(سفیراڈین)

۲۵۰ ملی گرام/۵۰۰ ملی گرام کیپسول
۱۲۵ ملی گرام/ ۵ ملی لیٹر، ۲۵۰ ملی گرام/ ۵ ملی لیٹر سسپنشن

DESCRIPTION
Velora (Cephradine) is a first-generation cephalosporin antibacterial given orally and by parenteral route in the treatment of susceptible infections and in the prophylaxis of infections during surgical procedures. Chemically, cephradine is (6R,7R)-7-[(R)-2-Amino-2-(1,4-cyclohexadien-1-yl)acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.
The molecular formul a is C16H19N3O4S and the structural formula is:



QUALITATIVE & QUANTITATIVE COMPOSITION
Velora (Cephradine) is available for oral administration as:

Velora Capsules 250mg
Each capsule contains:
Cephradine monohydrate equivalent to Cephradine BP… 250mg

Velora Capsules 500mg
Each capsule contains:
Cephradine monohydrate equivalent to Cephradine BP… 500mg

Velora Powder for Oral Suspension 125mg/5ml
Each reconstituted 5ml contains:
Cephradine monohydrate equivalent to Cephradine BP… 125mg

Velora Powder for Oral Suspension 250mg/5ml
Each reconstituted 5ml contains:
Cephradine monohydrate equivalent to Cephradine BP… 250mg

CLINICAL PHARMACOLOGY
Mechanism of Action
Cephradine inhibits the final transpeptidation step of the peptidoglycan synthesis in bacterial cell wall by binding to one or more of the penicillin binding proteins (PBPs), thus arresting cell wall synthesis leading to bacterial cell death.
Microbiology
The following organisms have shown in vitro sensitivity to cephradine:
Gram-positive:
Staphylococci (both penicillin sensitive and resistant strains), Streptococci, Streptococcus pyogenes (beta haemolytic) and Streptococcus pneumonia.
Gram-negative:
Escherichia coli, Klebsiella spp., Proteus mirabilis, Haemophilus influenza, Shigella spp., Salmonella spp., (including Salmonella typhi) and Neisseria spp.
Pharmacokinetics
Cephradine is rapidly and almost completely absorbed from the gastrointestinal tract after oral doses. Doses of 250mg, 500mg and 1g given orally produces peak plasma concentrations of about 9µg/mL, 17µg/mL and 24µg/mL respectively at 1 hour. Cephradine is widely distributed to body tissues and fluids, but does not enter the CSF in significant quantities. It crosses the placenta into fetal circulation and is distributed in small amounts into breast milk. Therapeutic concentrations may be found in bile. Only 8% to 12% is bound to plasma proteins. A plasma half-life of about 1 hour has been reported. Cephradine is excreted unchanged in the urine by glomerular filtration and tubular secretion. Over 90% of an oral dose is being recovered within 6 hours. Peak urinary concentrations of about 3µg/mL have been achieved after a 500mg oral dose.

D1A

Platinum
Pharmaceuticals (Pvt.) Ltd.

Product : Velora
Components : Velora Leaflet

Dimension : 85mm x 145
Started Date : 25-11-2019
Concepts By : Khalid Masood
Design By : Rahil Rahim
QAR No. AW19-0456

Colors
Pantone black C

Department	*Marketing*	*Regulatory*	*Quality Control*	*Quality Control Head*	*Procurement*
Remarks					
Signature					
Date / Time					

Special population
Renal Impairment
Plasma concentration of cephradine is prolonged in patients with renal impairment.

THERAPEUTIC INDICATIONS
Velora (Cephradine) is indicated in the treatment of following infections:

Upper respiratory tract infections:
Sinusitis, pharyngitis, tonsillitis, laryngo-tracheo bronchitis and otitis media.

Lower respiratory tract infections:
Acute and chronic bronchitis, lobar and bronchopneumonia.

Skin and soft tissue infections:
Impetigo, abscess, cellulitis and frunculosis.

Urinary tract infections:
Cystitis, urethritis and pyelonephritis.

Gastrointestinal tract infections:
Bacillary dysentery, enteritis and peritonitis.

DOSAGE & ADMINISTRATION
Velora (Cephradine) may be given with regards to meal.
Adults
Respiratory tract infections, skin and soft tissue infections:

The usual dose is 250mg or 500mg four times daily or 500mg or 1g twice daily depending upon the severity of infection.

Urinary tract infection:

The usual dose is 500mg four times daily or 1g twice daily. This may need to be increased for severe or chronic infections. Prolonged intensive therapy is needed for complications such as prostatitis and epididymitis.

Gastrointestinal tract infections:
500mg three or four times daily.

Pediatrics
The usual dose is 25 to 50mg/kg/day total, given in two or four equally divided doses. For otitis media daily doses from 75 to 100mg/kg in divided doses every 6 to 12 hours are recommended. The dose should not exceed 4g per day.

Duration of treatment
For severe or chronic infection larger dose of up to 1g four times daily may be given. Administration should be continued for a minimum of 48 - 72 hours after the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. For infections caused by hemolytic strains of streptococci, a minimum of 10 days treatment is recommended to guard against the risk of rheumatic fever or glomerulo-nephritis. For the treatment of chronic urinary tract infections, frequent bacteriological and clinical appraisal is necessary during therapy and may be necessary for several months afterwards. Persistent infections may require treatment for several weeks. Smaller doses than those indicated should not be used. Doses for children should not exceed those recommended for adults.

Special population
Renal Impairment Patients not on dialysis:
The following dosage schedule guideline is based on a dosage of 500mg 6 hourly and on creatinine clearance. Further modification in the dosage schedule may be required because of the dosage selected and individual variation.

Creatinine clearance interval	Dose	Time
> 20 mL/min	500 mg	6 hours
5 - 20 mL/min	250 mg	6 hours
< 5 mL/min	250 mg	12 hours

Patients on chronic, intermittent hemodialysis

250 mg	At start of hemodialysis
250 mg	6 - 12 hours after start
250 mg	36 - 48 hours after start
250 mg	At start of next hemodialysis if >30 hours after previous dose

Children may require dosage modification proportional to their weight and severity of infection.

Direction for Preparation Oral Suspension
Fill previously boiled and cooled water upto the given mark on the bottle and shake well. After reconstitution, the suspension should be stored in a refrigerator (2°C-8°C) and can be used within 14 days. If stored at 15°C-30°C after reconstitution, the suspension can be used within 7 days. Shake well before use.

ADVERSE REACTIONS
The most common adverse effects of oral cephalosporins are generally gastrointestinal disturbances and hypersensitivity reactions. The following adverse reactions have been reported following the use of cephradine:
Gastrointestinal: Glossitis, nausea, vomiting, diarrhea or loose stools, tenesmus, abdominal paincolitis and pseudomembranous colitis.
Hypersensitivity: Mild urticaria or skin rash, edema, erythema, pruritis, joint pain and drug fever.
Hematologic: Mild, transient eosinophilia, leukpenia and neutropenia.
Other: Headache, dizziness, dyspnea, paresthesia, candidal overgrowth and vaginitis.

CONTRAINDICATIONS
Cephradine is contraindicated in patients with known hypersensitivity to cephradine or to any excipient of the product.

PRECAUTIONS
- Cephradine should be used with caution in patients with known hypersensitivity to penicillins because of partial allergenicity between penicillins and the cephalosporins.

- Caution should be exercised in patients with renal failure and dosage should be reduced.

- False positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution or with reagent tablets such as Clinitest following administration of cephradine.

- Prolonged use with antibiotics may result in overgrowth of non-susceptible microorganisms.

Pregnancy
There are no adequate and well-controlled studies in pregnant women. As with all medicines, use should be avoided in pregnancy especially in the first trimester, unless considered essential by the physician.

Nursing mothers
Cephradine is excreted in breast milk and therefore should be used with caution in nursing mothers.

Drug Interactions
- Concomitant administration with loop diuretics may increase nephrotoxicity of cephalosporins.

- Concomitant administration of probenecid raises serum concentrations of cephradine, by reducing renal clearance.

OVERDOSAGE
There is no relevant data available on overdosage. In the event of overdose, the patient be treated symptomatically and supportive measures should be instituted as required.

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