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

U.V.A.CEF DRY SYRUP

1. Generic Name

Cefpodoxime Proxetil Oral Suspension I.P.

2. Qualitative and quantitative composition

U.V.A.CEF 50

Each combipack contains:

A) One bottle of Cefpodoxime Proxetil Oral Suspension

Each 5ml of the reconstituted suspension contains :

Cefpodoxime Proxetil I.P. equivalent to Cefpodoxime ….50mg

Excipients q.s.

Colour : Sunset Yellow Supra

B) One Ampoule (FFS) Containing 20ml sterile water for reconstitution

U.V.A.CEF 100

Each combipack contains:

A) One bottle of Cefpodoxime Proxetil Oral Suspension

Each 5ml of the reconstituted suspension contains :

Cefpodoxime Proxetil I.P. equivalent to Cefpodoxime ….100mg

Excipients q.s.

Colour : Sunset Yellow Supra

B) One Ampoule (FSS) Containing 20ml sterile water for reconstitution

3. Dosage form and strength

Dosage Form: Powder for suspension

Strength: 50mg & 100mg

4. Clinical particulars

4.1 Therapeutic indication

Cefpodoxime proxetil is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

Acute otitis media caused by *Streptococcus pneumoniae* (excluding penicillin resistant strains), *Streptococcus pyogenes*, *Haemophilus influenzae* (including beta-lactamase-producing strains), or *Moraxella* (*Branhamella*) *catarrhalis* (including beta-lactamase-producing strains).

Pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes*.

NOTE: Only penicillin by the intramuscular route of administration has been shown to be effective in the prophylaxis of rheumatic fever. Cefpodoxime proxetil is generally effective in the eradication of streptococci from the oropharynx. However, data establishing the efficacy of cefpodoxime proxetil for the prophylaxis of subsequent rheumatic fever are not available.

Community-acquired pneumonia caused by *S. pneumoniae* or *H. Influenzae* (including beta-lactamase-producing strains).

Acute bacterial exacerbation of chronic bronchitis caused by *S. pneumoniae, H. influenzae* (non-beta-lactamase-producing strains only), or *M. catarrhalis*. Data are insufficient at this time to establish efficacy in patients with acute bacterial exacerbations of chronic bronchitis caused by beta-lactamase-producing strains of H. influenzae.

Acute, uncomplicated urethral and cervical gonorrhea caused by *Neisseria gonorrhoeae* (including penicillinase-producing strains).

Acute, uncomplicated ano-rectal infections in women due to *Neisseria gonorrhoeae* (including penicillinase-producing strains).

NOTE: The efficacy of cefpodoxime in treating male patients with rectal infections caused by *N. gonorrhoeae* has not been established. Data do not support the use of cefpodoxime proxetil in the treatment of pharyngeal infections due to *N. gonorrhoeae* in men or women.

Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (including penicillinase-producing strains) or *Streptococcus pyogenes*. Abscesses should be surgically drained as clinically indicated.

NOTE: In reported clinical trials, successful treatment of uncomplicated skin and skin structure infections was dose-related. The effective therapeutic dose for skin infections was higher than those used in other recommended indications.

Acute maxillary sinusitis caused by *Haemophilus influenzae* (including betalactamase-producing strains), *Streptococcus pneumoniae,* and *Moraxella catarrhalis*.

Uncomplicated urinary tract infections (cystitis) caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, or *Staphylococcus saprophyticus*.

NOTE: In considering the use of cefpodoxime proxetil in the treatment of cystitis, cefpodoxime proxetil's lower bacterial eradication rates should be weighed against the increased eradication rates and different safety profiles of some other classes of approved agents.

Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify causative organisms and to determine their susceptibility to cefpodoxime. Therapy may be instituted while awaiting the results of these studies. Once these results become available, antimicrobial therapy should be adjusted accordingly.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefpodoxime Proxetil and other antibacterial drugs, Cefpodoxime Proxetil should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

4.2 Posology and method of administration

Posology

Dosage should be as directed by the Physician.

Method of administration

Direction for reconstitution: To make 30ml of suspension: Shake the bottle well to loosen the powder. Use enclosed sterile water supplied with this pack to reconstitute the powder up to the mark on the bottle. Discard remaining sterile water. After reconstitution keep the bottle in a refrigerator when not in use and use the reconstitute suspension within 14 days.

4.3 Contraindications

Cefpodoxime proxetil is contraindicated in patients with a known allergy to cefpodoxime or to the cephalosporin group of antibiotics.

4.4 Special warnings and precautions for use

Before therapy with cefpodoxime proxetil is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefpodoxime, other cephalosporins, penicillins, or other drugs. If cefpodoxime is to be administered to penicillin sensitive patients, caution should be exercised because cross hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefpodoxime proxetil occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen,intravenous fluids, intravenous antihistamine, and airway management, as clinically indicated

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefpodoxime proxetil 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.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. 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 *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

A concerted effort to monitor for C. difficile in cefpodoxime-treated patients with diarrhea was undertaken because of an increased incidence of diarrhea associated with *C. difficile* in early trials in normal subjects. *C. difficile* organisms or toxin was reported in 10% of the cefpodoxime-treated adult patients with diarrhea; however, no specific diagnosis of pseudomembranous colitis was made in these patients.

Reports of pseudomembranous colitis associated with the use of cefpodoxime proxetil have been also been received.

Precautions

In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of cefpodoxime proxetil should be reduced because high and prolonged serum antibiotic concentrations can occur in such individuals following usual doses. Cefpodoxime, like other cephalosporins, should be administered with caution to patients receiving concurrent treatment with potent diuretics.

As with other antibiotics, prolonged use of cefpodoxime proxetil may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Prescribing Cefpodoxime Proxetil 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.

4.5 Drugs interactions

Antacids

Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H2 blockers reduces peak plasma levels by 24% to 42% and the extent of absorption by 27% to 32%, respectively. The rate of absorption is not altered by these concomitant medications. Oral anti-cholinergics (e.g., propantheline) delay peak plasma levels (47% increase in Tmax), but do not affect the extent of absorption (AUC).

Probenecid

As with other beta-lactam antibiotics, renal excretion of cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC and 20% increase in peak cefpodoxime plasma levels.

Nephrotoxic drugs

Although nephrotoxicity has not been noted when cefpodoxime proxetil was given alone, close monitoring of renal function is advised when cefpodoxime proxetil is administered concomitantly with compounds of known nephrotoxic potential.

Drug/Laboratory Test Interactions

Cephalosporins, including cefpodoxime proxetil, are known to occasionally induce a positive direct Coombs' test.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Not Applicable

4.7 Effects on ability to drive and use machines

It has not been established that Cefpodoxime Proxetil impairs your ability to drive or operate any tools or machinery. However, you should not drive or use machines until it is established that your ability to perform such activities is not affected.

4.8 Undesirable effects

In reported clinical trials using multiple doses of cefpodoxime proxetil granules for oral suspension, 2128 pediatric patients (93% of whom were less than 12 years of age) were treated with the recommended dosages of cefpodoxime (10 mg/kg/day Q 24 hours or divided Q 12 hours to a maximum equivalent adult dose).

There were no deaths or permanent disabilities in any of the patients in these studies. Twenty-our patients (1.1%) discontinued medication due to adverse events thought possibly or probably related to study drug. Primarily, these discontinuations were for gastrointestinal disturbances, usually diarrhea, vomiting, or rashes.
Adverse events thought possibly or probably related, or of unknown relationship to cefpodoxime proxetil for oral suspension in multiple dose clinical trials (N=2128 patients treated with cefpodoxime) were:

Incidence Greater Than 1%

Diarrhoea	6%

The incidence of diarrhea in infants and toddlers (age 1 month to 2 years) was 12.8%.

Diaper rash/Fungal skin rash	2% (includes moniliasis)

The incidence of diaper rash in infants and toddlers was 8.5%.

Other skin rashes	1.8%
Vomiting	2.3%

Incidence Less Than 1%:

Body – Localized abdominal pain, abdominal cramp, headache, monilia, generalized abdominal pain, asthenia, fever, fungal infection.

Digestive: Nausea, monilia, anorexia, dry mouth, stomatitis, pseudomembranous colitis.

Hemic & Lymphatic: Thrombocythemia, positive direct Coombs' test, eosinophilia, leukocytosis, leukopenia, prolonged partial thromboplastin time, thrombocytopenic purpura.

Metabolic & Nutritional: Increased SGPT.

Musculo-Skeletal: Myalgia.

Nervous: Hallucination, hyperkinesia, nervousness, somnolence.

Respiratory: Epistaxis, rhinitis.

Skin: Skin moniliasis, urticaria, fungal dermatitis, acne, exfoliative dermatitis, maculopapular rash.

Special Senses: Taste perversion.

Laboratory Changes

Significant laboratory changes that have been reported in adult and pediatric patients in reported clinical trials of cefpodoxime proxetil, without regard to drug relationship, were:

Hepatic: Transient increases in AST (SGOT), ALT (SGPT), GGT, alkaline phosphatase, bilirubin, and LDH.

Hematologic: Eosinophilia, leukocytosis, lymphocytosis, granulocytosis, basophilia, monocytosis, thrombocytosis, decreased hemoglobin, decreased hematocrit, leukopenia, neutropenia, lymphocytopenia, thrombocytopenia, thrombocythemia, positive Coombs' test, and prolonged PT, and PTT.

Serum Chemistry: Hyperglycemia, hypoglycemia, hypoalbuminemia, hypoproteinemia, hyperkalemia, and hyponatremia.

Renal: Increases in BUN and creatinine.

Most of these abnormalities were transient and not clinically significant.

Post-marketing Experience

The following serious adverse experiences have been reported:

allergic reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme and serum sickness-like reactions, pseudomembranous colitis, bloody diarrhea with abdominal pain, ulcerative colitis, rectorrhagia with hypotension, anaphylactic shock, acute liver injury, in utero exposure with miscarriage, purpuric nephritis, pulmonary infiltrate with eosinophilia, and eyelid dermatitis. One death was attributed to pseudomembranous colitis and disseminated intravascular coagulation.

Cephalosporin Class Labeling

In addition to the adverse reactions listed above which have been observed in patients treated with cefpodoxime proxetil, the following adverse reactions and altered laboratory tests have been reported for cephalosporin class antibiotics:

Adverse Reactions and Abnormal Laboratory Tests: Renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, serum sickness-like reaction, hemorrhage, agranulocytosis, and pancytopenia.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

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 any point of contact of Torrent Pharma available at:
http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

4.9 Overdose

In acute rodent toxicity studies, a single 5 g/kg oral dose produced no adverse effects.

In the event of serious toxic reaction from overdosage, haemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised.

The toxic symptoms following an overdose of beta-lactam antibiotics may include nausea, vomiting, epigastric distress, and diarrhoea.

5. Pharmacological properties

5.1 Mechanism of Action

Cefpodoxime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefpodoxime has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of Gram-negative and Gram-positive bacteria.

Mechanism of Resistance

Resistance to Cefpodoxime is primarily through hydrolysis by beta-lactamase, alteration of penicillin-binding proteins (PBPs), and decreased permeability.

5.2 Pharmacodynamic properties

Cefpodoxime has been shown to be active against most isolates of the following bacteria, both in vitro and in clinical infections as described in the Indications section:

Gram-positive bacteria

Staphylococcus aureus (methicillin-susceptible strains, including those producing penicillinases)

Staphylococcus saprophyticus

Streptococcus pneumoniae (excluding penicillin-resistant isolates)

Streptococcus pyogenes

Gram-negative bacteria

Escherichia coli

Klebsiella pneumoniae

Proteus mirabilis

Haemophilus influenzae (including beta-lactamase producing isolates)

Moraxella catarrhalis

Neisseria gonorrhoeae (including penicillinase-producing isolates)

The following in vitro data are available, but their clinical significance is unknown. At least 90 percent of the following microorganisms exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for Cefpodoxime.

However, the efficacy of Cefpodoxime in treating clinical infections due to these microorganisms has not been established in adequate and well-controlled clinical trials.

Gram-positive bacteria

Streptococcus agalactiae

Streptococcus spp. (Groups C, F, G)

Gram-negative bacteria

Citrobacter diversus

Klebsiella oxytoca

Proteus vulgaris

Providencia rettgeri

Haemophilus parainfluenzae

Anaerobic Gram-positive bacteria

Peptostreptococcus magnus

Susceptibility Test Methods

When available, the clinical microbiology laboratory should provide the results of in vitro susceptibility test results for antimicrobial drug products used in resident hospitals to the physician as periodic reports that describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid the physician in selecting an antibacterial drug product for treatment.

5.3 Pharmacokinetic properties

Absorption and Excretion:

Cefpodoxime proxetil is a prodrug that is absorbed from the gastrointestinal tract and de-esterified to its active metabolite, cefpodoxime. In reported studies, following oral administration of 100 mg of cefpodoxime proxetil to fasting subjects, approximately 50% of the administered cefpodoxime dose was absorbed systemically. Over the recommended dosing range (100 to 400 mg), approximately 29 to 33% of the administered cefpodoxime dose was excreted unchanged in the urine in 12 hours. There is minimal metabolism of cefpodoxime in *vivo*.

Effects of Food:

When a 200 mg dose of the suspension was taken with food, the extent of absorption (mean AUC) and mean peak plasma concentration in fed subjects were not significantly different from fasted subjects, but the rate of absorption was slower with food (48% increase in Tmax).

In reported studies, In adult subjects, a 100 mg dose of oral suspension produced an average peak cefpodoxime concentration of approximately 1.5 mcg/mL (range: 1.1 to 2.1 mcg/mL), which is equivalent to that reported following administration of the 100 mg tablet. Time to peak plasma concentration and area under the plasma concentration-time curve (AUC) for the oral suspension were also equivalent to those produced with film-coated tablets in adults following a 100 mg oral dose.

The pharmacokinetics of cefpodoxime were investigated in 29 patients aged 1 to 17 years. Each patient received a single, oral, 5 mg/kg dose of cefpodoxime oral suspension. Plasma and urine samples were collected for 12 hours after dosing. The plasma levels reported from this study are as follows:

Cefpodoxime plasma levels (mcg/mL) in fasted patiENTS (1 to 17 years of age) after suspension administration.

Dose	Time After Oral Ingestion						
(Cefpodoxime Equivalents)	1 hr	2 hr	3 hr	4 hr	6 hr	8 hr	12 hr
5 mg/kg[1]	1.4	2.1	2.1	1.7	0.9	0.4	0.09
[1]Dose did not exceed 200 mg.							

Distribution

Protein binding of cefpodoxime ranges from 22 to 33% in serum and from 21 to 29% in plasma.

Skin Blister

Following multiple-dose administration every 12 hours for 5 days of 200 mg or 400 mg cefpodoxime proxetil, the mean maximum cefpodoxime concentration in skin blister fluid averaged 1.6 and 2.8 mcg/mL, respectively. Skin blister fluid cefpodoxime levels at 12 hours after dosing averaged 0.2 and 0.4 mcg/mL for the 200 mg and 400 mg multiple-dose regimens, respectively.

Tonsil Tissue

Following a single, oral 100 mg cefpodoxime proxetil , the mean maximum cefpodoxime concentration in tonsil tissue averaged 0.24 mcg/g at 4 hours post-dosing and 0.09 mcg/g at 7 hours post-dosing. Equilibrium was achieved between plasma and tonsil tissue within 4 hours of dosing. No detection of cefpodoxime in tonsillar tissue was reported 12 hours after dosing. These results demonstrated that concentrations of cefpodoxime exceeded the MIC_{90} of S. pyogenes for at least 7 hours after dosing of 100 mg of cefpodoxime proxetil.

Lung Tissue

Following a single, oral 200 mg cefpodoxime proxetil , the mean maximum cefpodoxime concentration in lung tissue averaged 0.63 mcg/g at 3 hours post-dosing, 0.52 mcg/g at 6 hours postdosing, and 0.19 mcg/g at 12 hours post-dosing. The results of this study indicated that cefpodoxime penetrated into lung tissue and produced sustained drug concentrations for at least 12 hours after dosing at levels that exceeded the MIC90 for S. pneumoniae and H. influenzae.

CSF

Adequate data on CSF levels of cefpodoxime are not available.

Effects of Decreased Renal Function

Elimination of cefpodoxime is reduced in patients with moderate to severe renal impairment (<50 mL/min creatinine clearance). In subjects with mild impairment of renal function (50 to 80 mL/min creatinine clearance), the average plasma half-life of cefpodoxime was 3.5 hours. In subjects with moderate (30 to 49 mL/min creatinine clearance) or severe renal impairment (5 to 29 mL/min creatinine clearance), the half-life increased to 5.9 and 9.8 hours, respectively. Approximately 23% of the administered dose was cleared from the body during a standard 3-hour hemodialysis procedure.

Effect of Hepatic Impairment (cirrhosis)

Absorption was somewhat diminished and elimination unchanged in patients with cirrhosis. The mean cefpodoxime T1/2 and renal clearance in cirrhotic patients were similar to those derived in studies of healthy subjects. Ascites did not appear to affect values in cirrhotic subjects. No dosage adjustment is recommended in this patient population.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Carcinogenesis, Mutagenesis, Impairment of Fertility

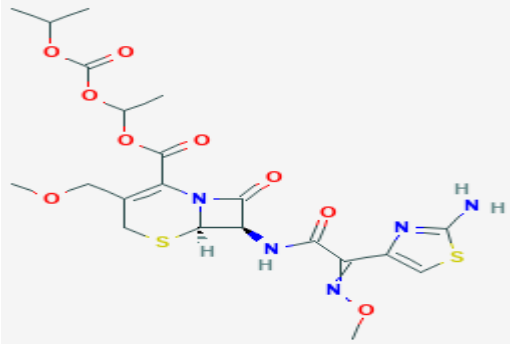
Long-term animal carcinogenesis studies of cefpodoxime proxetil have not been performed. Mutagenesis studies of cefpodoxime, including the Ames test both with and without metabolic activation, the chromosome aberration test, the unscheduled DNA synthesis assay, mitotic recombination and gene conversion, the forward gene mutation assay and the in vivo micronucleus test, were all negative. No untoward effects on fertility or reproduction were noted when 100 mg/kg/day or less (2 times the human dose based on mg/m2) was administered orally to rats.

Teratogenic Effects

Cefpodoxime proxetil was neither teratogenic nor embryocidal when administered to rats during organogenesis at doses up to 100 mg/kg/day (2 times the human dose based on mg/m2) or to rabbits at doses up to 30 mg/kg/day (1 to 2 times the human dose based on mg/m2).

7. Description

Cefpodoxime proxetil is an orally administered, extended spectrum, semisynthetic antibiotic of the cephalosporin class. Cefpodoxime proxetil is chemically 1-propan-2-yloxycarbonyloxyethyl (6R,7R)-7-[[2-(2-amino-1,3-thiazol-4-yl)-2-methoxyiminoacetyl]amino]-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate having molecular weight of 557.6 g/mol and molecular formula is $C_{21}H_{27}N_5O_9S_2$. The chemical structure is



U.V.A.CEF 50

Cefpodoxime Proxetil Oral Suspension is white to off-white coloured, granular powder.

U.V.A.CEF 100

Cefpodoxime Proxetil Oral Suspension is white to off-white coloured, granular powder.

8. Pharmaceutical particulars

8.1 Incompatibilities

None stated

8.1 Shelf-life

Do not use later than the date of expiry.

8.2 Packaging information

U.V.A CEF 50 Dry Syrup is available in combipack containing one bottle and one ampoule in a carton.

U.V.A CEF 100 Dry Syrup is available in combipack containing one bottle and one ampoule in a carton.

8.3 Storage and handing instructions

Store in a cool (below 25°C) and dry place. Protect from light.

9. Patient counselling information

U.V.A.CEF DRY SYRUP

Cefpodoxime Proxetil Oral Suspension I.P.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Keep all medicines out of reach of children
- If you have any further questions, ask your doctor or pharmacist.
- **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?

9.1 What U.V.A.CEF DRY SYRUP is and what it is used for

Cefpodoxime is an antibiotic medicine (a medicine used to treat bacterial infections).

U.V.A.CEF DRY SYRUP is used:

- for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below.
- Ear infections (Acute otitis media)
- inflammation of the pharynx (Pharyngitis) and tonsil inflammation (tonsillitis)
- Community-acquired pneumonia
- Acute bacteria
- exacerbation of chronic bronchitis (Inflammation of the lining of bronchial tubes)
- Acute, uncomplicated urethral and cervical gonorrhoea

- Acute, uncomplicated ano-rectal infections in women
- Uncomplicated skin and skin structure infection
- Acute maxillary sinusitis(Sinus Infection)
- Uncomplicated urinary tract infections (cystitis)

9.2 What you need to know before you take U.V.A.CEF DRY SYRUP

Do not take U.V.A.CEF DRY SYRUP

If you are allergic to Cefpodoxime Proxetil or any of the other ingredients of this medicine

Warnings and precautions

- Talk to your doctor before taking U.V.A.CEF DRY SYRUP
- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- Antibacterial drugs including U.V.A.CEF DRY SYRUP should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold).
- Although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by U.V.A.CEF DRY SYRUP or other antibacterial drugs in the future.
- Diarrhoea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, you should contact their physician as soon as possible.

Infants

Safety and efficacy in infants less than 2 months of age have not been established.

Other medicines and U.V.A.CEF DRY SYRUP

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Driving and using machines

It has not been established that U.V.A.CEF DRY SYRUP impairs your ability to drive or operate any tools or machinery. However, you should not drive or use machines until it is established that your ability to perform such activities is not affected.

9.3 How to take U.V.A.CEF DRY SYRUP

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Direction for reconstitution: To make 30ml of suspension: Shake the bottle well to loosen the powder. Use enclosed sterile water supplied with this pack to reconstitute the powder up to the

mark on the bottle. Discard remaining sterile water. After reconstitution keep the bottle in a refrigerator when not in use and use the reconstitute suspension within 14 days.

If you take more U.V.A.CEF DRY SYRUP than you should

Contact your doctor if you took more doses than you should. Your doctor will establish the best possible treatment of overdose.

The possible side effects of an overdose of U.V.A.CEF DRY SYRUP are nausea, vomiting, pain or discomfort right below your ribs in the area of your upper abdomen (epigastric distress), and diarrhoea.

If you forget to take U.V.A.CEF DRY SYRUP:

Contact your doctor if you have missed one or more doses.

Do not take a double dose to make up for a forgotten dose.

If you stop taking U.V.A.CEF DRY SYRUP

Should your doctor decide to stop your U.V.A.CEF DRY SYRUP treatment, he/she will instruct you about the gradual withdrawal of U.V.A.CEF DRY SYRUP.

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

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately or contact the casualty department at your nearest hospital, if you get any of the following serious side effects:

Diarrhoea, Diaper rash/Fungal skin rash, Other skin rashes, Vomiting

- Localized abdominal pain, abdominal cramp, headache, monilia, generalized abdominal pain, asthenia, fever, fungal infection.
- Nausea, monilia, anorexia, dry mouth, stomatitis, pseudomembranous colitis.
- Thrombocythemia, positive direct Coombs' test, eosinophilia, leukocytosis, leukopenia, prolonged partial thromboplastin time, thrombocytopenic purpura.
- Increased SGPT
- Myalgia
- Hallucination, hyperkinesia, nervousness, somnolence
- Epistaxis, rhinitis
- Skin moniliasis, urticaria, fungal dermatitis, acne, exfoliative dermatitis, maculopapular rash
- Taste perversion

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store U.V.A.CEF DRY SYRUP

Store in a cool (below 25°C) and dry place. Protect from light.

9.6 Contents of the pack and other information

What **U.V.A.CEF DRY SYRUP** contains

The active substances are Cefpodoxime Proxetil.

Cefpodoxime Proxetil I.P. equivalent to Cefpodoxime…....50/100 mg

10. Details of manufacturer

Manufactured in India by:

Hetero Labs Limited (Unit - I)

Village: Kalyanpur, Chakkan Road, Tehsil: Baddi,

Distt: Solan, Himachal Pradesh – 173205.

11. Details of permission or licence number with date

Mfg. Lic. No. MB/05/194 issued on 19.04.2016

12. Date of revision

Not Applicable

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/UVA CEF DRY SYRUP 50, 100 mg/AUG-20/01/PI