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OMNIX CV Tablets (Cefixime + Clavulanic acid)

Qualitative And Quantitative Composition

OMNIX CV Tablets
Each film-coated tablet contains:
Cefixime, USP, as a trihydrate equivalent to anhydrous Cefixime.....200 mg
Potassium Clavulanate diluted, IP, equivalent to Clavulanic Acid .....125 mg
Colour: Titanium Dioxide, IP

Dosage Form And Strength

Cefixime 200mg + Clavulanic Acid 125mg Oral Tablet

Clinical Particulars

▶ Therapeutic Indications

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefixime and other antibacterial drugs, cefixime should be used only to treat 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 antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
OMNIX CV Tablets are indicated in the treatment of adults and paediatric patients, 6 months of age or older, with the following infections when caused by susceptible isolates of the designated bacteria:

Uncomplicated urinary tract infections (e.g. cystitis, cystourethritis, uncomplicated pyelonephritis) caused by *Escherichia coli* and *Proteus mirabilis*.

Otitis media caused by *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pyogenes.*

Note: For patients with otitis media caused by *Streptococcus pneumoniae*, overall response was approximately 10% lower for cefixime than for the comparator.

Pharyngitis and tonsillitis caused by *Streptococcus pyogenes*.

Note: Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* infections. Cefixime is generally effective in the eradication of *Streptococcus pyogenes* from the nasopharynx; however, data establishing the efficacy of cefixime in the subsequent prevention of rheumatic fever is not available.

Acute exacerbations of chronic bronchitis caused by *Streptococcus pneumoniae* and *Haemophilus influenzae.*

Uncomplicated gonorrhoea (cervical/urethral) caused by *Neisseria gonorrhoeae* (penicillinase- and non-penicillinase-producing isolates).

For the treatment of enteric (typhoid) fever.

▶ Posology and Method of Administration

Adults and Children over 10 Years of Age

One tablet twice daily.

The usual course of treatment is 7 days. This may be continued for up to 14 days if required

Geriatric Patients

Elderly patients may be given the same dose as recommended for adults. Renal function should be assessed, and dosage should be adjusted in severe renal impairment.

Patients with Renal Impairment

Cefixime may be administered in the presence of impaired renal function. Normal dose and schedule may be given in patients with creatinine clearances of 20 mL/min or greater. In patients whose creatinine clearance is less than 20 mL/min, it is recommended that a dose of 200 mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis (CAPD) or haemodialysis should follow the same recommendation as that for patients with creatinine clearances of less than 20 mL/min.

▶ Contraindications

Cefixime is contraindicated in patients with a known allergy to cefixime or other cephalosporins or any of the other components of the product.

▶ Special Warnings and Precautions for Use

Hypersensitivity Reactions

Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. There is some evidence of partial cross-allergenicity between the penicillins and cephalosporins. Before therapy with cefixime is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins or other drugs. If this product is to be given 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 cefixime occurs, discontinue the drug.

Clostridium difficile-associated Diarrhoea

Clostridium difficile-associated diarrhoea (CDAD) has been reported with the use of nearly all antibacterial agents, including cefixime, and may range in severity from mild diarrhoea 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 isolates 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 diarrhoea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over 2 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.

Dose Adjustment in Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing CAPD and haemodialysis. Patients on dialysis should be monitored carefully.

Coagulation Effects

Cephalosporins, including cefixime, may be associated with a fall in prothrombin activity. Those at risk include patients

with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilised on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Encephalopathy

Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.

Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome and drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in some patients on cefixime. When severe cutaneous adverse reactions occur, cefixime should be discontinued and appropriate therapy and/or measures should be taken. Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs.

Haemolytic Anaemia

Drug-induced haemolytic anaemia, including severe cases with a fatal outcome, has been described for cephalosporins (as a class). The recurrence of haemolytic anaemia after re-administration of cephalosporins in a patient with a history of cephalosporin (including cefixime)-associated haemolytic anaemia has also been reported.

Acute Renal Failure

As with other cephalosporins, cefixime may cause acute renal failure, including tubulointerstitial nephritis as an underlying pathological condition. When acute renal failure occurs, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Development of Drug-resistant Bacteria

Prescribing cefixime in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Drug Interactions

Carbamazepine

Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Warfarin and Anticoagulants

In common with other cephalosporins, increases in prothrombin times with or without clinical bleeding have been noted in a few patients. Care should, therefore, be taken in patients receiving anticoagulation therapy.

Effects on Laboratory Tests

A false-positive reaction for ketones in the urine may occur with tests using nitroprusside, but not with those using nitroferricyanide.

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.

A false-positive direct Coomb’s test has been reported during treatment with other cephalosporins; therefore, it should be recognised that a positive Coomb’s test may be due to the drug.

Use in Special Populations

Pregnancy

Pregnancy Category B

There are no adequate and well-controlled studies in pregnant women. Cefixime should, therefore, not be used in pregnancy or in nursing mothers unless considered essential by the physician.

Lactating Women

It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Paediatric Patients

Safety and effectiveness of cefixime in children aged less than 6 months old have not been established. The incidence of gastrointestinal adverse reactions, including diarrhoea and loose stools, in the paediatric patients receiving the suspension was comparable with the incidence seen in adult patients receiving tablets. No data are available in case of paediatric patients with impaired renal or hepatic function.

Geriatric Patients

Clinical studies did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. A pharmacokinetic study in the elderly detected differences in pharmacokinetic parameters. These differences were small and do not indicate a need for dosage adjustment of the drug in the elderly.

Patients with Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing CAPD and haemodialysis. Patients on dialysis should be monitored carefully.

Patients with Hepatic Impairment

No data on dosing is available for patients with impaired hepatic function.

Effects on Ability to Drive and Use Machines

In the case of side effects such as encephalopathy (which may include convulsion, confusion, impairment of consciousness, movement disorders), the patient should not operate machines or drive a vehicle.

▶ Undesirable Effects

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.

The listed adverse reactions mentioned below have been observed during clinical studies and/or during marketed use.

Blood and Lymphatic System Disorders	Eosinophilia Hypereosinophilia Agranulocytosis Leucopaenia Neutropaenia Granulocytopaenia Haemolytic anaemia Thrombocytopaenia Thrombocytosis
Gastrointestinal Disorders	Abdominal pain Diarrhoea* Dyspepsia Nausea Vomiting Flatulence
Hepatobiliary Disorders	Jaundice
Infections and Infestations	Pseudomembranous colitis

Investigations	Aspartate aminotransferase increased Alanine aminotransferase increased Blood bilirubin increased Blood urea increased Blood creatinine increased
Nervous System Disorders	Dizziness Headache Cases of convulsions have been reported with cephalosporins, including cefixime (frequency not known)** Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment (frequency not known)**
Respiratory, Thoracic and Mediastinal Disorders	Dyspnoea
Renal and Urinary Disorders	Renal failure acute, including tubulointerstitial nephritis as an underlying pathological condition
Immune System Disorders, Administrative Site Conditions, Skin and Subcutaneous Tissue Disorders	Anaphylactic reaction Serum sickness-like reaction DRESS Pruritus Rash Drug fever Arthralgia Erythema multiforme Stevens-Johnson syndrome Toxic epidermal necrolysis Angio-oedema Urticaria Pyrexia Face oedema Genital pruritus Vaginitis

*Diarrhoea has been more commonly associated with higher doses. Some cases of moderate-to-severe diarrhoea have been reported; this has occasionally warranted cessation of therapy. Cefixime should be discontinued if marked diarrhoea occurs.

** Cannot be estimated from available data

Postmarketing Experience

The following adverse reactions have been reported following the use of cefixime. Incidence rates were less than 1 in 50 (less than 2%).

Gastrointestinal: Several cases of documented pseudomembranous colitis were identified in clinical trials. The onset of pseudomembranous colitis symptoms may occur during or after therapy.

Hypersensitivity Reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities), skin rashes, urticaria, drug fever, pruritus, angio-oedema, and facial oedema. erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported.

Hepatic: Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, and jaundice.
Renal: Transient elevations in BUN or creatinine, acute renal failure.
Central Nervous System: Headaches, dizziness, seizures.
Haemic and Lymphatic System: Transient thrombocytopaenia, leucopaenia, neutropaenia, prolongation in prothrombin time, elevated LDH, pancytopaenia, agranulocytosis, and eosinophilia.
Abnormal Laboratory Tests: Hyperbilirubinaemia.

Other Adverse Reactions

Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis. Spontaneous reported cases of acute generalised exanthematous pustulosis (AGEP) associated with the treatment using cefixime deduce that there is a potential risk for systemic involvement in patients with AEGP.

Adverse Reactions Reported for Cephalosporin-class Drugs

Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction, including cholestasis, aplastic anaemia, haemolytic anaemia, haemorrhage, and colitis.

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 Suspected Adverse Reactions

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme (PvPI) of India by calling on 1800 267 7779 (Cipla number) or you can report to PvPI on 1800 180 3024. By reporting side effects, you can help provide more information on the safety of this product.

▶ Overdose

There is no experience with overdoses with cefixime. Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by haemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of cefixime did not differ from the profile seen in patients treated at the recommended doses.

Pharmacological Properties

▶ Mechanism of Action

As with other cephalosporins, the bactericidal action of cefixime results from inhibition of cell wall synthesis. Cefixime is stable in the presence of certain beta-lactamase enzymes. As a result, certain organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases may be susceptible to cefixime. However, cefixime was found to be ineffective against bacteria that produce ESBL enzymes and resistance is seen in such types of bacteria. Clavulanic acid contains a beta-lactam ring in its structure that binds in an irreversible fashion to beta-lactamases, preventing them from inactivating certain beta-lactam antibiotics, with efficacy in treating susceptible Gram-positive and Gram-negative infections.

▶ Pharmacodynamic Properties

Pharmacotherapeutic group: third generation cephalosporin, ATC code: J01DD08

Cefixime is an oral third-generation cephalosporin that has marked *in vitro* bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms.

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens, including *Streptococcus*

pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Klebsiella species, *Haemophilus influenzae* (beta-lactamase positive and negative), *Branhamella catarrhalis* (beta-lactamase positive and negative) and *Enterobacter* species. It is highly stable in the presence of beta-lactamase enzymes.

Clavulanic acid is an irreversible 'suicide' inhibitor of intracellular and extracellular beta-lactamases, demonstrating concentration-dependent and competitive inhibition. It has a high affinity for the class A beta-lactamases. This wide range of beta-lactamases, which includes the plasmid-mediated TEM and SHV enzymes, is found frequently in members of the *Enterobacteriaceae*, *Haemophilus influenza* and *Neisseria gonorrhoeae* spp. The chromosomally mediated beta-lactamases of *Klebsiella pneumoniae*, *Proteus mirabilis*, *Proteus vulgaris*, *Bacteroides fragilis* and *Moraxella catarrhalis* are also inhibited, as are the extended-spectrum beta-lactamases. The frequency of beta-lactamase-mediated resistance has continued to rise over the years, but the majority of clinically significant beta-lactamases are inhibited by clavulanate.

Resistance

Resistance to cefixime in isolates of *Haemophilus influenzae* and *Neisseria gonorrhoeae* is most often associated with alterations in penicillin-binding proteins (PBPs). Cefixime may have limited activity against Enterobacteriaceae-producing extended-spectrum beta-lactamases (ESBLs). *Pseudomonas* species, *Enterococcus* species, strains of Group D streptococci, *Listeria monocytogenes,* most strains of staphylococci (including methicillin-resistant strains), most strains of *Enterobacter* species, most strains of *Bacteroides fragilis,* and most strains of *Clostridium* species are resistant to cefixime.

Antimicrobial Activity

Cefixime has been shown to be active against most isolates of the following bacteria, both *in vitro* and in clinical infections:

Gram-positive Bacteria

Streptococcus pneumoniae

Streptococcus pyogenes

Gram-negative Bacteria

Haemophilus influenzae (beta-lactamase-positive and -negative)

Moraxella catarrhalis

Escherichia coli

Proteus mirabilis

Neisseria gonorrhoeae

Also, clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens, including *Branhamella catarrhalis* (beta-lactamase-positive and -negative) and *Enterobacter* species.

The following *in vitro* data are available, but their clinical significance is unknown. At least 90% of the following bacteria exhibit an *in vitro* minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for cefixime against isolates of similar genus or organism group. However, the efficacy of cefixime in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

Gram-positive Bacteria

Streptococcus agalactiae

Gram-negative Bacteria

Citrobacter amalonaticus

Citrobacter diversus

Haemophilus parainfluenzae

Klebsiella oxytoca

Klebsiella pneumoniae

Pasteurella multocida
Proteus vulgaris
Providencia species
Salmonella species
Serratia marcescens
Shigella species

▶ Pharmacokinetic Properties

The absolute oral bioavailability of cefixime is in the range of 22–54%. Absorption is not significantly modified by the presence of food. Cefixime may, therefore, be given without regard to meals.
From *in vitro* studies, serum or urine concentrations of 1 mcg/mL or greater were considered to be adequate for most common pathogens against which cefixime is active. Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mcg/mL. Little or no accumulation of cefixime occurs following multiple dosing.
The pharmacokinetics of cefixime was evaluated in healthy elderly (age >64 years) and young volunteers (age 11–35 years) by comparing the administration of 400 mg doses once daily for 5 days. Mean C_{max} and AUC values were slightly greater in the elderly. Elderly patients may be given the same dose as the general population.
Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine.
Serum protein-binding is well characterised for human and animal sera; cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30%. Protein-binding of cefixime is only concentration-dependent in human serum at very high concentrations, which are not seen following clinical dosing.
Transfer of ^{14}C-labelled cefixime from lactating rats to their nursing offspring through breast milk was quantitatively small (approximately 1.5% of the mothers' body content of cefixime in the pup). No data are available on secretion of cefixime in human breast milk. Placental transfer of cefixime was small in pregnant rats dosed with labelled cefixime.

Non-Clinical Properties

Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. Cefixime did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage *in vitro* and did not exhibit clastogenic potential *in vivo* in the mouse micronucleus test. In rats, fertility and reproductive performance were not affected by cefixime at doses up to 25 times the adult therapeutic dose.

Description

OMNIX CV Tablets are a formulation containing cefixime and clavulanic acid.
Cefixime is a semisynthetic, cephalosporin antibacterial for oral administration. Chemically, it is (*6R,7R*)-7--8-oxo-3-vinyl-5-thia-1-azabicyclo oct-2-ene-2-carboxylic acid, 72-(*Z*)- trihydrate.
Molecular weight = 507.50 as the trihydrate. Chemical formula is C16H15N5O7S2.3H2O
Clavulanic acid is a beta-lactamase inhibitor that is frequently combined with beta-lactam antibiotic to fight antibiotic resistance by preventing their degradation by beta-lactamase enzymes, broadening their spectrum of susceptible bacterial infections. Clavulanic acid is derived from the organism *Streptomyces clavuligerus*.

Pharmaceutical Particulars

▶ Incompatibilities

Not applicable.

▶ Shelf-Life

As on the pack.

▶ Packaging Information

OMNIX CV Tablets: Each strip pack contains 10 tablets

▶ Storage and Handling Instructions

Store below 25°C, Protect from moisture. Keep out of reach of children

Patient Counselling Information

● What is OMNIX CV Tablets and what is it used for?
OMNIX CV Tablets contain cefixime and clavulanic acid. Cefixime belongs to a group of antibiotics called 'cephalosporins' that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.
● Do not take if you have an allergy to this drug
Do not take OMNIX CV Tablets if you are allergic to cefixime, any other cephalosporin antibiotics including penicillin or to any of the other ingredients of this medicine.
Signs of an allergic reaction include a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.
Do not take this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.
● Before you take OMNIX CV Tablets, tell your HCP about other medication.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because OMNIX CV Tablets can affect the way some other medicines work. Also some medicines can affect the way OMNIX CV Tablets work.
In particular, tell your doctor if you are taking the following:
• Medicines to thin the blood such as warfarin
● How to take OMNIX CV Tablets
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
• Take this medicine by mouth
• If you feel the effect of the medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.
Carefully read the label from the pharmacist. Ask your pharmacist if you are not sure about the dose to take. The medicine should be taken for the prescribed number of days.
If you take more OMNIX CV Tablets than you should: If you have too much of this medicine, talk to your doctor straight away.
If you forget to take OMNIX CV Tablets: If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.
If you stop taking OMNIX CV Tablets: Do not stop taking this medicine without talking to your doctor. You should not stop taking this medicine just because you feel better. This is because the infection may come back or get worse again
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

● What are the possible side effects?
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Tell your doctor straightaway or go to the nearest hospital casualty department if you notice any of the following serious side effects – you may need urgent medical treatment:
• You have an allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue
• Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.
• Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'toxic epidermal necrolysis'.
• You have a skin rash or skin lesions with a pink/red ring and a pale centre, which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'.
• You get infections more easily than usual. This could be because of a blood disorder. This normally gets better after stopping the medicine. You may also bruise or bleed more easily than normal. This could be because of a blood disorder. This normally gets better after stopping the medicine
• If your child gets nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), and shortness of breath. This may be due to haemolytic anaemia.
• Changes in the way the kidneys are working or blood in your child's urine.
• Fits (convulsions) – frequency not known
• A brain condition with symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. This may be something called 'encephalopathy'.. This side effect is more likely if you have taken an overdose or you already have a problem with your kidneys
Stop taking this medicine and contact your doctor without delay if you get
• severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called 'pseudomembranous colitis'.
Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:
• Feeling sick (nausea) or being sick (vomiting)
• Stomach pains, indigestion or wind
• Headaches
• Feeling dizzy
• Feeling itchy in the genital or vaginal area Tell your doctor if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.
Blood tests OMNIX CV Tablets can cause blood clots or small changes to the way the liver and kidneys work. This would be seen in blood tests. This is not common and goes back to normal after stopping this medicine.
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.
● How should I store OMNIX CV Tablets?
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date (which is stated on the label and blister pack after EXP:). Store below 25°C.
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

● General information about the safe and effective use of this drug

Talk to your doctor or pharmacist before taking OMNIX CV Tablets

if you have ever had colitis

if you have kidney problems

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine can cause symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. If you experience any of these effects don’t drive or use machinery.

Medical tests

If you require any tests (such as blood or urine tests) while taking OMNIX CV Tablets, please make sure your doctor knows that you are taking this medicine.

● Any other information

Not applicable.

Details Of The Manufacturer

Manufactured by: M/s Hetero Labs Limited (Unit-I)
Village: Kalyanpur, Chakkan Road, Tehsil: Baddi,
Distt: Solan, Himachal Pradesh-173205

Details Of Permission Or Licence Number With Date

L.No: MB/05/194

Date Of Revision

16-12-2019

OMNIX CV Tablets