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

xxxxxxxx-8883

TORCOXIA BCD

(Etoricoxib Tablets)

COMPOSITION

Torcoxia BCD - 60

Each Film coated tablet contains:

Etoricoxib 60 mg

(With Betacyclodextrin)

Excipients q.s.

Torcoxia BCD - 90

Each Film coated tablet contains:

Etoricoxib 90 mg

(With Betacyclodextrin)

Excipients q.s.

Torcoxia BCD - 120

Each Film coated tablet contains:

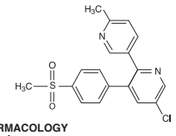
Etoricoxib 120 mg

(With Betacyclodextrin)

Excipients q.s.

DESCRIPTION

Etoricoxib, which is chemically described as 5-chloro-6'-methyl- 3-[4-(methyl sulfonyl) phenyl]-2,3'-bipyridine. Etoricoxib is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities. It is selective cyclo oxygenase-2(COX-2) inhibitor. Its empirical formula is $C_{18}H_{15}ClN_2O_2S$ and molecular weight is 358.84. The structural formula is:



CLINICAL PHARMACOLOGY

Pharmacodynamics

Etoricoxib is an oral, selective cyclo-oxygenase-2 (COX-2) inhibitor within the clinical dose range. Across clinical pharmacology studies, etoricoxib produced dose- dependent inhibition of COX-2 without inhibition of COX-1 at doses up to 150 mg daily. Etoricoxib did not inhibit gastric prostaglandin synthesis and had no effect on platelet function.

Cyclo-oxygenase is responsible for generation of prostaglandins. Two isoforms, COX-1 and COX-2, have been identified. COX-2 is the isoform of the enzyme that has been shown to be induced by pro-inflammatory stimuli and has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. COX-2 is also involved in ovulation, implantation and closure of the ductus arteriosus, regulation of renal function, and central nervous system functions (fever induction, pain perception and cognitive function). It may also play a role in ulcer healing.

Pharmacokinetics

Absorption

Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Following 120 mg once-daily dosing to steady state, the peak plasma concentration (geometric mean C_{max} = 3.6 μg/ml) was observed at approximately 1 hour (T_{max}) after administration to fasted adults. The geometric mean area under the curve (AUC0-24hr) was 37.8 μg.hr/ml. The pharmacokinetics of etoricoxib are linear across the clinical dose range. Dosing with food (a high-fat meal) had no effect on the extent of absorption of etoricoxib after administration of a 120 mg dose. The rate of absorption was affected, resulting in a 36% decrease in C_{max} and an increase in T_{max} by 2 hours. These data are not considered clinically significant. In clinical trials, etoricoxib was administered without regard to food intake.

Distribution

Etoricoxib is approximately 92% bound to human plasma protein over the range of concentrations of 0.05 to 5 μg/ml. The volume of distribution at steady state (Vdss) was approximately 120 L in humans. Etoricoxib crosses the placenta in rats and rabbits, and the blood-brain barrier in rats.

Metabolism

Etoricoxib is extensively metabolised with <1% of a dose recovered in urine as the parent drug. The major route of metabolism to form the 6'-hydroxymethyl derivative is catalysed by CYP enzymes. CYP3A4 appears to contribute to the metabolism of etoricoxib in vivo. In vitro studies indicate that CYP2D6, CYP2C9, CYP1A2 and CYP2C19 also can catalyse the main metabolic pathway, but their quantitative roles in vivo have not been studied. Five metabolites have been identified in man. The principal metabolite is the 6'-carboxylic acid derivative of etoricoxib formed by further oxidation of the 6'-hydroxymethyl derivative. These principal metabolites either demonstrate no measurable activity or are only weakly active as COX-2 inhibitors. None of these metabolites inhibit COX-1.

Elimination

Following administration of a single 25-mg radiolabeled intravenous dose of etoricoxib to healthy subjects, 70% of radioactivity was recovered in urine and 20% in faeces, mostly as metabolites. Less than 2% was recovered as unchanged drug. Elimination of etoricoxib occurs almost exclusively through metabolism followed by renal excretion. Steady state concentrations of etoricoxib are reached within seven days of once daily administration of 120 mg, with an accumulation ratio of approximately 2, corresponding to a half-life of approximately 22 hours. The plasma clearance after a 25-mg intravenous dose is estimated to be approximately 50 ml/min.

Special populations

Elderly: Pharmacokinetics in the elderly (65 years of age and older) are similar to those in the young.

Gender: The pharmacokinetics of etoricoxib are similar between men and women.

Hepatic insufficiency: Patients with mild hepatic dysfunction (Child-Pugh score 5-6) administered etoricoxib 60 mg once daily had an approximately 16% higher mean AUC as compared to healthy subjects given the same regimen. Patients with moderate hepatic dysfunction (Child-Pugh score 7-9) administered etoricoxib 60 mg every other day had similar mean AUC to the healthy subjects given etoricoxib 60 mg once daily. There are no clinical or pharmacokinetic data in patients with severe hepatic dysfunction (Child-Pugh score -10).

Renal insufficiency: The pharmacokinetics of a single dose of etoricoxib 120 mg in patients with moderate to severe renal insufficiency and patients with end-stage renal disease on haemodialysis were not significantly different from those in healthy subjects. Haemodialysis contributed negligibly to elimination (dialysis clearance approximately 50 ml/min).

Paediatric patients: The pharmacokinetics of etoricoxib in paediatric patients (<12 years old) have not been studied. In a pharmacokinetic study (n=16) conducted in adolescents (aged 12 to 17 years) the pharmacokinetics in adolescents weighing 40 to 60 kg given etoricoxib 60 mg once daily and adolescents > 60 kg given etoricoxib 90 mg once daily were similar to the pharmacokinetics in adults given etoricoxib 90 mg once daily. Safety and effectiveness of etoricoxib in paediatric patients have not been established.

INDICATIONS

It is indicated in the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), acute gouty arthritis, acute pain associated with dental surgery and primary dysmenorrhoea.The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

CONTRAINDICATIONS

- History of hypersensitivity to the active substance or to any of the excipients
- Active peptic ulceration or active gastro-intestinal (GI) bleeding.
- Patients who have experienced bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema,urticaria,or allergic-type reactions after taking acetylsalicylic acid or NSAIDs including COX-2 (cyclooxygenase-2) inhibitors.
- Pregnancy and lactation
- Severe hepatic dysfunction (serum albumin<25 g/l or Child-Pugh score ≥10).
- Estimated renal creatinine clearance <30 ml/min.
- Children and adolescents under 16 years of age.
- Inflammatory bowel disease.
- Congestive heart failure (NYHA II-IV).
- Patients with hypertension whose blood pressure has not been adequately controlled.
- Established ischaemic heart disease and/or cerebrovascular disease.

WARNINGS AND PRECAUTIONS

Cardiovascular effects

This drug should be used with caution in patients suffering from Coronary Heart Disease (CHD)/ Cardiovascular Disorder. Clinical trials suggest that the selective COX-2 inhibitor class of drugs may be associated with a risk of thrombotic events (especially MI and stroke), relative to placebo and some NSAIDs. As the cardiovascular risks of etoricoxib may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis. Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) or peripheral arterial disease should only be treated with etoricoxib after careful consideration. COX-2 selective inhibitors are not a substitute for acetylsalicylic acid for prophylaxis of cardiovascular thromboembolic diseases because of their lack of antiplatelet effect. Therefore antiplatelet therapies should not be discontinued.

Gastro-intestinal effects

Upper gastro-intestinal complications [perforations, ulcers or bleedings (PUBs)], some of them resulting in fatal outcome, have occurred in patients treated with etoricoxib. Caution is advised with treatment of patients most at risk of developing a gastro-intestinal complication with NSAIDs: the elderly, patients using any other NSAID or acetylsalicylic acid concomitantly, or patients with a prior history of gastro-intestinal disease, such as ulceration and GI bleeding. There is a further increase in the risk of gastro-intestinal adverse effects (gastro-intestinal ulceration or other gastro-intestinal complications) when etoricoxib is taken concomitantly with acetylsalicylic acid (even at low doses). A significant difference in GI safety between selective COX-2 inhibitors+ acetylsalicylic acid vs. NSAIDs + acetylsalicylic acid has not been demonstrated in long-term clinical trials.

Renal effects

Renal prostaglandins may play a compensatory role in the maintenance of renal perfusion. Therefore, under conditions of compromised renal perfusion, administration of etoricoxib may cause a reduction in prostaglandin formation and, secondarily, in renal blood flow, and thereby impair renal function. Patients at greatest risk of this response are those with pre-existing significantly impaired renal function, uncompensated heart failure, or cirrhosis. Monitoring of renal function in such patients should be considered.

Fluid retention, oedema and hypertension

As with other drugs known to inhibit prostaglandin synthesis, fluid retention, oedema and hypertension have been observed in patients taking etoricoxib. Caution should be exercised in patients with a history of cardiac failure, left ventricular dysfunction, or hypertension and in patients with pre-existing oedema from any other reason. If there is clinical evidence of deterioration in the condition of these patients, appropriate measures including discontinuation of etoricoxib should be taken. Etoricoxib may be associated with more frequent and severe hypertension than some other NSAIDs and selective COX-2 inhibitors, particularly at high doses. Therefore, special attention should be paid to blood pressure monitoring during treatment with etoricoxib. If blood pressure rises significantly, alternative treatment should be considered.

Hepatic effects

Elevations of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (approximately three or more times the upper limit of normal) have been reported in approximately 1% of patients in clinical trials treated for up to one year with etoricoxib 60 and 90 mg daily. Any patients with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver function test has occurred, should be monitored. If signs of hepatic insufficiency occur, or if persistently abnormal liver function tests (three times the upper limit of normal) are detected, etoricoxib should be discontinued.

General

If during treatment, patients deteriorate in any of the organ system functions described above, appropriate measures should be taken and discontinuation of etoricoxib therapy should be considered. Medically appropriate supervision should be maintained when using etoricoxib in the elderly and in patients with renal, hepatic, or cardiac dysfunction. Caution should be used when initiating treatment with etoricoxib in patients with dehydration. It is advisable to rehydrate patients prior to starting therapy with etoricoxib. Serious skin reactions, including exfoliative dermatitis, Stevens - Johnson syndrome, and toxic epidermal necrolysis, have been reported in association with the use of NSAIDs including other COX-2 (cyclo-oxygenase-2) inhibitors and cannot be ruled out for etoricoxib. Hypersensitivity reactions (anaphylaxis, angioedema) have been reported in patients receiving etoricoxib. Etoricoxib should be discontinued at the first sign of hypersensitivity. Etoricoxib may mask fever and other signs of inflammation. Caution should be exercised when co-administering etoricoxib with warfarin or other oral anticoagulants. The use of etoricoxib, as with any medicinal product known to inhibit cyclo- oxygenase/ prostaglandin synthesis, is not recommended in women attempting to conceive. Etoricoxib tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DRUG-INTERACTIONS

Pharmacodynamic interactions

Oral anticoagulants: In subjects stabilized on chronic warfarin therapy, the administration of etoricoxib 120 mg daily was associated with an approximate 13% increase in prothrombin time International Normalised Ratio (INR). Therefore, patients receiving oral anticoagulants should be closely monitored for their prothrombin time INR, particularly in the first few days when therapy with etoricoxib is initiated or the dose of etoricoxib is changed. Diuretics, ACE inhibitors and Angiotensin II Antagonists: NSAIDs may reduce the effect of diuretics and other antihypertensive drugs. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function) the co-administration of an ACE inhibitor or angiotensin II antagonist and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. These interactions should be considered in patients taking etoricoxib concomitantly with ACE inhibitors or angiotensin II antagonists.

Therefore the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter.

Acetylsalicylic Acid: In a study in healthy subjects, at steady state, etoricoxib 120 mg once daily had no effect on the anti-platelet activity of acetylsalicylic acid (81 mg once daily). Etoricoxib can be used concomitantly with acetylsalicylic acid at doses used for cardiovascular prophylaxis (low-dose acetylsalicylic acid). However, concomitant administration of low-dose acetylsalicylic acid with etoricoxib may result in an increased rate of GI ulceration or other complications compared to use of etoricoxib alone. Concomitant administration of etoricoxib with doses of acetylsalicylic acid above those for cardiovascular prophylaxis or with other NSAIDs is not recommended. Ciclosporin and tacrolimus: Although this interaction has not been studied with etoricoxib, co-administration of ciclosporin or tacrolimus with any NSAID may increase the nephrotoxic effect of ciclosporin or tacrolimus. Renal function should be monitored when etoricoxib and either of these drugs is used in combination.

Pharmacokinetic interactions

The effect of etoricoxib on the pharmacokinetics of other drugs

Lithium: NSAIDs decrease lithium renal excretion and therefore increase lithium plasma levels. If necessary, monitor blood lithium closely and adjust the lithium dosage while the combination is being taken and when the NSAID is withdrawn.

Methotrexate: Two studies investigated the effects of etoricoxib 60, 90 and 120 mg administered once daily for seven days in patients receiving once-weekly methotrexate doses of 7.5 to 20 mg for rheumatoid arthritis. Etoricoxib at 60 and 90 mg had no effect on methotrexate plasma concentrations or renal clearance. In one study, etoricoxib 120 mg had no effect, but in the other study, etoricoxib 120 mg increased methotrexate plasma concentrations by 28% and reduced renal clearance of methotrexate by 13%. Adequate monitoring for methotrexate-related toxicity is recommended when etoricoxib and methotrexate are administered concomitant.

Oral contraceptives: Etoricoxib 60 mg given concomitantly with an oral contraceptive containing 35 mcg ethinyl estradiol (EE) and 0.5 to 1 mg norethindrone for 21 days increased the steady state AUC0-24hr of EE by 37%. Etoricoxib 120 mg given with the same oral contraceptive concomitantly or separated by 12 hours, increased the steady state AUC0-24hr of EE by 50 to 60%. This increase in EE concentration should be considered when selecting an oral contraceptive for use with etoricoxib. An increase in EE exposure can increase the incidence of adverse events associated with oral contraceptives (e.g. venous thrombo-embolic events in women at risk).

Hormone Replacement Therapy: Administration of etoricoxib 120 mg with hormone replacement therapy consisting of conjugated estrogens (0.625 mg) for 28 days, increased the mean steady state AUC0-24hr of unconjugated estrone (41%), equilin (76%) and 17-b-estradiol (22%). The effect of the recommended chronic doses of etoricoxib (60 and 90 mg) has not been studied.

Prednisone/prednisolone: In drug-interaction studies, etoricoxib did not have clinically important effects on the pharmacokinetics of prednisone/prednisolone.

Digoxin: Etoricoxib 120 mg administered once daily for 10 days to healthy volunteers did not alter the steady-state plasma AUC0-24hr or renal elimination of digoxin. There was an increase in digoxin Cmax (approximately 33%). This increase is not generally important for most patients. However, patients at high risk of digoxin toxicity should be monitored for this when etoricoxib and digoxin are administered concomitantly.

Effect of etoricoxib on drugs metabolised by sulfotransferases

Etoricoxib is an inhibitor of human sulfotransferase activity, particularly SULT1E1, and has been shown to increase the serum concentrations of ethinyl estradiol. It may be prudent to exercise care when administering etoricoxib concurrently with other drugs primarily metabolised by human sulfotransferases (e.g. oral salbutamol and minoxidil).

Effect of etoricoxib on drugs metabolised by CYP isoenzymes

Based on in vitro studies, etoricoxib is not expected to inhibit cytochromes P450 (CYP) 1A2, 2C9, 2C19, 2D6, 2E1 or 3A4. In a study in healthy subjects, daily administration of etoricoxib 120 mg did not alter hepatic CYP3A4 activity as assessed by the erythromycin breath test.

Effects of other drugs on the pharmacokinetics of etoricoxib

CYP3A4 appears to contribute to the metabolism of etoricoxib in vivo. In vitro studies indicate that CYP2D6, CYP2C9, CYP1A2 and CYP2C19 also can catalyse the main metabolic pathway, but their quantitative roles have not been studied in vivo.

Ketoconazole: Ketoconazole, a potent inhibitor of CYP3A4, dosed at 400 mg once a day for 11 days to healthy volunteers, did not have any clinically important effect on the single-dose pharmacokinetics of 60 mg etoricoxib (43% increase in AUC).

Rifampicin: Co-administration of etoricoxib with rifampicin, a potent inducer of CYP enzymes, produced a 65% decrease in etoricoxib plasma concentrations. This interaction may result in recurrence of symptoms when etoricoxib is co-administered with rifampicin. While this information may suggest an increase in dose, doses of etoricoxib greater than those listed for each indication have not been studied in combination with rifampicin and are therefore not recommended.

Antacids: Antacids do not affect the pharmacokinetics of etoricoxib to a clinically relevant extent.

Pregnancy and lactation

Pregnancy

The use of etoricoxib, as with any drug substance known to inhibit COX-2, is not recommended in women attempting to conceive. No clinical data on exposed pregnancies are available for etoricoxib. The potential for human risk in pregnancy is unknown. Etoricoxib, as with other medicinal products inhibiting prostaglandin synthesis, may cause uterine inertia and premature closure of the ductus arteriosus during the last trimester. Etoricoxib is contraindicated in pregnancy. If a woman becomes pregnant during treatment, etoricoxib should be discontinued.

Lactation

It is not known whether etoricoxib is excreted in human milk. Women who use etoricoxib should not breast feed.

ADVERSE REACTIONS

The following undesirable effects were reported in clinical trials in patients with OA, RA, chronic low back pain or ankylosing spondylitis treated with etoricoxib, or in post-marketing experience:

[Very Common (≥1/10) Common (≥100 to <1/10) Uncommon (≥1/1000 to <1/100) Rare (≥1/10,000 to <1/1,000) Very rare (<1/10,000), not known (cannot be estimated from the available data)]

Infections and infestations:

Uncommon: gastroenteritis, upper respiratory infection, urinary tract infection.

Blood and lymphatic system disorders:

Uncommon: anaemia (primarily associated with gastro-intestinal bleeding), leukopenia, thrombocytopenia.

Immune system disorder:

Very rare: hypersensitivity reactions, including angioedema, anaphylactic/anaphylactoid reactions including shock.

Metabolism and nutrition disorders:

Common: oedema/fluid retention

Uncommon: appetite increase or decrease, weight gain.

Psychiatric disorders:

Uncommon: anxiety, depression, mental acuity decreased.

Very rare: confusion, hallucinations. *Not known:* restlessness

Nervous system disorder:

Common: dizziness, headache.

Uncommon: dysgeusia, insomnia, paresthaesia/hypaesthesia, somnolence.

Eye disorders:

Uncommon: blurred vision, conjunctivitis.

Ear and labyrinth disorders:

Uncommon: tinnitus, vertigo.

Cardiac disorders:

Common: palpitations.

Uncommon: atrial fibrillation, congestive heart failure, non-specific ECG changes, angina pectoris, myocardial infarction.

Not known: tachycardia, arrhythmia.

Vascular disorders:

Common: hypertension.

Uncommon: flushing, cerebrovascular accident, transient ischaemic attack.

Very rare: hypertensive crisis.

Respiratory, thoracic and mediastinal disorders:

Uncommon: cough, dyspnoea, epistaxis.

Very rare: bronchospasm.

Gastrointestinal disorders:

Common: gastrointestinal disorders (e.g., abdominal pain, flatulence, heartburn), diarrhoea, dyspepsia, epigastric discomfort, nausea.

Uncommon: abdominal distention, acid reflux, bowel movement pattern change, constipation, dry mouth, gastroduodenal ulcer, irritable bowel syndrome, oesophagitis, oral ulcer, vomiting, gastritis.

Very rare: peptic ulcers including gastrointestinal perforation and bleeding (mainly in the elderly).

Not known: pancreatitis.

Hepatobiliary disorders:

Common: ALT increased, AST increased.

Very rare: hepatitis.

Not known: jaundice.

Skin and subcutaneous tissue disorders:

Common: ecchymosis.

Uncommon: facial oedema, pruritus, rash.

Rare: erythema.

Very rare: urticaria, Stevens-Johnson syndrome, toxic epidermal necrolysis.

Musculoskeletal, connective tissue and bone disorders:

Uncommon: muscular cramp/spasm, musculoskeletal pain/stiffness.

Renal and urinary disorders:

Uncommon: proteinuria, serum creatinine increased.

Very rare: renal insufficiency, including renal failure.

General disorders and administration site conditions:

Common: asthenia/fatigue, flu-like disease.

Uncommon: chest pain.

Investigations:

Uncommon: blood urea nitrogen increased, creatine phosphokinase increased, hyperkalaemia, uric acid increased.

Rare: blood sodium decreased.

The following serious undesirable effects have been reported in association with the use of NSAIDs and cannot be ruled out for etoricoxib: nephrotoxicity including interstitial nephritis and nephrotic syndrome; hepatotoxicity including hepatic failure.

Overdose

In clinical studies, reports of, administration of single doses of etoricoxib up to 500 mg and multiple doses up to 150 mg/day for 21 days did not result in significant toxicity. There have been reports of acute overdosage with etoricoxib, although adverse experiences were not reported in the majority of cases. The most frequently reported adverse experiences were consistent with the safety profile for etoricoxib (e.g. gastrointestinal events, cardiorenal events). In the event of overdose, it is reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the GI tract, employ clinical monitoring, and institute supportive therapy, if required. Etoricoxib is not dialysable by haemodialysis; it is not known whether etoricoxib is dialysable by peritoneal dialysis.

Osteoarthritis

The recommended dose is 60 mg once daily.

The dose for OA should not exceed 60 mg daily.

Rheumatoid arthritis

The recommended dose is 90 mg once daily.

The dose for RA should not exceed 90 mg daily.

Acute gouty arthritis

The recommended dose is 120 mg once daily. Etoricoxib 120 mg should be used only for the acute symptomatic period. In clinical trials for acute gouty arthritis, etoricoxib was given for 8 days. Doses greater than those recommended for each indication have either not demonstrated additional efficacy or have not been studied. Therefore, the dose for each indication is the maximum recommended dose. The dose for acute gout should not exceed 120 mg daily, limited to a maximum of 8 days treatment.

Acute Pain: The recommended dose is 120 mg once daily. Etoricoxib 120 mg should be used only for acute symptomatic period, limited to a maximum of 8 days treatment.

Primary dysmenorrhoea: The recommended dose is 60 mg once daily. Etoricoxib should be used only for the acute symptomatic period.

Elderly: No dosage adjustment is necessary for elderly patients.

Hepatic insufficiency: In patients with mild hepatic dysfunction (Child-Pugh score 5-6) a dose of 60 mg once daily should not be exceeded. In patients with moderate hepatic dysfunction (Child-Pugh score 7-9) the recommended dose of 60 mg every other day should not be exceeded.

Administration of 30mg once daily can also be considered.

Clinical experience is limited, particularly in patients with moderate hepatic dysfunction and caution is advised. There is no clinical experience in patients with severe hepatic dysfunction (Child-Pugh score -10); therefore, its use is contraindicated in these patients.

Renal insufficiency: No dosage adjustment is necessary for patients with creatinine clearance ≥30 ml/min. The use of etoricoxib in patients with creatinine clearance <30 ml/min is contraindicated. Paediatric use: Etoricoxib is contraindicated in children and adolescents under 16 years of age.

EXPIRY DATE:

Do not use later than the date of expiry.

STORAGE

Store below 30^{0}C, protect from light

PRESENTATION

White colour, round, biconvex, film coated tablets plain on both sides.

HOW SUPPLIED

Blister pack of 10 tablets.

torrent PHARMA

Manufactured by :

TORRENT PHARMACEUTICALS LTD.

Baddi 173 205, Dist. Solan (H.P.) INDIA.

PRODUCT NAME	:	TORCOXIA BCD	**COUNTRY :** Reg. Eng.	**LOCATION :** Baddi	**Supersedes A/W No.:**		
ITEM / PACK	:	Insert	**NO. OF COLORS:** 1	**REMARK :**			
DESIGN STYLE	:	Front/Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**			
CODE	:	xxxxxxxxx-8883	Black	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM)	:	150 x 250		Prepared By	**Pkg.Dev**			
ART WORK SIZE	:	S/S		Reviewed By	**Pkg.Dev**			
DATE	:	29-05-2015		Reviewed By	**RA**			
				Approved By	**CQA**			