Pharmacokinetics in the elderly (65 years of age and older) are similar to those in the subjects given the same regimen. Patients with moderate hepatic insufficiency (Child-Pugh score 7-9) administered etoricoxib 60 mg once daily had an approximately 16% higher mean AUC as compared to healthy subjects. Patients with mild hepatic insufficiency (Child-Pugh score 5-6) administered etoricoxib clearance is estimated to be approximately 50 mL/min.

Following administration of a single 25-mg radiolabeled intravenous dose of etoricoxib to healthy volunteers, the mean plasma elimination half-life of etoricoxib was approximately 120 L in humans. The elimination of etoricoxib is predominantly hepatic, with a volume of distribution at steady state (Vdss) is approximately 50 mL/min.

The pharmacokinetics of etoricoxib in 12 healthy subjects were similar (comparable AUC, Cmax, Tmax, and elimination half-life) across the dose range from 10 to 150 mg. These findings are consistent with the COX-2 selectivity of etoricoxib. Pharmacokinetic parameters are not changed by the route of administration (oral vs intravenous) or the interval between doses of etoricoxib, within the dosing range of 10 to 150 mg.

The pharmacokinetics of etoricoxib in pediatric patients (<12 years of age) have not been established. The pharmacokinetics of etoricoxib in pediatric patients have not been established. Therefore, under conditions of compromised renal perfusion, administration of ARCOXIA may increase the risk of thrombotic events (especially MI and stroke), relative to placebo and ARCOXIA is contraindicated in patients with:

- Hypersensitivity to any component of this product.

ARCOXIA is contraindicated in patients with:

- Hypersensitivity to any component of this product.

The pharmacokinetics of etoricoxib in elderly patients (<12 years of age) have not been established.

In a pharmacokinetic study (N=16) conducted in adolescents (aged 12 to 17) the pharmacokinetics of etoricoxib is in adolescents approximately 60 mg once daily and in adolescents >60 kg given etoricoxib 60 mg once daily and in 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 pediatric patients has not been established.

Drug Interactions with Additional Pharmacokinetic Data

The pharmacokinetics of etoricoxib are similar to those in the subjects given the same regimen. Patients with moderate hepatic insufficiency (Child-Pugh score 7-9) administered etoricoxib 60 mg once daily had an approximately 16% higher mean AUC as compared to healthy subjects. Patients with mild hepatic insufficiency (Child-Pugh score 5-6) administered etoricoxib clearance is estimated to be approximately 50 mL/min.

DOSAGE AND ADMINISTRATION

ARCOXIA is contraindicated in patients with:

- Hypersensitivity to any component of this product.

The pharmacokinetics of etoricoxib in elderly patients (<12 years of age) have not been established.

In a pharmacokinetic study (N=16) conducted in adolescents (aged 12 to 17) the pharmacokinetics of etoricoxib is in adolescents approximately 60 mg once daily and in adolescents >60 kg given etoricoxib 60 mg once daily and in 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 pediatric patients has not been established.
Caution should be taken when initiating treatment with ARCOXIA in patients with considerable dehydration. It is advisable to rehydrate patients prior to starting therapy with ARCOXIA.

As with other drugs known to inhibit prostaglandin synthesis, fluid retention, edema, and hypertension have been observed in some patients taking ARCOXIA. The possibility of fluid retention, edema, and hypertension in these patients should be considered in patients with pre-existing edema, hypertension, or heart failure. Etoricoxib may be associated with more frequent and severe hypertension than some other NSAIIDs and selective COX-2 inhibitors at high doses. Etoricoxib, a member of this class, does not inhibit platelet aggregation, antiplatelet therapies should not be discontinued.

1. Independent of treatment with ARCOXIA, patients with a prior history of GI ulcer, ulcer complications or hemorrhage should be monitored closely and appropriate measures should be considered in patients with severe ulcer complications or hemorrhage.

Warnings:

Serious cardiovascular side effects have been reported by patients taking drugs in this class. As with other drugs known to inhibit prostaglandin synthesis, ARCOXIA may increase plasma lithium levels. This interaction should be given consideration in patients taking ARCOXIA concomitantly with lithium. If increases in plasma lithium levels are observed, appropriate dosage adjustments should be made.

As with other drugs known to inhibit prostaglandin synthesis, use of ARCOXIA should be used with caution in patients who have previously experienced acute myocardial infarction, in patients with congestive heart failure, in patients with hypertension, or in patients who have a history of cerebrovascular accidents. The increased risk of having a cardiovascular adverse event associated with this class of drugs is generally balanced by an increased risk of GI perforation or bleeding associated with NSAIDs. A patient’s history of congestive heart failure, cerebrovascular accidents, and cardiovascular disease should be considered when selecting post-menopausal hormone therapy for use with ARCOXIA.

Other: In drug-interaction studies, ARCOXIA did not have clinically important effects on the pharmacokinetics of prednisone/prednisolone or digoxin. Antacids and ketoconazole (a potent inhibitor of CYP3A4) did not have clinically important effects on the pharmacokinetics of ARCOXIA.

SIDE EFFECTS

In clinical trials, ARCOXIA was evaluated for safety in approximately 4800 individuals, including approximately 2000 patients treated with ARCOXIA and at an incidence greater than placebo: anxiety, insomnia, confusion, hallucinations.

The following adverse reactions were reported during clinical trials with ARCOXIA 120 mg: nausea, vomiting, headache, abdominal pain, upper respiratory infection, diarrhea, fever, edema, dizziness, tremor, rash, dry skin, pruritus, arthralgia, myalgia, chest pain, and paresthesia.

Post-marketing experience


OVERDOSAGE

No overdoses of ARCOXIA were reported during clinical trials. In clinical studies, administration of ARCOXIA at single doses up to 500 mg and multiple doses up to 1400 mg/day in RA patients and OA patients with ankylosing spondylitis (ASS) were well tolerated. In the event of overdose, it is reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive therapy as required.

Etoricoxib is not dialyzable by hemodialysis; it is not known whether etoricoxib is dialyzable by peritoneal dialysis.

STORAGE


Available: To be filled in locally.