Product Name: Carlos Tenoxicam 20mg Capsule	
Module: 1 Administrative Information	1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE SPECIALTY
Carlos Tenoxicam 20mg Capsule

2. INTERNATIONAL COMMON NAME

Tenoxicam capsules 2 0 mg

3. PHARMACEUTICAL FORM AND PRESENTATION
Available in blister packs of 10 capsules and boxes of 1 blister.

4. QUANTITATIVE AND QUALITATIVE COMPOSITION

Composition	Quantity (mg / caps)
Active ingredient	
Tenoxicam	2 0.000
Excipients	
Lactose	231.00
Sodium Lauryl Sulphate	4.00
Sodium Starch Glycolate	15.00
Aerosil	3.00
Magnesium Stearate	3.00
Total	**276.0**

5. THERAPEUTIC PROPERTIES
Action mechanism
Tenoxicam is a nonsteroidal anti-inflammatory drug (NSAID) that has anti-inflammatory, analgesic, antipyretic properties and also inhibits platelet aggregation. Tenoxicam reduces prostaglandin biosynthesis by inhibiting cyclooxygenases 1 (COX1) and 2 (COX2), both in vitro (sheep seminal vesicles) and in vivo (protection from arachidonic acid-induced toxicity in mice).
An in vitro study on cyclooxygenase isoenzymes prepared from human COS-7 cells showed that tenoxicam inhibits COX-1 and COX-2 isoenzymes to approximately the same extent, i.e., the COX- 2 / COX-1 is equal to 1.34.
In vitro leukocyte peroxidase assays suggest that tenoxicam may act as an active oxygen scavenger at the site of inflammation.
Tenoxicam is a potent in vitro inhibitor of human metalloproteinases (stromelysin and collagenase) inducing cartilage degradation.
Another possible mechanism of action is the reduction of nitrite levels indicating an alteration of NO pathways.

These pharmacological effects explain, at least in part, the therapeutic advantage of Tenex in the treatment of painful inflammatory and degenerative disorders of the musculoskeletal system.
The clinical effectiveness of tenoxicam is demonstrated in clinical studies for:
Rheumatoid arthritis: A dose of 20 or 40 mg once daily has been shown to be effective and the effect is maintained for up to two years.

Clinical/Efficacy Studies
Osteoarthritis: Tenoxicam is effective in the treatment of osteoarthritis. The anti-inflammatory and analgesic effects were maintained for up to three years.
Extra-articular disorders: tenoxicam (20 mg once daily) was at least as effective as piroxicam (20 mg daily) and diclofenac (75 mg daily). Tenoxicam was better tolerated than diclofenac .

Pharmacokinetics
Absorption
Tenoxicam is long-acting; a single daily dose is effective.

After oral administration, Tenoxicam is absorbed rapidly and completely as unchanged drug. Concomitant foods reduce the rate of absorption of Tenoxicam, but not its extent of absorption. Tenoxicam penetrates well into synovial fluid to give concentrations approximately half those in plasma. The average plasma elimination half-life is approximately 72 hours.

With the recommended dosage of 20 mg once daily, steady-state plasma concentrations are achieved within 10 to 15 days, without unanticipated accumulation. The average steady-state concentration is 11 mg/L when tenoxicam is administered in oral doses of 20 mg once daily, and this does not change, even during treatment, for a period of up to 'at four years old.

Tenoxicam is strongly bound to plasma proteins. As expected from the kinetics of single dose administration, steady-state plasma concentrations are six times higher than those achieved after a single dose.

The pharmacokinetics of tenoxicam is linear in the dose range studied from 10 to 100 mg

No age-specific changes in the pharmacokinetics of Tenex have been noted, although interindividual variation tends to be higher in older adults.

Distribution

During the first two hours after intravenous administration of tenoxicam , plasma concentrations of the drug decrease rapidly.

After this short period, no difference in plasma concentration between intravenous and oral doses was noted. The average volume of distribution at steady state is 10 to 12 L.

In the blood, more than 99% of the drug is bound to albumin. Tenoxicam penetrates well into the synovial fluid. Maximum concentrations are reached later than in plasma.

Metabolism and elimination
Tenex is eliminated from the body almost exclusively through metabolism. Approximately two thirds of the administered dose is excreted in urine, primarily as the pharmacologically inactive metabolite 5-hydroxypyridyl, and the remainder in bile, primarily as glucuronide conjugates and hydroxyl metabolites. Less than 1% of the administered dose is recovered in the urine as the parent drug. The average elimination half-life of tenoxicam is 72 hours (range 59 to 74 hours). Total plasma clearance is 2 mL /min.

Special Populations
Studies in the elderly and in patients with renal impairment or liver cirrhosis suggest that no dose adjustment is necessary to achieve plasma concentrations similar to those observed in healthy subjects.

Patients with rheumatic diseases and the elderly present the same kinetic profile as healthy volunteers.

Due to the high plasma binding of tenoxicam to plasma proteins, caution should be exercised when plasma albumin levels are markedly reduced (see section 4.4 Special warnings and precautions for use, Laboratory tests).

Preclinical safety data
Carcinogenicity

Tenoxicam showed no carcinogenic effects in animals.

Mutagenicity
Tenoxicam showed no mutagenic effects in animals.

Teratogenicity
Tenoxicam showed no teratogenic effects in rats.

6. PHARMACOLOGICAL AND/OR THERAPEUTIC CLASS
Antibiotic .

7. NATURE OF PRIMARY PACKAGING
172mm printed aluminum foil background (0.25 micron)
180mm PVC film (250 micron)

8. THERAPEUTIC INDICATIONS
Tenoxicam is indicated for the relief of pain and inflammation in osteoarthritis and rheumatoid arthritis. It is also indicated for the short-term management of acute musculoskeletal disorders, including strains, sprains

and other soft tissue injuries. Intravenous, IM tenoxicam is also available for these indications in patients considered unable to take oral tenoxicam .

9. DOSAGE AND ROUTE OF ADMINISTRATION

For oral administration.

To be taken preferably with or after meals.

Adverse effects can be minimized by using the lowest effective dose for the shortest duration needed to control symptoms.

Adults

A single daily dose of 20 mg of Tenex should be taken at the same time each day. Tenex tablets should be administered orally with water or other liquid.

Higher doses should be avoided because they generally do not result in a significantly greater therapeutic effect, but may be associated with a higher risk of adverse effects.

In acute musculoskeletal disorders, treatment should normally not be required for more than 7 days, but in severe cases it may be continued for up to a maximum of 14 days.

Old people

Elderly people are at increased risk of serious consequences of adverse reactions. They are also more likely to receive concomitant treatment or to have impaired liver, kidney, or cardiovascular function. If an NSAID is deemed necessary, the lowest and shortest effective dose possible should be used. The patient should be monitored regularly for gastrointestinal bleeding during treatment with NSAIDs.

The children

There are insufficient data to recommend the administration of Tenex to children.

Use in renal and hepatic failure

Creatinine clearance	Dosage regimen
More than 25 ml/min	Usual dosage but monitor patients carefully
Less than 25 ml/min	Insufficient data to make dosing recommendations

Due to the high plasma protein binding of tenoxicam , caution should be exercised when plasma albumin concentrations are markedly reduced (e.g. in nephrotic syndrome) or when bilirubin concentrations are elevated.

There is insufficient information available to recommend the dosage of Tenoxicam in patients with pre-existing hepatic impairment.

10. CONTRAINDICATIONS

Active or history of recurrent peptic ulcer/hemorrhage (two or more distinct episodes of proven ulceration or bleeding).

History of gastrointestinal bleeding (melaena, hematemesis), perforation related to previous treatment with NSAIDs or severe gastritis.

Hypersensitivity to tenoxicam or any of the excipients.

NSAIDs are contraindicated in patients who have previously experienced hypersensitivity reactions (inducing symptoms of asthma, rhinitis, angioedema or urticaria) in response to salicylates, ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs (NSAIDS).
Severe kidney, liver or heart failure.
Tenoxicam is contraindicated during the last trimester of pregnancy

11. WARNINGS AND SPECIAL PRECAUTIONS FOR USE
WARNINGS :
Adverse effects can be minimized by using the lowest effective dose and shortest duration necessary to control symptoms (see section 4.2 and Gastrovascular and cardiovascular risks below).

Use of Tenex with concomitant NSAIDs, including selective cyclooxygenase-2 inhibitors or drugs that may increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin , selective inhibitors Serotonin reuptake or anti-platelet drugs such as aspirin should be avoided (see section 4.5).

Gastrointestinal bleeding, ulceration and perforation
Gastrointestinal bleeding, ulceration, or perforation, which may result in death, has been reported with all NSAIDs at any time of treatment, with or without warning symptoms or a history of serious gastrointestinal events.
The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing doses of NSAIDs, in patients with a history of ulcer, particularly in cases of hemorrhage or perforation (see section 4.3) and in the elderly. These patients should begin treatment at the lowest available dose. Combination therapy with protective agents (e.g., misoprostol or proton pump inhibitors) should be considered for these patients, as well as for patients requiring concomitant low-dose aspirin or other medications that may cause complications. increase gastrointestinal risk (see below and section 4.5).
Patients with a history of gastrointestinal toxicity, particularly in the elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding), especially early in treatment.
Caution is advised in patients receiving concomitant therapy that may increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin , selective serotonin reuptake inhibitors, or antiplatelets such as aspirin (see section 4.5).
If gastrointestinal bleeding or ulceration occurs in patients receiving tenoxicam , treatment should be discontinued.
NSAIDs should be administered with caution to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn 's disease), as these conditions may be exacerbated (see section 4.8).
SLE and mixed connective tissue disease:
In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders, the risk of aseptic meningitis may be increased (see section 4.8).

Dermatological:
Serious, sometimes fatal, skin reactions, such as exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN), have very rarely been reported in association with the use of NSAIDs (see section 4.8). Patients should be informed of the signs and symptoms and monitored closely for skin reactions. Patients appear to be at the highest risk of developing these reactions early in treatment: the onset of the reaction appears in the majority of cases within the first month of treatment. Tenex should be discontinued at the first appearance of rash, mucosal damage, or any other sign of hypersensitivity. The best outcomes in

management of SJS and TEN come from early diagnosis and immediate discontinuation of any suspected medications. Early withdrawal is associated with a better prognosis.
If the patient has developed SJS or TEN with the use of tenoxicam , tenoxicam should not be restarted in that patient at any time .

Impairment cardiovascular , renal And hepatic
In rare cases , non- steroidal anti- inflammatory drugs can to provoke a nephritis interstitial , a glomerulonephritis , a necrosis papillary and nephrotic syndrome . These agents inhibit prostaglandin synthesis kidney that plays A supporting role in the maintenance of renal perfusion in patients whose flow blood kidney and blood volume are diminished . In these patients, administration of a nonsteroidal anti-inflammatory drug can precipitate a decompensation renal manifest , which returns to the state prior to treatment after stopping the drug . Patients most exposed to this type of reaction are those who present a insufficiency renal pre- existing condition (including diabetics with insufficiency renal) , nephrotic syndrome , decreased blood volume , disease hepatic , a insufficiency congestive heart disease , patients receiving concomitant treatment with diuretics or medication potentially nephrotoxic . THE people elderly . Functions renal , hepatic And cardiac conditions of these patients must be subject to close monitoring (see also section 4.3), and the dose must be maintained Also weak as possible in patients with a insufficiency renal , hepatic Or cardiac .

Respiratory disorders
Caution is advised in patients suffering from asthma bronchial Or having a history asthma bronchial , because ibuprofen would have caused bronchospasm in these patients .
Elevations occasional serum transaminases Or others function indicators hepatic have summer reported . In most cases , these increases have summer minimal and transient above normal . If the anomaly East significant Or persistent , you must Stop Tenoxicam and perform follow-up testing . Special attention East required in patients with a disease hepatic pre-existing .
Tenoxicam reduced aggregation platelet And may prolong bleeding time . That must be taken into account for patients who undergo a major surgery (for example , replacement joint) and which must determine the bleeding time .

The people elderly
The frequency of reactions adverse reactions to NSAIDs , particularly gastrointestinal bleeding and perforation, can be fatal in people elderly (see section 4.2). The patients weakened seem tolerate ulcerations or bleeding less GOOD than the others . Most gastrointestinal events mortals associated with non- steroidal anti- inflammatory drugs are occurring in elderly patients and or weakened .

A care particular must be taken to monitor elderly patients regularly in order to detect possible interactions with concomitant treatment and to review function renal , hepatic and cardiovascular , potentially influenced by non- steroidal anti- inflammatory drugs .

Effects eyepieces
Effects unwanted on the eyes have summer reported with nonsteroidal anti- inflammatory drugs . He East SO recommended that patients experiencing vision problems during treatment with Tenoxicam undergo a assessment ophthalmic .

Effects cardiovascular And cerebrovascular

Monitoring and advice appropriate are necessary in patients with a history hypertension and/ or of insufficiency mild to moderate congestive heart disease , because a retention fluid and edema have summer reported in association with NSAID treatment .
The studies clinics and the data epidemiological suggest that the use of certain NSAIDs (especially in high doses and in long - term treatment) may be associated with a slight increase in risk of events thrombotic arterial (e.g. myocardial infarction or vascular accident cerebral). The data are insufficient to exclude A such risk for tenoxicam .
Patients presenting uncontrolled hypertension , insufficiency congestive heart disease , heart disease ischemic established , a disease arterial peripheral and or a disease cerebrovascular born must be treated with tenoxicam only after an examination attentive . A consideration similar should be done before starting a long - term treatment of patients with risk factors for disease cardiovascular (e.g. hypertension , hyperlipidemia , diabetes sweet , smoking).

Effects antipyretics
As we know for others anti- inflammatory drugs , Tenoxicam can hide the signs infection usual .

Laboratory tests
NSAIDs inhibit the synthesis renal prostaglandins And can therefore have an effect undesirable on hemodynamics kidney and the balance of salts and water. He is necessary to monitor the patient adequate , paying particular attention to the functions cardiac and renal (BUN , creatinine , development of edema , weight gain , etc.) when administering Tenoxicam to patients at risk increased to develop a insufficiency renal , such that insufficiency renal pre-existing , insufficiency renal in diabetics , cirrhosis hepatic , insufficiency congestive heart disease , decrease in volume or concomitant treatment with medications potentially nephrotoxic drugs , diuretics and corticosteroids . This patient group presents a risk particularly during the per and postoperative phases major surgery due to the risk of serious blood loss . They require SO close monitoring during periods postoperative and recovery .

Due to the high plasma protein binding of tenoxicam plasma , it caution should be exercised when rates plasma albumin are clearly reduced .
Tablets Tenex film-coated contain lactose
Patients with problems hereditary rare galactose intolerance , lapp lactase deficiency or glucose - galactose malabsorption should not take This medicine .

Fertility feminine scaled down
Using Tenoxicam can harm fertility And is not recommended for women trying to conceive . In women who have difficulty conceiving or who undergo a investigation on infertility , Tenex withdrawal must be considered .

12. USE IN PREGNANCY AND BREASTFEEDING
Fertility
The use of tenoxicam , as with any other drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended in women trying to conceive. In women who have difficulty conceiving or are undergoing infertility investigation, tenoxicam withdrawal should be considered. (See section 4.4).

Pregnancy

Inhibition of prostaglandin synthesis may harm pregnancy and/or embryonic/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage, heart defects and gastroschisis after the use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk of cardiovascular malformation was increased from less than 1% to approximately 1.5%. The risk is thought to increase with dose and duration of treatment. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo -fetal lethality. In addition, an increased incidence of various malformations, including cardiovascular, has been reported in animals receiving a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimesters of pregnancy, tenoxicam should not be administered unless absolutely necessary. If tenoxicam is used by a woman who is trying to conceive or during the first and second trimesters of pregnancy, the dose should be kept as low as possible and the duration of treatment as short as possible.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction which may lead to renal failure with oligohydramniosis ;
the mother and the newborn, at the end of pregnancy, to:
- possible prolongation of bleeding time, anti-aggregant effect which may occur even at low doses.
- inhibition of uterine contractions leading to delayed or prolonged labor.
Therefore, tenoxicam is contraindicated during the third trimester of pregnancy.

Lactation
In the limited studies available to date, NSAIDs may appear in breast milk at very low concentrations. NSAIDs should, if possible, be avoided during breastfeeding.
Based on single dose results, a very small amount (average value less than 0.3% of the dose) of tenoxicam passes into breast milk (see section 5.2 Pharmacokinetic properties). There is no evidence of adverse effects in breastfed infants of mothers taking Mobiflex . However, infants should be weaned or the drug stopped.

13. DRUGS INTERACTIONS

Other painkillers, including selective cyclooxygenase-2 inhibitors
Avoid using two or more NSAIDs (including aspirin) at the same time, as this may increase the risk of side effects.

Acetylsalicylate and salicylates
Salicylates may displace tenoxicam from protein binding sites and thereby increase the clearance and volume of distribution of Mobiflex . Concomitant treatment with salicylates should therefore be avoided due to the increased risk of adverse reactions (especially gastrointestinal).

Antacids and H2 receptor antagonists
Antacids may reduce the rate of absorption of Mobiflex , but not the extent. The differences are not expected to have clinical significance. No interaction has been observed with concomitantly administered cimetidine.

Anticoagulants
Tenoxicam is strongly bound to serum albumin and, like all NSAIDs, may enhance the effects of anticoagulants such as warfarin (see section 4.4). Close monitoring of the effects of anticoagulants and oral blood glucose agents is recommended, particularly during the early stages of treatment with Mobiflex . No

interaction with digoxin was observed. In healthy subjects, no clinically relevant interactions between Mobiflex and low molecular weight heparin have been observed.

Cardiac glycosides
NSAIDs may exacerbate heart failure, reduce GFR, and increase plasma levels of cardiac glycosides when coadministered with cardiac glycosides.

Cyclosporin
As with all NSAIDs, cyclosporine is co -administered with caution, due to the increased risk of nephrotoxicity .

Quinolone antibiotics
Animal data indicate that NSAIDs may increase the risk of seizures associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing seizures.

Lithium
Nonsteroidal anti-inflammatory drugs have been reported to reduce lithium elimination. If tenoxicam is prescribed to a patient receiving lithium therapy, the frequency of lithium monitoring should be increased, the patient is cautioned to maintain fluid intake and to be aware of symptoms of lithium intoxication.

Diuretics and antihypertensives
Nonsteroidal anti-inflammatory drugs may cause sodium, potassium, and fluid retention and may interfere with the natriuretic action of diuretic agents, which may increase the risk of nephrotoxicity. NSAIDs. These properties should be kept in mind when treating patients with heart failure, cardiac function, or hypertension, as they could lead to worsening of these conditions.

No clinically significant interactions between Mobiflex and furosemide have been noted, but Tilcotil attenuates the blood pressure lowering effect of hydrochlorothiazide . As is known from other NSAIDs, Mobiflex may attenuate the antihypertensive effects of alpha-blockers and ACE inhibitors.

No interactions have been reported between Mobiflex and alpha agonists or centrally acting calcium channel blockers.

There was no clinically relevant interaction when Mobiflex was administered concurrently with atenolol . During clinical trials, no interactions were reported in patients treated concomitantly with digitalis products. Thus, the concomitant administration of Mobiflex and digoxin appears to be without major risk.

Methotrexate
Caution is recommended in case of concomitant administration of methotrexate due to possible improvement in its toxicity, as NSAIDs would reduce the elimination of methotrexate.

Oral antidiabetics
The clinical effect of the oral antidiabetics glibornuride , glibenclamide , tolbutamide was also not modified by Mobiflex . However, as with other NSAIDs, careful monitoring is recommended when patients are concurrently receiving oral antidiabetic agents.

Colestyramine
Colestyramine may increase the clearance and reduce the half-life of tenoxicam .

Dextromethorphan
Concomitant administration of tenoxicam and dextromethorphan may increase the analgesic effect compared to monotherapy.

Food
tenoxicam absorption is not influenced by food, but the rate of absorption (Cmax) may be slower than in the fasted state.

Others
Concomitant administration of probenecid and tenoxicam may increase the plasma concentration of tenoxicam . The clinical significance of this observation has not been established.

Mifepristone
NSAIDs should not be used for 8 to 12 days after administration of mifepristone , as they may reduce the effects of mifepristone .

Corticosteroids
As with all NSAIDs, co- administration of corticosteroids should be administered with caution due to the increased risk of gastrointestinal ulceration or bleeding (see section 4.4).

Antiplatelets and selective serotonin reuptake inhibitors (SSRIs)
The risk of gastrointestinal bleeding is increased (see section 4.4) when anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs) are combined with NSAIDs.

Tacrolimus
There is a risk of nephrotoxicity when NSAIDs are administered with tacrolimus .

Zidovudine
There is an increase risk of hematological toxicity when NSAIDs are combined with zidovudine. There is evidence of an increased risk of hemarthroses and hematoma in HIV(+) hemophiliacs receiving concomitant treatment with zidovudine and ibuprofen.

Gold / Penicillamine
No clinically significant interactions were observed in a small number of patients receiving treatment with penicillamine or parental gold.

14. ADVERSE EFFECTS

Reported adverse reactions were generally mild and transient. In a small proportion of patients, treatment interruption due to adverse effects was necessary.
Within system organ classes, adverse reactions are listed under frequency sections (number of patients likely to experience the event), using the following categories:

Very common (≥1/10)

Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from available data)

Blood and lymphatic disorders
Not known: agranulocytosis, anemia, aplastic anemia , hemolytic anemia, leukopenia, thrombocytopenia , non- thrombocytopenic purpura , eosinophilia

Immune system disorders
Not known: hypersensitivity reactions such as asthma, anaphylactic reactions, angioedema
Metabolism and nutrition disorders
Common: anorexia
Rare: metabolic abnormalities (such as: hyperglycemia, increased/decreased weight)

Psychiatric disorders
Rare: sleep disorder (e.g. insomnia), depression, nervousness, dream abnormalities, frequency unknown: confusional state, hallucinations

Nervous system disorders
Common: dizziness, headache
Not known: drowsiness, paresthesia

Eye disorders
Not known: vision disturbances (such as visual impairment and blurred vision), swollen eyes, eye irritation

Ear and labyrinth disorders
Rare: vertigo
Not known: tinnitus

Heart problems
Rare: palpitations
Unknown frequency: heart failure
The possibility of precipitating congestive heart failure in elderly patients or those with compromised cardiac function should therefore be kept in mind.

Vascular disorders
Rare: thrombotic events (e.g. myocardial infarction or stroke)
Not known: vasculitis, hypertension

Clinical studies and epidemiological data suggest that the use of selective cyclooxygenase 2 inhibitors (COX2 inhibitors) and certain NSAIDs (especially at high doses and in long-term treatment) may be associated with slight increased risk of arterial thrombosis (for example, myocardial infarction or stroke).) (see section 4.4). Furthermore, tenoxicam has not shown an increase in thrombotic events such as myocardial infarction, data are insufficient to exclude such a risk with tenoxicam .

Respiratory, thoracic and mediastinal disorders
Rare: bronchospasm, aggravated asthma, dyspnea
Not known: epistaxis
Bronchospasm and worsening asthma have been reported following treatment with NSAIDs.

Gastrointestinal problems
Very common: gastric, epigastric and abdominal pain and discomfort, dyspepsia, nausea, vomiting, flatulence, constipation, diarrhea, indigestion, epigastric distress, stomatitis
Common: gastrointestinal bleeding, gastrointestinal perforation, gastrointestinal ulcers, gastric ulcer, sometimes fatal, especially in the elderly, hematemesis, melena, constipation, diarrhea, mouth ulceration, dry mouth, exacerbation of colitis and Crohn 's disease (see section 4.4) and precautions for use).
Very rare: pancreatitis

Hepatobiliary disorders
Uncommon: increased liver enzymes
Not known: hepatitis, jaundice

Skin and subcutaneous tissue disorders
Uncommon: pruritus, erythema, exanthema, rash, urticaria
Rare: vesiculo -bullous reactions.
Very rare: Severe cutaneous adverse reactions (SCAR): Stevens-Johnson syndrome, toxic epidermal necrolysis (see section 4.4).
Frequency unknown: photosensitivity reaction.

Nail disorders and photosensitivity reaction and alopecia have rarely been reported following NSAID treatment.

Kidney and urinary disorders
Uncommon: increased blood urea nitrogen or creatinine
Not known: nephrotoxicity (e.g. renal failure, interstitial nephritis, nephrotic syndrome, increased blood urea nitrogen or creatinine).

Reproductive system and breast disorders
Isolated cases of female infertility have been reported with drugs known to inhibit cyclooxygenase/prostaglandin synthesis, including tenoxicam .

General disorders and administration site conditions
Uncommon: fatigue, edema -
Unknown frequency: Malaise

15. OVERDOSE
Symptoms
In general, symptoms of NSAID overdose usually include nausea, vomiting, epigastric pain, rarely diarrhea, gastrointestinal bleeding, tinnitus, headache, blurred vision, and dizziness. Isolated cases of more serious toxicity have been reported after ingestion of substantial quantities; they include seizures, excitement,

drowsiness, hypotension, apnea, electrolyte imbalance, and renal failure. Exacerbation of asthma is a possible effect.

Management:
Patients should be treated symptomatically if necessary. In case of overdose, discontinuation of the drug, administration of activated charcoal, gastric lavage, antacids and proton pump inhibitors may be indicated. Within an hour of ingesting a potentially toxic amount, activated charcoal should be considered. There is no specific antidote. The benefits of gastric decontamination are uncertain. Dialysis does not significantly remove NSAIDs from the bloodstream. Good urine flow should be ensured - maintain adequate hydration. Renal and liver function should be closely monitored. Patients should be monitored for at least four hours after ingestion of potentially toxic quantities. Frequent or prolonged seizures should be treated with intravenous diazepam. Other measures may be indicated by the clinical condition of the patient.

16. SPECIAL STORAGE PRECAUTIONS
Store below 30 ^{0}C, protected from humidity.

17. AVAILABLE
Available in blister packs of 10 capsules and boxes of 1 blister.

19. NAME AND ADDRESS OF THE LABORATORY

Carlos Pharmaceuticals Ltd,
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