



# Dorixina

## Lysine clonixinate

Oral use  
Tablets

### Formula

Each tablet contains Lysine clonixinate 125 mg. Excipients: Microcrystalline Cellulose; Corn Starch; Magnesium Stearate; Hydroxypropyl Methylcellulose; Titanium Dioxide; Triacetin; Polyethyleneglicol 6000.

### Therapeutic action

Analgesic – Anti-inflammatory.

### Indications

**Dorixina** is indicated for the treatment of somatic or visceral pain.

### Pharmacological action

**Dorixina** is an analgesic non-steroidal anti-inflammatory drug, with mainly analgesic action. It exerts its effect by inhibiting prostaglandin synthesis. It was recently shown that it acts principally on the enzyme that catalyzes the production of prostaglandins responsible for inflammation (cyclooxygenase-2 or COX-2) with less activity on the enzyme that catalyzes the synthesis of prostaglandins of the gastrointestinal mucosa and the kidneys (cyclooxygenase-1 or COX-1), where these substances have a protecting role.

### Pharmacokinetics:

Lysine clonixinate is rapidly absorbed reaching its peak plasma level about 40 to 60 minutes following administration.

Its bioavailability is of about 56%, with some individual variability. The plasma half-life of Lysine clonixinate in humans is of about  $1.75 \pm 0.10$  hours (mean  $\pm$  SD). It is excreted in the form of metabolites, principally in the urine (60%). Its concentration in milk is of about 7 to 10% of the plasma concentration.

### Dosage and administration

#### Dorixina tablets:

Adults and children over 12 years of age: Unless otherwise prescribed, administer 1 tablet 3 or 4 times per day at regular intervals, according to pain intensity.

Swallow the tablets whole, without chewing them and with abundant liquid.

Maximum daily dosage: 6 tablets.

### Contraindications

Known hypersensitivity to Lysine clonixinate. Active peptic ulcer or gastroduodenal hemorrhage.

Pregnancy. Children under 12 years of age.

Patients with a history of bronchospasms, nasal polyps, angioedema or urticaria caused by the administration of acetylsalicylic acid (aspirin) or other NSAIDs.

### Warnings

In cases of allergic skin and/or mucosal reactions or symptoms of peptic ulcer or gastrointestinal hemorrhage contact your physician and discontinue treatment with **Dorixina**.

### Precautions

Caution should be used when administering to patients with a history of digestive diseases like gastroduodenal peptic ulcer or gastritis and in patients treated with anticoagulants.

Although no case with the administration of Lysine clonixinate has been reported, it is known that NSAIDs inhibit the synthesis of prostaglandins which have a supportive role in the maintenance of renal perfusion. In patients with impaired renal blood-flow administration of NSAIDs may precipitate overt renal decompensation, usually reversible with the discontinuation of the product. Patients at greatest risk of this reaction are dehydrated patients, patients with congestive heart failure, hepatic cirrhosis, nephrotic syndrome or other overt renal diseases, patients taking diuretics or those who underwent major surgeries with subsequent hypovolemia. Control the amount of diuresis and renal function in these patients before treatment.

Although also not observed during treatment with Lysine clonixinate, administration of NSAIDs may increase transaminase plasma levels or other liver parameters. In most cases these elevations over normal limits are small and transient.

Pregnancy: Although preclinical toxicological studies did not show teratogenic effects, there is no sufficient experience available with the administration of Lysine clonixinate to pregnant women. Therefore **Dorixina** should not be administered during pregnancy.

Nursing: Studies carried out in humans showed that excretion of Lysine clonixinate in human milk is very low. Notwithstanding this, before administering Lysine clonixinate to nursing mothers the risk/benefit ratio should be evaluated.

Pediatric use: There are no clinical studies available with Lysine clonixinate administered to children under 12 years of age, therefore its use is contraindicated in patients of this age group.

Geriatric use: Like with other anti-inflammatories, Lysine clonixinate should be administered with caution to elderly patients, as they may have impairment of their cardiac, hepatic or renal functions.

### Drug interactions

Other NSAIDs (including high doses of acetylsalicylic acid): Increase of the risk of gastroduodenal ulcer and hemorrhages due to their synergistic action.

Oral anticoagulants, ticlopidine, heparin (systemic administration), thrombolytics: Major risk of hemorrhages. If concomitant administration is unavoidable, strict controls of blood coagulation must be performed accordingly adjusting the dosage of those medicines which modify coagulation parameters.

Lithium: Usually NSAIDs increase lithium plasma levels. Closely monitor lithium plasma levels when starting, modifying or discontinuing treatment with **Dorixina**.

Methotrexate: Concomitant treatment with methotrexate and NSAIDs may increase the hematological toxicity of methotrexate. In these cases, strict hematological controls must be performed.



Diuretics: In patients with dehydration, treatment with NSAIDs increases the potential risk of acute renal failure. In cases of concomitant treatment with Lysine clonixinate and diuretics patients must be properly hydrated and their renal function controlled before initiating treatment.

Antihypertensives (for example, beta-adrenergic receptor blocking agents, ACE-inhibitors, vasodilators, diuretics): During concomitant treatment with antihypertensive agents and NSAIDs a decrease in antihypertensive effect has been reported due to the inhibition of vasodilating prostaglandins.

#### **Adverse reactions**

At therapeutic doses **Dorixina** is well tolerated. In rare cases, specially when administered to sensitive patients, nausea, vomiting, gastritis and somnolence may occur.

#### **Overdosage**

No cases of overdosage with **Dorixina** were informed.

After a thorough evaluation of the patient, considering the time lapsed from administration, the amount of drug taken and discarding the contraindication of certain procedures, the physician will decide upon carrying out the general rescue treatment: Gastric evacuation (vomiting or gastric lavage), strict clinical control (specially gastroduodenal and renal function) and symptomatic supportive care. There exists no specific antidote.

#### **How supplied**

##### **Dorixina Tablets:**

Packages containing 20 and 50 tablets.

White, cylindrical tablets, marked with the letter D on both sides.

**Swallow the tablets whole, without chewing them and with abundant liquid.**

Sold under prescription.

*Made in Argentina.*

Product authorized by the Ministry of Health.

Certificate N° 34,746

Technical Director: Jorgelina D'Angelo, Pharmacist.

#### **Medicinal product.**

**Keep out of the reach of children.**

**Keep in a dry place at temperature below 30°C.**

Manufactured by:

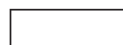
**Roemmers S.A.I.C.F.**

Fray Justo Sarmiento 2350,

B1636AKJ Olivos, Buenos Aires, Argentina.

Distributed by:

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