

Piromed Dispersible Tablet

(Piroxicam –β-Cyclodextrin eq .to Piroxicam 20 mg)

Piromed is a new formulation of piroxicam as a complex with β - Cyclodextrin in the molar ratio of 1:2:5.

B- Cyclodextrin, produced by enzymatic hydrolysis of common starch, has a particular chemical structure that enable it to from inclusion compounds (molecular encapsulation) with various drugs. In this way it is able to improve solubility, stability and bioavailability .**Piromed** is soluble in water and has a more rapid and complete absorption than plain piroxicam after oral or rectal administration. The improved solubility leads to a rapid increase in plasma levels and peak value is reached earlier, in clinical terms this means a quicker and more intense analgesic and anti—inflammatory effect.

The long half life of **Piromed,** which is the same as that of plain piroxicam, allows for just one single daily dose. Due to its pharmacodynamic and pharmacokinetic properties, **Piromed** is particiculary suitable for the treatment of disorder with painful symptoms that could seriously affected the general conditions and normal activity of patients and where a repaid and intense efficacy is required.

INDICATION:

Acute painful conditions

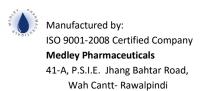
PERSENTATION AND DOSAGE:

Tablet: 1 tablet (equivalent to 20 mg of piroxicam) per day in elderly patients it may be necessary to reduce the dosage (half a tablet and limit the duration of treatment)

CONTRANINDICATIONS:

Piroxicam must not be used in subject know to be hypersensitive to the drug, nor in subjects with gastro duodenal ulcer, gastritis, dyspepsia, severe hepatic or renal disturbance. It is possible that cross sensitivity with acetylsalicylic acid or other NSAIDs exist. Therefore piroxicam must not be administered to patients in whom acetylsalicylic acid or NSAIDs induce the symptoms of asthma, rhinitis or urticaria. The product is contraindicated in ascertained or suspected pregnancy, during lactation and in children.

PRECAUTIONS:





The product must be used under strict medical control in patients with a medical history of disturbance in the upper gastrointestinal tract. Particular caution must be taken in subject with cardio circulatory insufficiency, arterial hypertension, reduced hepatic or renal function, previous or current blood alterations, bronchial asthma and elderly patients. Piroxicam may affect concentration and it is therefore not advisable to driver or undertakes any activity requiring quick reflex action. As with other drugs having similar activity piroxicam may increase BUN in some patients; however, BUN does not keep on increasing as the therapy continues but reaches a steady level, BUN is not associated with an increase of serum creatinine. Piroxicam like other NSAIDs decreases platelet aggregation and prolongs bleeding, this should be recommended when hematological tests are carried out and when patients undergo concomitant treatment with drugs that inhibit platelet aggregations.

SIDE EFFECTS:

The most commonly found side effects are gastrointestinal disturbances which are represented by nausea, epigastric distress, constipation and diarrhea.

Other noted side effects:

Signs of hypersensitivity (skin rash), headache and vertigo, asthenia, changes in blood chemistry, increased BUN.

Rare side effects:

Gastric ulcer with or without hemorrhages, vomiting, allergic edema of the face and hand, increase of cutaneous photosensitivity, ocular disturbances, aplastic, anemia, pancytopenia, thrombocytopenia, increase of liver function parameters, jaundice, acute renal insufficiency, increases of liver function parameters, water retention that may occur in the form of edema (mainly ankle edema), or cardio circulatory disturbance (Hypertension, Congestive Heart Failure). Sporadic cases of gastric ulcer with perforation, Steven's – Johnson Syndrome, Lyell's disease, agranulocyosis, bladder disorder, shock and warming symptoms, acute heart failure, stomatitis, alopecia and nail growth disorders have been associated with the use of piroxicam.

OVERDOSAGE:

In the event of an overdose with **Piromed** a supportive and symptomatic therapy should be given.

PACKAGES:

Box of 20 tablets in Alu-Alu pack.

KEEP OUT OF THE REACH OF CHILDREN.

