Milran

Milnacipran Hydrochloride

COMPOSITION

Milran 12.5 Tablet: Each film coated tablet contains Milnacipran Hydrochloride INN 12.5 mg.

Milran Tablet: Each film coated tablet contains Milnacipran Hydrochloride INN 50 mg.

PHARMACOLOGICAL INFORMATION

Milnacipran is a potent inhibitor of neuronal norepinephrine and serotonin reuptake in approximately 1:3 ratio respectively. These actions simultaneously works synergistically to treat both depression and fibromyalgia and also improve multiple fibromyalgia symptoms such as peripheral and central pain, depressiveness, sleep and quality of life.

Absorption: T_{max} is approximately 2 to 4 h. Oral bioavailability is approximately 85%-90%.

Distribution: Protein binding is 13%. Volume of distribution (V_d) is approximately 400 L.

Metabolism: There is some (45%) biotransformation. The metabolic pathway is predominantly a Phase II metabolism, producing Milnacipran carbamoyl-O-glucuronide compounds. And it is active between the two major metabolites (l-Milnacipran and-d-Milnacipran).

Elimination: Milnacipran and its metabolites are eliminated primarily by renal excretion. Following oral administration of Milnacipran, approximately 55% of the dose was excreted in urine as unchanged Milnacipran (24% as l-Milnacipran and 31% as d-Milnacipran). Terminal half-life is approximately 6 to 8 h.

CLINICAL INFORMATION

Indications and usage

Milran is indicated for-

- Management of fibromyalgia
- Major depressive disorder

Dosage and administration

The recommended dose of Milnacipran Hydrochloride is 50 mg twice daily. Maximum dosage is 100 mg twice daily.

Based on efficacy and tolerability, dosing may be titrated according to the following schedule:

Day 1	: 12.5 mg once
Day 2-3	: 12.5 mg twice daily (25 mg/day)
Day 4-7	: 25 mg twice daily (50 mg/day)
After day 7	: 50 mg twice daily (100 mg/day)

The recommended dose for depression is 100 mg/day (given as 50 mg, 2 times daily), with a starting period of 4 days on 25 mg/day.

After successful treatment of the acute depressive episode, patients should be maintained on Milnacipran for several months (normally 9 months) in order to prevent relapse of depression.

Use in special population

Pregnancy & lactation

It is not been adequately studied in pregnant women. Milnacipran has been assigned to pregnancy category C. It may be given to a pregnant woman if the physician believes that the benefits to the woman outweigh any possible risk to the unborn child. There are no data on the excretion of Milnacipran into human milk.

Children

It is not approved for use in pediatric patients due to insufficient clinical data.

Precaution

After extended use, the dose should be tapered and not abruptly discontinued. Withdrawal symptoms have been reported in patients when discontinuing treatment with Milnacipran. A gradual dose reduction is recommended.

At least 14 days should elapse between discontinuation of an MAOI and initiation of therapy with Milnacipran. In addition, allow at least 5 days after stopping Milnacipran before starting an MAOI.

Contraindication

Milnacipran is contraindicated to concomitant use with MAOIs or within 14 days of discontinuing treatment with an MAOI & uncontrolled narrow-angle glaucoma.

Drug interaction

In vitro and in vivo studies showed that Milnacipran is unlikely to be involved in clinically significant pharmacokinetic drug interactions with MAOIs, $5HT_1$ receptor antagonist, Epinephrine, Nor-epinephrine, Clonidine, Digitalis etc.

Side effects

Generally nausea, headache, constipation, dizziness, hot flush, hyperhidrosis, vomiting, palpitations, dry mouth may arise.

PHARMACEUTICAL INFORMATION

Storage condition

Store below 30°C and dry place, away from light. Keep out of the reach of children.

Presentation & packaging

Milran 12.5 Tablet: Each commercial box contains 50 tablets in Alu-Alu blister pack.

Milran Tablet: Each commercial box contains 20 tablets in Alu-Alu blister pack.

Manufactured By
BEACON®
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