

Migaba[®]

Mirogabalin

COMPOSITION:

Migaba[®] 2.5 Tablet : Each film coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 2.5 mg.

Migaba[®] 5 Tablet : Each film coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 5 mg

PHARMACOLOGY:

Mirogabalin belongs to the class of gamma-aminobutyric acid and its derivatives. Mirogabalin selectively binds $\alpha_2\delta$ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca^{2+}) influx and neurotransmission which inhibits neurotransmitter release in presynaptic neuron endings. Due to the inhibition of neurotransmitter release, the hyper- excitability of central nervous system (CNS) neurons decreases.

INDICATION:

Peripheral neuropathic pain (PNP), Diabetic peripheral neuropathic pain (DPNP) and Postherpetic neuralgia (PHN).

DOSAGE AND ADMINISTRATION:

Route of administration: Oral. The initial dose for adults is 5 mg of Mirogabalin twice daily. Then the dose is gradually increased by 5 mg at an interval of at least a week to 15 mg twice daily. The dose may be adjusted appropriately between 10 mg and 15 mg twice daily depending on ages and symptoms.

Hepatic Impairment

A single 15 mg dose of Mirogabalin does not produce significant adverse reaction, in patients with mild to moderate hepatic impairment. No data available for severe hepatic impairment.

Renal Impairment

In mild renal dysfunction, the initial dose starts from 5 mg twice a day, slowly increased by 5 mg at an interval of 1 week to 10 mg. In moderate renal dysfunction, the initial dose starts from 2.5 mg twice a day, slowly increased by 2.5 mg at an interval of 1 week to 7.5 mg twice a day. In severe renal dysfunction, the initial dose starts from 2.5 mg once a day, slowly increased by 2.5 mg at an interval of 1 week to 7.5 mg once a day.

CONTRAINDICATIONS:

Mirogabalin is contraindicated in patients with known hypersensitivity to Mirogabalin or any of its components.

Warnings and Precautions

This medicine may cause blurred vision and double vision. So, avoid operating dangerous machinery. This medicine may cause weight gain. If a sign of obesity appears, consult with your doctor.

SIDE EFFECTS:

Common side effects: Somnolence, dizziness, edema and weight gain.

Rare side effects: Light headedness, loss of consciousness, general malaise, loss of appetite, nausea, vomiting and jaundice.

USE IN PREGNANCY & LACTATION

Use in pregnancy: There are no adequate and well-controlled studies with Mirogabalin in pregnant women to inform a drug-associated risk. Therefore, it should be used during pregnancy where there are no alternatives and benefits outweigh risks.

Use in lactation: There are no data available on the excretion of Mirogabalin into human milk. A decision should be made to discontinue nursing or discontinue the drug, considering the importance of the drug to the mother.

USE IN CHILDREN & ADOLESCENTS: The safety and effectiveness of Mirogabalin have not been established in patients under the age of 18 years.

Use in renal impairment: No dose adjustment is recommended in mild renal impairment. Reduce the 50% dose in moderate renal impairment. Reduce the 75% dose in severe renal impairment and End-Stage Renal Disease patient.

Use in hepatic impairment: No dose adjustment is recommended in mild or moderate hepatic impairment. No PK data of Mirogabalin are available for severe hepatic impairment patients.

DRUG INTERACTION:

With Medicine : Co-administration of Mirogabalin with Cimetidine or Probenecid may raise the Mirogabalin plasma concentration. Importantly, if Mirogabalin is taken with Lorazepam, the depressive effects on the CNS may be potentiated.

With food & others : Administration of Mirogabalin with food has no clinically relevant effect on the total absorption of Mirogabalin. Avoid consuming alcohol while taking Mirogabalin, as Mirogabalin may potentiate the impairment of motor skills and sedating effects of alcohol.

OVERDOSAGE

Repeated-dose toxicity studies showed that the dose-limiting toxicity was considered abnormal clinical signs associated with CNS depression, resulting from exaggerated pharmacological action.

STORAGE:

Store in a dry and cool place below 30°C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Migaba[®] 2.5 Tablet : Each box contains 2X15's tablets in Alu-Alu blister pack.

Migaba[®] 5 Tablet: Each box contains 2X15's tablets in Alu-Alu blister pack.



Manufactured by

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