W=100 mm

Miraba

Tablet

Mirogabalin

Composition

Miraba 2.5 : Each film-coated tablet contains Mirogabalin Besilate INN equivalent to Mirogabalin 2.5 mg.
Miraba 5 : Each film-coated tablet contains Mirogabalin Besilate INN equivalent to Mirogabalin 5 mg.
Miraba 10 : Each film-coated tablet contains Mirogabalin Besilate INN equivalent to Mirogabalin 10 mg.

Pharmacology

Mirogabalin belongs to the class of gamma amino acids and its derivatives. Mirogabalin selectively binds α2δ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca2+) 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.

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 and Lactation

There are no adequate data on the developmental risk associated with the use of Mirogabalin in pregnant women.

Use in Children and Adolescent

It is not known if Mirogabalin is safe and effective in children and adolescent.

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.

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.

Overdose

No data available.

Storage

Store below 30^0C temperature and dry place, protected from light.
Keep all medicines out of reach of children.

Packing

Miraba 2.5 : Each box contains 2x10 tablets in Alu-Alu blisters.
Miraba 5 : Each box contains 2x10 tablets in Alu-Alu blisters.
Miraba 10 : Each box contains 2x10 tablets in Alu-Alu blisters.

***Further information is available on request.**

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Manufactured by:
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