Mirovan

Mirogabalin Besylate INN

COMPOSITION

Mirovan 2.5 Tablet: Each film coated tablet contains Mirogabalin 2.5 mg as Mirogabalin Besylate INN.
Mirovan 5 Tablet: Each film coated tablet contains Mirogabalin 5 mg as Mirogabalin Besylate INN.
Mirovan 10 Tablet: Each film coated tablet contains Mirogabalin 10 mg as Mirogabalin Besylate INN.

PHARMACOLOGY

Mirogabalin is an analog of the neurotransmitter, gamma-aminobutyric acid (GABA). It is a potent and specific ligand of the $\alpha_2\delta$ subunit of voltage-dependent Ca^{2+}channels, which reduces calcium (Ca^{2+}) influx and neurotransmission in dorsal root ganglia (DRGs), inhibiting neurotransmitter release in presynaptic neuron endings.

INDICATIONS

Mirovan is indicated for the management of-
• Diabetic Peripheral Neuropathic Pain (DPNP)
• Postherpetic Neuralgia (PHN)

DOSAGE & ADMINISTRATIONS

The initial oral dose for adults is 5 mg twice daily, and then gradually increase to 10 mg twice daily with an interval of at least 1 week. Based on individual patient response and tolerability, the dose can be increased up to the maximum dose of 15 mg twice daily with an interval of at least 1 week.

CONTRAINDICATIONS

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

WARNING & PRECAUTIONS

Mirogabalin may impair the ability to drive or operate machinery. Elderly people should be aware of falling and fracture.

SIDE EFFECTS

Nasopharyngitis, somnolence, dizziness, peripheral edema and weight gain etc. may occur.

DRUG INTERACTIONS

Co-administrated with OAT1, OAT3, OCT2, MATE1, MATE2-K or UGT inhibitors may increase Mirogabalin exposure, should be used with caution.

USE IN SPECIAL GROUP

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.

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 below 25°C, keep in dry place and protect from light.
• Keep out of the reach of the children.

PACKING

Mirovan 2.5 Tablet: Each box contains 20 Tablets in blister pack.
Mirovan 5 Tablet: Each box contains 20 Tablets in blister pack.
Mirovan 10 Tablet: Each box contains 20 Tablets in blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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