Miroflex

Mirogabalin

COMPOSITION:

Miroflex 2.5 Tablet: Each film coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 2.5 mg.
Miroflex 5 Tablet: Each film coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 5 mg.
Miroflex 10 Tablet: Each film coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 10 mg.

PHARMACOLOGY

Mirogabalin exhibits analgesic activity by reducing calcium ions via binding to the $\alpha_2\delta$ subunit of voltage-gated calcium channels in the nervous system. The analgesic activity of Mirogabalin is also involved in activating the noradrenergic pathway in the descending pain inhibitory system.

INDICATION

It is indicated for the treatment of diabetic peripheral neuropathic pain (DPNP) & postherpetic neuralgia (PHN) in adults.

DOSAGE AND ADMINISTRATION

For adults, the starting dose is usually 5 mg taken twice daily (orally). The dose may be gradually increased by 5 mg at weekly intervals or longer, up to 15 mg twice daily. Depending on the patient's age and symptoms, the dose can be adjusted within a range of 10 to 15 mg per dose, administered twice daily.

Dose adjustment for patients with renal impairment:

		Severity grade of renal impairment (creatinine clearance [CLcr]: ml/min)		
		Mild (90 > CLcr ≥ 60)	Moderate (60 > CLcr ≥ 30)	Severe (Including patients on hemodialysis) (30 > CLcr)
Daily Dose		10 - 30 mg	5 - 15 mg	2.5 - 7.5 mg
Initial Dose		5 mg twice daily	2.5 mg twice daily	2.5 mg once daily
Effective Dose	Minimum Dose	10 mg twice daily	5 mg twice daily	5 mg once daily
	Recommended Dose	15 mg twice daily	7.5 mg twice daily	7.5 mg once daily

CONTRAINDICATION

It is contraindicated in patients with hypersensitivity to the active substances or any of the excipients.

WARNING & PRECAUTION

It may cause dizziness, somnolence or loss of consciousness. Avoid operating dangerous machinery, such as driving a car; especially for elderly patients, careful attention should be taken because there is a case resulting in falls and fractures due to these symptoms. It may cause weight gain, blurred vision and double vision. If any of these symptoms are observed, consult with a doctor.

SIDE EFFECT

The most commonly reported side effects are somnolence, dizziness, constipation, edema, gait disturbance, weight increase and hepatic enzyme increase.

USE IN PREGNANCY & LACTATION

For pregnant women and women who may be pregnant, Mirogabalin should be administered only if the expected therapeutic benefits outweigh the possible risks associated with treatment. An animal study (in rats) has shown that it crossed the placenta.
The continuation or discontinuation of breastfeeding should be considered while taking into account the expected therapeutic benefits and the benefits of maternal feeding. An animal study (in rats) has shown that Mirogabalin transferred to breast milk.

USE IN CHILDREN & ADOLESCENTS

Clinical studies in children have not been conducted.

DRUG INTERACTION

Probenecid, Cimetidine: May potentiate the effect of Mirogabalin.
Lorazepam, Alcohol drinking: May facilitate the decrease in attention and balance function.

OVERDOSAGE

There have been reports on overdoses of up to 60 mg/day in an overseas clinical study in patients with fibromyalgia. Symptoms of overdose euphoric mood, dysarthria, headache, dysphagia, arthritis, joint swelling and asthenia. Hemodialysis is reported to remove 15.3% of Mirogabalin.

STORAGE

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

HOW SUPPLIED

Miroflex 2.5 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Miroflex 5 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Miroflex 10 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.

NIPRO JMI Pharma

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