SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Miro 2.5 mg Tablet

Miro 10 mg Tablet

Miro 15 mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Mirogabalin (as besylate) 2.5mg

Mirogabalin (as besylate) 5mg

Mirogabalin (as besylate) 10mg

Mirogabalin (as besylate) 15mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Miro 2.5 mg film-coated tablets:

Pink color spindle shaped coated tablet, one side engraved NQ and other side is bisection.

Miro 5 mg film-coated tablets:

Pink color spindle shaped coated tablet, one side engraved NQ and other side is bisection.

Miro 10 mg film-coated tablets:

Yellow color spindle shaped coated tablet, one side engraved NQ and other side is bisection.

Miro 15 mg film-coated tablets:

Orange color spindle shaped coated tablet, one side engraved NQ and other side is bisection

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Miro Tablet is indicated for the treatment of peripheral neuropathic pain in adults.

4.2. Posology and method of administration

Posology

Adults:

Initial dose: 5 mg orally twice daily.

Titration: Increase by 5 mg per dose at intervals of at least one week.

Maintenance dose: 10 mg to 15 mg orally twice daily, adjusted based on patient response and tolerability.

Renal impairment:

Mild (CrCl ≥60 to <90 mL/min): Initial dose of 5 mg twice daily; maximum 15 mg twice daily. Moderate (CrCl ≥30 to <60 mL/min): Initial dose of 2.5 mg twice daily; maximum 7.5 mg twice daily.

Severe (CrCl <30 mL/min) and patients on hemodialysis: Initial dose of 2.5 mg once daily; maximum 7.5 mg once daily.

No dose adjustment is required for patients with hepatic impairment.

Paediatric population:

The safety and efficacy of Miro Tablet in children have not been established.

Elderly population:

Dose selection should be cautious, reflecting the greater frequency of decreased renal function in this population.

Method of administration

For oral use. Miro Tablet can be taken with or without food.

4.3. Contraindications

Hypersensitivity to mirogabalin or to any of the excipients listed in Section 6.1.

4.4. Special warnings and precautions for use

Dizziness and somnolence: May increase the risk of accidental injury (fall). Patients should be advised to exercise caution until they are familiar with the potential effects of the medication. Weight gain: Monitor patients for signs of weight gain. Appropriate management should be instituted if necessary.

Withdrawal symptoms: Abrupt discontinuation may result in symptoms such as insomnia, nausea, diarrhea, and decreased appetite. It is advisable to taper the dose gradually when discontinuing therapy.

Ophthalmic effects: Blurred vision and other visual disturbances have been reported. Patients should report any changes in vision promptly.

4.5. Interaction with other medicinal products and other forms of interaction

CNS depressants: Concomitant use with CNS depressants (e.g., benzodiazepines, opioids) may enhance the risk of sedation and somnolence.

Alcohol: Patients should be advised to avoid alcohol while taking Miro Tablet due to potential enhancement of sedative effects.

4.6. Pregnancy and lactation

Pregnancy:

There are no adequate data on the use of mirogabalin in pregnant women. Miro Tablet should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation:

It is unknown whether mirogabalin is excreted in human milk. A decision must be made whether to discontinue breastfeeding or to discontinue the drug, considering the benefit of breastfeeding for the child and the benefit of therapy for the woman.

4.7. Effects on ability to drive and use machines

Miro Tablet has minor or moderate influence on the ability to drive and use machines. Patients experiencing dizziness, somnolence, or other central nervous system symptoms should refrain from such activities.

4.8. Undesirable effects

Common adverse reactions include:

Nervous system disorders: Dizziness, somnolence.

Gastrointestinal disorders: Constipation.

General disorders: Edema, weight gain.

Hepatobiliary disorders: Elevated liver enzymes.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

4.9. Overdose

Symptoms of overdose may include euphoric mood, dysarthria, headache, dysphagia, arthritis, joint swelling, and asthenia. In case of overdose, supportive treatment should be provided as necessary. Hemodialysis removes approximately 15.3% of mirogabalin and may be considered in patients with severe renal impairment.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, other analgesics and antipyretics, ATC code: N02BF03. Mirogabalin is a ligand for the α_2 δ subunit of voltage-gated calcium channels, reducing calcium influx and subsequent release of excitatory neurotransmitters, thereby exerting analgesic effects.

5.2. Pharmacokinetic properties

Absorption: Mirogabalin is rapidly absorbed, with peak plasma concentrations occurring approximately 1-hour post-dose.

Distribution: The apparent volume of distribution is approximately 40 L.

Metabolism: Mirogabalin undergoes minimal metabolism.

Elimination: Primarily excreted unchanged in urine, with a terminal half-life of approximately 4.5 to 6 hours.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and carcinogenic potential. Reproductive toxicity studies showed no adverse effects on fertility or fetal development at clinically relevant exposures.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Miro 2.5 mg tablet

Tablet core:

Mannitol

Microcrystalline cellulose (Avicel pH-102)

Carmellose calcium

Tocopherol

Magnesium aluminum silicate

Citric acid monohydrate

Magnesium stearate

Tablet coating:

Color Coat FC4WA White

Ferric oxide red

Miro 5 mg tablet

Tablet core:

Mannitol

Microcrystalline cellulose (Avicel pH-102)

Carmellose calcium

Tocopherol

Magnesium aluminum silicate

Citric acid monohydrate

Magnesium stearate

Tablet coating:
Color Coat FC4WA White
Ferric oxide red
Tablet core:
Mannitol
Microcrystalline cellulose (Avicel pH-102)
Carmellose calcium
Tocopherol
Magnesium aluminum silicate
Citric acid monohydrate
Magnesium stearate
Tablet coating:
Color Coat FC4WA White
Ferric oxide yellow
Miro 15 mg tablet
Tablet core:
Mannitol
Microcrystalline cellulose (Avicel pH-102)
Carmellose calcium
Tocopherol
Magnesium aluminum silicate
Citric acid monohydrate
Magnesium stearate
Tablet coating:
Color Coat FC4WA White
Instacoat Brown IC-5215

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

Please refer to packaging.

6.4. Special precautions for storage

Store below 30°C. Store in the original package in order to protect from moisture.

6.5. Nature and contents of container

Unit carton ALU/ALU-blister, each containing 10 film-coated tablets.

Miro 2.5 mg film-coated tablets Pack size: 3x10's film coated tablets.

6.6 Special precautions

For disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product:

Precautions Concerning the Dispensing of the Drug

For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drugs from the package prior to use. If the PTP sheet itself is mistakenly swallowed, the sharp edges of the sheet may be inserted into and puncture the esophageal mucosa, resulting in serious complications, such as mediastinitis.

7. MARKETING AUTHORISATION HOLDER

Nabiqasim Industries (Pvt) Ltd

17/24, Korangi Industrial Area, Karachi

8. MARKETING AUTHORISATION NUMBER(S)

H2026/CTD13008/27778

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18.01.2026

10. DATE OF REVISION OF THE TEXT

18.01.2026