SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Nervijen – NP Tablets.

2. Qualitative and quantitative composition

Each film-coated tablet contains:

Pregabalin 75 mg

Nortriptyline Hydrochloride B.P. equivalent to Nortriptyline 10 mg

Mecobalamin J.P. 1500 mcg

Excipients with known effect

Each tablet contains Lactose.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet (solid dosage form).

A printed Alu-Alu strip containing brown coloured, oval film-coated tablets with a breakline on one side and plain on the other side.

4. Clinical particulars

4.1 Therapeutic indications

NERVIJEN – NP Tablets provide a variety of benefits:

- Used in the treatment of neuropathic pain.
- Prevents megaloblastic or pernicious anaemia that can lead to weakness, fatigue, numbness of fingers and toes, and problems in thinking.
- Used in the treatment of generalized anxiety disorder.
- Used as an additional treatment of partial seizures.
- Used in the management of postherpetic neuralgia, painful peripheral neuropathy due to diabetes, nerve-related pain due to spinal cord injury and fibromyalgia.

4.2 Posology and method of administration

Parameter	Details
Dosage form	Film-coated tablet
Route of administration	Oral
Method of administration	Swallow by mouth
Dose schedule	To be taken two to three times daily or as directed by the physician

4.3 Contraindications

- Contraindicated in patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

- Do not use if allergic to the product or any of its ingredients.
- Do not use Nervijen – NP Tablet on the advice of a friend or family member. Similarly, do not give it to another person with similar symptoms.
- Use with caution in patients with kidney disease; dose adjustment may be required.
- Do not drive unless you are feeling well.

- Use with alcohol may be unsafe.
- Avoid operating machinery if you are not feeling well.
- Consult your doctor for side effects related to swelling of the face, lips or tongue.
- Consult your doctor if you experience sudden mood changes.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of other medicines, over-the-counter products, vitamins or herbal supplements may alter the effects of Nervijen – NP Tablet, increase the risk of side effects or reduce efficacy. Patients should inform the doctor about all medicines and supplements being used.

The source document lists possible interactions with: Cimetidine, Clonidine, Diltiazem, Fluconazole, Fluoxetine, Lorazepam, Nabilone, Oxycodone, Phenobarbitone, Phenytoin, Rauwolfia Reserpine and Riboflavin.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation: It may be unsafe to use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Do not drive or operate machinery unless you are feeling well. Nervijen – NP Tablet may cause dizziness, sleepiness, tiredness or uncoordinated body movements, which may affect the ability to drive or use machines.

4.8 Undesirable effects

The following undesirable effects are listed in the source document:

System/clinical area	Undesirable effects
Nervous system / general	Dizziness or sleepiness; tiredness; headache; uncoordinated body movements
Gastrointestinal / oral	Bitter taste in the mouth; loss of appetite; dry mouth
Skin and immune system	Allergic skin reactions; swelling of face, lips or tongue
Cardiorespiratory	Chest tightness
Other	Sudden mood changes

Reporting of suspected adverse reactions: Healthcare professionals are asked 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 cardiac dysrhythmias, severe hypotension, shock, pulmonary oedema, convulsions, CNS depression, confusion, restlessness, hot flushes, dizziness and nausea.

Management of overdose

- Urgently call a Poison Control Center or seek emergency medical attention.
- Transfer the patient immediately to hospital. Rapid disposal of the ingested product by gastric lavage or other symptomatic measures should be undertaken as medically advised.
- Bring the medicine box, container or label to assist doctors with necessary information.
- A minimum of six hours of observation with cardiac monitoring and observation for CNS or respiratory depression, hypotension, cardiac dysrhythmias and/or

conduction blocks and seizures is necessary. If signs of toxicity occur at any time during this period, extended monitoring is required.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Active ingredient	ATC code	Pharmacotherapeutic group / description
Pregabalin	N03AX16	Modulator of calcium channel function with anti-nociceptive and antiseizure effects; GABA derivative.
Mecobalamin	B03BA05	Coenzyme form of Vitamin B12 effective in neuropathies; Vitamin B12 derivative.
Nortriptyline Hydrochloride	N06AA10	Tricyclic antidepressant; N-demethylated active metabolite of amitriptyline; dibenzocycloheptene derivative.

5.2 Pharmacokinetic properties

Pregabalin

Absorption: Under fasting conditions, oral administration of pregabalin results in peak plasma concentrations occurring within 1.5 hours. Pregabalin oral bioavailability is ≥90% and is independent of dose. The rate of absorption is decreased when given with food, with an approximately 25% to 30% decrease in Cmax and an increase in Tmax to approximately 3 hours; however, administration with food has no clinically relevant effect on total absorption.

Distribution: Pregabalin does not bind to plasma proteins. The apparent volume of distribution following oral administration is approximately 0.5 L/kg. Pregabalin is a substrate for system L transporter and has been shown in animals to cross the blood-brain barrier, placenta, and be present in milk of lactating rats.

Metabolism: Approximately 90% of the administered radiolabelled dose was recovered in urine as unchanged pregabalin. The N-methylated derivative accounted for 0.9% of the dose. Pregabalin did not undergo racemization to the R-enantiomer in preclinical studies.

Elimination: Pregabalin is eliminated primarily by renal excretion as unchanged drug, with a mean elimination half-life of 6.3 hours in subjects with normal renal function. Elimination is nearly proportional to creatinine clearance.

Mecobalamin

Absorption: Following oral administration of single doses of 1500 mcg to healthy adult volunteers, peak serum total vitamin B12 concentration was reached in approximately 3 hours in a dose-dependent manner.

Distribution: Mecobalamin is distributed and stored primarily in the liver as coenzyme B12. The bone marrow stores a significant amount of absorbed vitamin B12. It crosses the placenta and is distributed into breast milk. Enterohepatic recirculation conserves systemic stores.

Metabolism: It is metabolised in the liver.

Elimination: Elimination is primarily through bile; excess mecobalamin is excreted unchanged in urine.

Nortriptyline

Absorption: Nortriptyline is well absorbed from the gastrointestinal tract. Peak plasma concentrations occur within 4 to 8.8 hours after oral administration, with a mean time of 5.5 hours. The mean oral bioavailability is 51%.

Distribution: The apparent volume of distribution after intravenous administration is 1633 ± 268 L, with a range of 1460 to 2030 L (21 ± 4 L/kg). Nortriptyline may cross the placental barrier. Plasma protein binding is approximately 93%.

Metabolism: Nortriptyline is metabolised in the liver by CYP2D6 via demethylation and hydroxylation followed by conjugation with glucuronic acid. The metabolism is subject to genetic polymorphism. The main active metabolite is 10-hydroxynortriptyline.

Elimination: Nortriptyline and its metabolites are mainly excreted in urine, with only small amounts (2%) recovered as unchanged parent compound. The elimination half-life after oral administration is approximately 26 hours.

5.3 Preclinical safety data

Pregabalin: Preclinical studies have documented analgesic actions in different pain models including neuropathic pain. Administration of pregabalin has been reported to alleviate carrageenan-induced thermal hyperalgesia and to block late-phase nocifensive response in formalin-induced nociception. In neuropathic pain models, it has been reported to attenuate pain symptoms.

Mecobalamin: Mecobalamin has excellent tolerability and no known toxicity.

Nortriptyline Hydrochloride: Not known.

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline Cellulose, Lactose, Colloidal Silicone Dioxide, Talcum, Magnesium Stearate.

6.2 Incompatibilities

Not relevant.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep the medicine out of reach of children.

6.5 Nature and contents of container

Nervijen – NP tablets are packed in an Alu-Alu strip of printed aluminium foil (208 mm) and plain aluminium foil (246 mm). A single Alu-Alu strip is packed in a printed unit carton with a pack insert.

Pack size: Alu-Alu strip of 10 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorisation holder

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8. Marketing Authorization Number

H2025/CTD10808/22090

9. Date of first authorization/renewal of the authorization

12/08/2025

10. Date of revision of the text

12/08/2025