

Pregahike NT Tablet

**Pregabalin (75 mg) + Nortriptyline (10 mg)
Tablet**

**Category: Analgesic, Antidepressant,
Neuropathic Pain Management
Dosage Form: Oral Tablet**

Description

This combination tablet contains Pregabalin (75 mg) and Nortriptyline (10 mg), formulated to manage neuropathic pain and depression. Pregabalin is an anticonvulsant and analgesic, primarily used to relieve nerve-related pain, while Nortriptyline is a tricyclic antidepressant that is effective in treating depression and has analgesic properties that further help reduce chronic pain. The combination targets both the emotional and physical aspects of chronic pain, improving overall quality of life for patients suffering from conditions such as diabetic neuropathy, post-herpetic neuralgia, and fibromyalgia.

Composition (Per Tablet):

- **Pregabalin: 75 mg**
- **Nortriptyline: 10 mg**

Indications:

- 1. Neuropathic Pain:**
 - Effective in treating pain caused by nerve damage, such as diabetic neuropathy, post-herpetic neuralgia, and fibromyalgia.
- 2. Depression and Anxiety (adjunctive treatment):**

- Nortriptyline has antidepressant effects, useful for managing depression that may accompany chronic pain conditions.
- 3. Chronic Pain Syndromes:**
 - Provides relief from other types of chronic pain, including musculoskeletal and mixed pain conditions.
 - 4. Sleep Disturbances Associated with Pain:**
 - Helps improve sleep quality, which is often disrupted due to pain or underlying depression.

Dosage and Administration:

- **Adults:**
 - **Initial Dose:** Typically, 1 tablet (75 mg Pregabalin + 10 mg Nortriptyline) once a day, preferably at night to minimize daytime drowsiness.
 - **Maintenance Dose:** Based on response, the dose may be adjusted to 1–2 tablets daily.
 - **Maximum Dose:** The dose should not exceed the prescribed daily dosage of Pregabalin (up to 300 mg) or Nortriptyline (up to 75 mg).
- **Renal Impairment:**
 - For patients with renal impairment, dose adjustments for Pregabalin may be required.
- **Administration:**
 - Take the tablet orally with a glass of water, with or without food.

Mechanism of Action:

1. Pregabalin:

- Pregabalin binds to calcium channels in the central nervous system, reducing the release of excitatory neurotransmitters. This action diminishes the transmission of pain signals from damaged nerves and reduces the sensation of neuropathic pain.

2. Nortriptyline:

- Nortriptyline works by inhibiting the reuptake of serotonin and norepinephrine in the brain, which helps improve mood and provides pain relief. The antidepressant effect also helps in managing anxiety and sleep disturbances commonly seen with chronic pain.

- Hypersensitivity to Pregabalin or any of its components.
- History of substance abuse or addiction, as Pregabalin can be misused.

• Nortriptyline:

- Hypersensitivity to tricyclic antidepressants or any ingredients in the formulation.
- Acute recovery phase following a myocardial infarction or history of heart arrhythmias.
- Patients with narrow-angle glaucoma.

• General Contraindications:

- Should not be used in combination with monoamine oxidase inhibitors (MAOIs), or within 14 days of their discontinuation.

Pharmacokinetics:

• Pregabalin:

- **Absorption:** Rapidly absorbed from the gastrointestinal tract.
- **Half-life:** Approximately 6–7 hours, allowing for once-daily or twice-daily dosing.
- **Excretion:** Excreted unchanged in urine.

• Nortriptyline:

- **Absorption:** Well absorbed with peak plasma concentrations occurring within 2–8 hours after administration.
- **Half-life:** 16–40 hours, supporting once-daily dosing.
- **Metabolism:** Metabolized in the liver, and excreted primarily via urine.

Warnings and Precautions:

1. Pregabalin:

- May cause drowsiness, dizziness, or blurred vision. Use caution when engaging in activities that require mental alertness (e.g., driving).
- Abrupt discontinuation of Pregabalin can result in withdrawal symptoms; gradually tapering the dose is recommended.
- Patients with a history of substance abuse should be monitored closely.

2. Nortriptyline:

- **Suicidal Thoughts:** May increase the risk of suicidal thoughts or behavior, especially in young adults. Patients should be closely monitored during treatment, particularly during the initial stages.
- **Cardiovascular:** Caution in patients with heart disease,

Contraindications:

• Pregabalin:

hypertension, or arrhythmias, as Nortriptyline may cause orthostatic hypotension or exacerbate these conditions.

3. Combined Use:

- When used together, the combination may increase the risk of sedation and drowsiness. Avoid alcohol or other central nervous system depressants during treatment.

Adverse Effects:

- **Pregabalin:**
 - **Common:** Drowsiness, dizziness, dry mouth, weight gain, peripheral edema (swelling), blurred vision, difficulty concentrating.
 - **Serious:** Suicidal thoughts, severe allergic reactions (e.g., rash, swelling), muscle problems (e.g., weakness), or changes in mood.
- **Nortriptyline:**
 - **Common:** Drowsiness, dry mouth, constipation, blurred vision, weight gain, dizziness.
 - **Serious:** Cardiac arrhythmias, confusion, urinary retention, suicidal thoughts.
- **Overall:**
 - Risk of sedation or drowsiness may increase when both drugs are taken together.

Storage Instructions:

- Store at room temperature (15–25°C), in a dry place.
- Keep the tablet container tightly closed to protect it from moisture.
- Keep out of reach of children.

Key Points for Use:

- This combination is particularly effective for patients suffering from neuropathic pain and depression or anxiety associated with chronic pain.
- Regular monitoring is recommended to assess effectiveness and manage potential side effects.
- It is important to follow the prescribed dosage and consult a healthcare provider if any side effects or concerns arise during treatment.

Note: This combination therapy should be used under the supervision of a healthcare provider and is not intended to replace other pain management or psychiatric treatments unless advised by a doctor.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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