Information For the Use Naproxen (500mg) + Domperidone (10mg)

Naprohike D Tablet

Product Information: Naproxen (500mg) + Domperidone (10mg) Tablet

Composition:

- Naproxen (500mg): A nonsteroidal anti-inflammatory drug (NSAID).
- Domperidone (10mg): A dopamine antagonist with antiemetic properties.

Pharmacological Class:

- Naproxen: Nonsteroidal Antiinflammatory Drug (NSAID).
- Domperidone: Anti-emetic and prokinetic agent (Dopamine receptor antagonist).

Indications:

This combination tablet is indicated for:

- Pain management: Relief from moderate to severe pain associated with conditions such as arthritis, musculoskeletal disorders, back pain, and dental pain.
- Inflammatory conditions: Treatment of conditions like rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and bursitis.
- Fever reduction: Effective in reducing fever associated with infections or inflammatory conditions.

• Preventing nausea and vomiting: Associated with NSAID therapy or other gastrointestinal disturbances.

The addition of Domperidone helps reduce nausea and vomiting that can sometimes be caused by Naproxen.

Mechanism of Action:

- 1. Naproxen:
 - Inhibits cyclooxygenase enzymes (COX-1 and COX-2), leading to decreased production of prostaglandins, chemicals involved in inflammation, pain, and fever. By reducing prostaglandins, Naproxen helps alleviate pain, reduce inflammation, and lower fever.
- 2. Domperidone:
 - Acts by blocking dopamine receptors in the chemoreceptor trigger zone (CTZ) in the brain. This action helps to reduce nausea and vomiting by preventing dopamine-induced stimulation of the vomiting center.

Dosage and Administration:

- Adults:
 - Initial dose: 1 tablet (500mg Naproxen + 10mg Domperidone) once or twice

daily, depending on the severity of the condition.

- Maximum dose: 1000mg of Naproxen (2 tablets) per day.
- For gastrointestinal protection: Take with food or after meals to reduce stomach irritation.
- Swallow the tablet whole with a glass of water. Do not chew or crush.
- Pediatric use: Not recommended for children under 18 years due to the potential risk of adverse effects.

Contraindications:

- Hypersensitivity to Naproxen, Domperidone, or any other ingredient of the formulation.
- Active peptic ulcer or gastrointestinal bleeding.
- Severe renal or hepatic impairment.
- Congestive heart failure (NYHA Class II-IV).
- Pregnancy: Avoid in the third trimester (risk of premature closure of the ductus arteriosus in the fetus).
- Lactation: Should not be used by breastfeeding mothers unless advised by a healthcare provider.
- Severe cardiovascular diseases or history of heart attack or stroke.

Warnings and Precautions:

• Cardiovascular risk: Long-term use of NSAIDs like Naproxen may increase the risk of heart attack, stroke, and hypertension. Monitor for signs of cardiovascular side effects, especially in those with a history of heart disease.

- Gastrointestinal effects: NSAIDs may cause ulcers, bleeding, or perforation of the stomach or intestines. This risk is higher with long-term use or in older adults.
- Renal impairment: Naproxen should be used with caution in patients with pre-existing kidney disease. Renal function should be monitored regularly.
- Liver function: Both Naproxen and Domperidone are metabolized in the liver, and patients with liver disease should use this combination with caution.
- Domperidone use: Long-term use of Domperidone can increase the risk of serious cardiac side effects, including QT prolongation. Caution is advised in patients with underlying cardiac conditions.

Adverse Effects:

- Naproxen:
 - Common: Gastrointestinal upset (nausea, dyspepsia, abdominal pain), headache, dizziness, rash.
 - Serious: Gastrointestinal bleeding or ulcers, cardiovascular events (heart attack, stroke), kidney or liver damage, fluid retention, and hypertension.
- Domperidone:
 - Common: Dry mouth, headache, abdominal discomfort, dizziness.
 - Serious: Cardiac arrhythmias (QT prolongation), dizziness,

and confusion (especially in elderly patients).

- Rare: Extrapyramidal symptoms (tremors, rigidity), allergic reactions (rash, swelling), and prolonged use can cause galactorrhea (milk secretion).
- Combined effects:
 - Nausea or gastrointestinal discomfort may still occur in some patients despite the presence of Domperidone.

Drug Interactions:

- Anticoagulants (e.g., warfarin): Increased risk of bleeding when combined with Naproxen. Regular monitoring of INR (International Normalized Ratio) is recommended.
- Antihypertensives: Naproxen may reduce the effectiveness of antihypertensive drugs like ACE inhibitors, diuretics, or betablockers.
- Lithium: Naproxen may increase lithium levels, leading to toxicity.
- CYP3A4 inhibitors (e.g., ketoconazole, erythromycin): Can increase Domperidone plasma levels, raising the risk of cardiac side effects.
- Other QT-prolonging drugs: Concurrent use with other drugs that prolong the QT interval (e.g., certain antiarrhythmics, antidepressants) may increase the risk of arrhythmias.

Use in Special Populations:

- Pregnancy: Avoid in the third trimester, as it can cause premature closure of the fetal ductus arteriosus. Use with caution in the first and second trimesters only if absolutely necessary.
- Lactation: Domperidone is excreted in breast milk, and Naproxen passes into breast milk in small amounts. Consult a healthcare provider before using this combination while breastfeeding.
- Elderly: Increased risk of adverse effects such as gastrointestinal bleeding, cardiovascular events, and renal or hepatic dysfunction. Monitor for side effects, especially in older adults.
- Renal and Hepatic Impairment: Use with caution in patients with impaired liver or kidney function. Adjustments to dosing may be necessary.

Storage:

- Store below 25°C in a cool, dry place.
- Keep the tablets in their original packaging to protect from moisture.
- Keep out of reach of children.

Packaging:

• Available in blister packs of 10, 20, or 30 tablets.

Patient Instructions:

1. Take the tablet with food to minimize gastrointestinal upset.

- 2. Do not exceed the prescribed dosage.
- 3. If you experience any side effects such as chest pain, shortness of breath, or unusual heart rhythms, seek immediate medical attention.
- 4. For prolonged use, regular follow-up with your healthcare provider is recommended to monitor for any potential side effects, especially gastrointestinal or cardiovascular issues.

Naproxen (500mg) + Domperidone (10mg) Tablet combines the analgesic and antiinflammatory effects of Naproxen with the antiemetic properties of Domperidone, providing effective relief for pain and associated nausea. Always follow the recommended dosage and consult your healthcare provider to ensure safe and effective use.

Manufactured in India for:



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