

# **Tormax Plus**

(Naproxen + Esomeprazole)

# ٹورمیکس پلس

(نیپروکسن + ایسومپرازول)

## COMPOSITION

**Tormax 375mg + 20mg Tablet**

**Each modified release tablet contains**

Naproxen ..... 375mg (Enteric coated core)

Esomeprazole as Magnesium Trihydrate ..... 20mg

(Immediate release coat)

Product Complies Innovator's Specs.

**Tormax 500mg + 20mg Tablet**

**Each modified release tablet contains**

Naproxen ..... 500mg (Enteric coated core)

Esomeprazole as Magnesium Trihydrate ..... 20mg

(Immediate release coat)

Product Complies Innovator's Specs.

## Description

**Tormax Plus** is a preparation of Naproxen and Esomeprazole combination. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic properties. It works by reducing the levels of prostaglandins. Esomeprazole is a proton pump inhibitor that inhibits the final step of the gastric acid formation process.

## Indications

**Tormax Plus** is indicated for the relief of sign and symptoms of Osteoarthritis, Rheumatoid Arthritis, Ankylosing Spondylitis and to reduce the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

## Dosage and administration

**Tormax Plus** is to be taken at least 30 minutes before meals.

*Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis:*

The dosage is one tablet twice daily of (375 mg Naproxen + 20 mg Esomeprazole) or (500 mg Naproxen + 20 mg Esomeprazole).

*Geriatric Patients:* Use cautiously when high doses are required and some adjustment of dosage may be required in elderly patients. As with other drugs used in the elderly use the lowest effective dose.

*Pediatric Patients:* The safety and efficacy of this drug has not been established in children younger than 18 years.

Therefore it is not recommended for use in children.

*Moderate to severe renal impairment:* Naproxen containing products are not recommended for use in patients with moderate to severe renal impairment (creatinine clearance <30 ml/min).

*Hepatic insufficiency:* It should be avoided in patients with severe hepatic impairment.

## Use in pregnancy and lactation

Pregnancy Category C. In late pregnancy, as with other NSAIDs, Naproxen should be avoided because it may cause premature closure of the ductus arteriosus in the fetus. It should not be used in nursing mothers due to the Naproxen component.

## Side effect

The most common side effects are erosive gastritis, dyspepsia, gastric ulcer, upper abdominal pain, nausea, esophagitis, constipation, erosive duodenitis, diarrhea, dizziness, drowsiness, peripheral edema, and headache.

## Precaution

Patients with known cardiovascular disease/risk factors may be at greater risk. This combination should be used with caution in patients with fluid retention or heart failure.

## Contraindication

This combination is contraindicated in patients with known hypersensitivity to Naproxen, Esomeprazole or to any of the excipients. It is also contraindicated in patients who have experienced asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDs. This combination is also contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

## Overdose

There is no clinical data on overdosage with this combination. Significant Naproxen overdosage may be characterized by lethargy, dizziness, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations in liver function, hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea, disorientation or vomiting. Gastrointestinal bleeding can also occur.

Significant Esomeprazole overdosage may be characterized by confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache, dry mouth, and other adverse reactions.

## Drug interaction

Several studies conducted with Naproxen & Esomeprazole combination have shown no interaction between the two components. Drug interactions may be with ACE inhibitors, certain antifungals, certain diuretics, Iron supplements, anticoagulants and antiplatelets or otherwise increase the risk for bleeding, thrombolytics, some protease inhibitors, selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) medications.

## Storage

Store below 30°C in a dry place, protect from light. To be dispensed on the prescription of a registered medical practitioner only. Keep out of the reach of children.

## Presentation

Tormax Plus 375mg+20mg tablets are available in 4x7's blister in a carton.

Tormax Plus 500mg+20mg tablets are available in 3x10's blister in a carton.

### ہدایات :

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،

روشنی سے بچائیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

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