DOMSTAL NP

For Registered Medical Practitioners, Hospitals, or Laboratories Only

Abbreviated Prescribing Information for **DOMSTAL NP** (Domperidon 10mg tablets + Naproxen 250/500mg) [Please refer to the complete prescribing information for more details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Domperidone is a dopamine antagonist with anti-emetic properties; its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema. Naproxen has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action of naproxen, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2). Because naproxen is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

INDICATIONS: It is indicated for the treatment of migraine.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Known hypersensitivity to naproxen, domperidone or any components of the drug product, History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs, In the setting of coronary artery bypass graft (CABG) surgery, prolactinoma, gastrointestinal haemorrhage, mechanical obstruction or perforation, prolonged QTc / cardiac conduction intervals, congestive heart failure, co-administration with QT prolonging drugs, Co-administration with potent CYP3A4 inhibitors.

WARNINGS & PRECAUTIONS: Domperidone***: Cardiovascular effects***. Treatment should be stopped if signs or symptoms occur that may be associated with cardiac arrhythmia; ***Renal impairment*** The elimination half-life of domperidone is prolonged in severe renal impairment Naproxen***:*** *Cardiovascular Thrombotic Events* The lowest effective dose for the shortest duration possible should be followed to minimize the potential risk for the adverse CV events in NSAIDS, i.e: CV, MI and stroke that can be fatal; ***Gastrointestinal Bleeding, Ulceration, and Perforation****:* Naproxen, cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine, which can be fatal.; ***Hepatotoxicity****:* If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), discontinue DOMSTAL NP and perform a clinical evaluation of the patient; ***Hypertension***: Patients taking angiotensin converting enzyme (ACE) inhibitors, thiazide diuretics, or loop diuretics may have impaired response to these therapies when taking NSAIDs; ***Heart Failure and Edema****:* Avoid the use of DOMSTAL NP in patients with severe heart failure; ***Renal Toxicity and Hyperkalemia***: If DOMSTAL NP is used in patients with advanced renal disease, monitor patients for signs of worsening renal function. Increases in serum potassium concentration, including hyperkalemia, have been reported with use of NSAIDs; *Anaphylactic Reactions Exacerbation of Asthma Related to Aspirin Sensitivity*; *Serious Skin Reactions*; *Premature Closure of Fetal Ductus Arteriosus; Hematologic Toxicity; Masking of Inflammation and Fever.*

DRUG INTERACTIONS: Hydroquinidine, Quinidine, Amiodarone, Toremifene, Pentamidine, Potent CYP3A4 inhibitors: Erythromycin, Clarithromycin, Haloperidol, Aspirin, ACE Inhibitors, Angiotensin Receptor Blockers, and Beta-Blockers, Diuretics, Digoxin, Methotrexate, Lithium, Cyclosporine,

ADVERSE REACTIONS: Dry mouth, Loss of libido, Anxiety, Somnolence, Headache, Diarrhoea, Rash, Pruritus, Galactorrhoea, Breast pain, Breast tenderness, Asthenia, Anaphylactic reaction (including anaphylactic shock), Agitation, Nervousness, Convulsion, Extrapyramidal disorder,

Oculogyric crisis, Ventricular arrhythmias, Sudden cardiac death, QTc prolongation, Torse de Pointes, Urticaria, Angioedema, Urinary retention, Gynaecomastia, Amenorrhoea and Increased Prolactin. Cardiovascular Thrombotic Events, GI Bleeding, Ulceration, perforation, Hepatotoxicity, Hypertension, Heart Failure and Edema, Renal Toxicity, Hyperkalemia, Anaphylactic Reactions, Serious Skin Reactions and hematologic Toxicity.

MARKETED BY:

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(Additional information is available on request)