For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Paracetamol Tablets and Dicylomine Hydrochloride

Baralgan® NU

COMPOSITION
Each uncoated tablet contains: Paracetamol IP: 500mg & Dicyclomine Hydrochloride IP:.20 mg

THERAPEUTIC INDICATION
Relief from spasmodic pain and discomfort due to biliary colic, intestinal colic, renal colic and spasmodic dysmenorrhea

DOSAGE AND ADMINISTRATION
1 tablet three times a day. This product is not to be used in children below 12 years of age

CONTRAINDICATIONS: In patients who have previously demonstrated hypersensitivity to dicyclomine, paracetamol, any other component of this product ;Urinary tract disorder, Severe ulceration of the colon; Obstructive uropathy ;Obstructive disease of the gastrointestinal tract Severe ulcerative colitis ; Reflux esophagitis; Unstable cardiovascular status in acute hemorrhage; Glaucoma; Myasthenia gravis; children below 12 years of age.

WARNINGS AND PRECAUTIONS: Dosage in excess of those recommended may cause severe liver damage. Patients suffering from liver or kidney disease and prostrate disorder should only take Baralgan-NU under medical supervision. Hepatotoxicity may occur with paracetamol even at therapeutic doses, after short treatment duration and in patients without pre-existing liver dysfunction. Do not co-administer Baralgan® NU with other paracetamol-containing products. Caution is advised in patients with underlying sensitivity to aspirin and/or to non-steroidal anti-inflammatory drugs (NSAIDs). Baralgan® NU may produce drowsiness or blurred vision. The patient should be warned not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery or to perform hazardous work while taking this drug. Severe cutaneous adverse reactions (SCARs): Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS), and Toxic epidermal necrolysis (TEN) have been reported with the use of Paracetamol. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If symptoms or signs of SJS and TEN (e.g. progressive skin rash often with blisters or mucosal lesions) occur, patients should stop immediately the Paracetamol treatment and seek medical advice. Patients taking paracetamol and antivitamin K should be monitored for appropriate coagulation and bleeding complications.

PREGNANCY & LACTATION: Should be used during pregnancy only if potential benefit justifies potential risk to fetus. Since Dicyclomine hydrochloride has been reported to be excreted in human milk, Baralgan® NU is contraindicated in nursing mothers

ADVERSE REACTIONS:
Constipation; loss of appetite; pallor; dry mouth, nausea, vomiting, constipation, bloated feeling, abdominal pain, taste loss, anorexia; liver damage may become apparent 12 to 48 hours after ingestion.;dizziness, light-headedness, tingling, headache, drowsiness,weakness, nervousness, numbness, mental confusion and/or excitement (especially in elderly persons), dyskinesia, lethargy, syncope, speech disturbance, insomnia ; blurred vision, diplopia, mydriasis, cycloplegia, increased ocular tension
Dermatologic/Allergic: rash, urticaria, itching, and other dermal manifestations; severe allergic reaction or drug idiosyncrasies including anaphylaxis; urinary hesitancy, urinary retention ;

tachycardia, palpitations; Cardiac arrhythmias have been reported; dyspnea, apnea, asphyxia. Blood and lymphatic system disorders - Very rare: thrombocytopenia, neutropenia, leucopenia. Not known: agranulocytosis, haemolytic anaemia in patients with underlying glucose 6-phosphate-deshydrogenase deficiency. Immune system disorders - Not known: anaphylactic shock, angioedema. Cardiac disorders - Not Known: Kounis syndrome. Respiratory, thoracic and mediastinal disorders - Not known: bronchospasm. Skin and subcutaneous disorders - Very rare: erythema, urticaria, rash. Not known: Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis, fixed drug eruption. Hepatobiliary disorders - Not known: cytolytic hepatitis, which may lead to acute hepatic failure

For full prescribing information write to: Sanofi India Ltd., Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400 072

File to note: The details in the Overdose section & Drug interactions are not added from the GLU, since the API does not have a section on overdose and drug interactions.

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Modified: Dec 2013

Sources:

Baralgan – NU pack insert
GLU of Paracetamol (22-Nov-2013)