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

Abridged Rx Information

Baralgan® NU

Dicylomine Hydrochloride and Paracetamol Tablets

NSAID & Anti-cholinergic

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 & Administration: 1 tablet three times a day. This product is not to be used in children below 12 years.

SAFETY-RELATED INFORMATION

Contraindications: In patients who have previously demonstrated hypersensitivity to dicyclomine, paracetamol, any other component of this product. It is contraindicated in severe hepatocellular insufficiency. Known idiosyncrasy to dicyclomine hydrochloride.

PREGNANCY & LACTATION: Should be used during pregnancy only if potential benefit justifies potential risk to fetus. Dicyclomine hydrochloride is excreted in human milk. Caution should be exercised when Baralgan®NU is administered during breastfeeding.

WARNINGS AND PRECAUTIONS:

Paracetamol: 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). 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.

ADVERSE REACTIONS:

Dicyclomine: Metabolism and nutrition disorders -Not known: thirst, Nervous system disorders-Not known: dizziness, headache, sedation, Eye disorders- Not known: blurred vision, Gastrointestinal disorders-Not known: constipation, dry mouth, nausea, vomiting, Skin and subcutaneous tissue disorders- Not known: rash, Renal and urinary disorders- Not known: dysuria, General disorders and administration site conditions- Not known: fatigue, anorexia

Paracetamol: Blood and lymphatic system disorders - Very rare: thrombocytopenia, neutropenia, leucopenia. Not known: agranulocytosis, hemolytic anemia in particular in patients with underlying glucose 6-phosphate-deshydrogenase deficiency. Immune system disorders - Not known: anaphylactic shock, angioedema. 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. Metabolism and nutrition system disorders: Not known: pyroglutamic acidosis, in patients with pre-disposing factors for glutathione depletion

For full prescribing information please contact: Sanofi India Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 400072

Source:

- Dicycloverine hydrochloride-CCSI-v1.1-LRC-24-May-2017.
- CCDS of Paracetamol v.4 dated 08th July 2021

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