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

This package insert is continually updated: Please read carefully before using a new pack.

Dicylomine Hydrochloride and Paracetamol Tablets
Baralgan® NU

COMPOSITION

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

THERAPEUTIC INDICATIONS

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

DOSAGE AND METHOD OF ADMINISTRATION

1 tablet upto four times a day.

This product is not to be used in children below 12 years of age

CONTRAINDICATIONS

Baralgan®NU should not be administered to 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.

SPECIAL WARNINGS & PRECAUTIONS FOR USE

Dicyclomine hydrochloride
Products containing dicyclomine hydrochloride should be used with caution in any patient with or suspected of having glaucoma or prostatic hypertrophy. Use with care in patients with hiatus hernia associated with reflux oesophagitis because anticholinergic drugs may aggravate the condition.

Paracetamol
Hepatotoxicity may occur with paracetamol even at therapeutic doses, after short treatment duration and in patients without pre-existing liver dysfunction (See Section “Adverse reactions”).

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 Baralgan®NU treatment and seek medical advice.

To avoid the risk of overdose:

Check that paracetamol is absent from the composition of other medicinal products taken concomitantly.

PRECAUTIONS

Caution is advised in patients with underlying sensitivity to aspirin and/or to non-steroidal anti-inflammatory drugs (NSAIDs).

Paracetamol should be used upon medical advice in patients with:

- Mild-to-moderate hepatocellular insufficiency
- Severe renal insufficiency
- Chronic alcohol use including recent cessation of alcohol intake
- Low glutathione reserves
- Glucose-6-phosphate-dehydrogenase deficiency
- Gilbert´s syndrome

DRUG INTERACTIONS

Dicyclomine hydrochloride
None

Paracetamol:
The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes, such as certain antiepileptics (such as phenobarbital, phenytoin, carbamazepine, topiramate), rifampicin and alcohol. The induced metabolism results in an elevated production of the hepatotoxic oxidative metabolite of paracetamol. Hepatotoxicity will occur if this metabolite exceeds the normal glutathione binding capacity.

Paracetamol may increase the risk of bleeding in patients taking warfarin and other antivitamin K. Patients taking paracetamol and antivitamin K should be monitored for appropriate coagulation and bleeding complications.

Co-administration of flucloxacillin with paracetamol may lead to metabolic acidosis, particularly in patients presenting risk factors of glutathione depletion, such as sepsis, malnutrition or chronic alcoholism.

Chelating resin can decrease the intestinal absorption of paracetamol and potentially decrease its efficacy if taken simultaneously. In general, there must be an interval of more than 2 hours between taking the resin and taking paracetamol, if possible.

The absorption rate of paracetamol may be increased by metoclopramide or domperidone.

PREGNANCY

Dicyclomine Hydrochloride:
Epidemiological studies in pregnant women with products containing dicyclomine hydrochloride (at doses up to 40mg/day) have not shown that dicyclomine hydrochloride increases the risk of fetal abnormalities if administered during the first trimester of pregnancy. Reproduction studies have been performed in rats and rabbits at doses of up to 100 times the maximum recommended dose (based on 60mg per day for an adult person) and have revealed no evidence of impaired fertility or harm to the foetus due to dicyclomine hydrochloride. Dicyclomine hydrochloride should be used during pregnancy only if the benefit outweighs the risk.

Paracetamol:
A large amount of data on pregnant women indicates neither malformative, nor feto/neonatal toxicity. Paracetamol can be used during pregnancy if clinically needed however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

LACTATION

Paracetamol is excreted in breast milk but not in a clinically significant amount. It is not known whether Dicyclomine hydrochloride is excreted in human milk. Caution should be exercised when Baralgan®NU is administered during breastfeeding.

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: Hypersensitivity such as anaphylactic shock, angioedema

Respiratory, thoracic and mediastinal disorders:
Not known: bronchospasm (see Section "Warnings")

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 (see section warnings).

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

OVERDOSAGE

Paracetamol:

Elderly persons, small children, patients with liver disorders, chronic alcohol consumption or chronic malnutrition, as well as patients concomitantly treated with enzyme-inducing drugs are at an increased risk of intoxication, including fatal outcome.

Signs and Symptoms

Dicyclomine

Symptoms of Dicyclomine hydrochloride overdosage are headache, dizziness, nausea, dry mouth, difficulty in swallowing, dilated pupils and hot dry skin.

Paracetamol

Nausea, vomiting, anorexia, pallor, abdominal pain, generally appear during the first 24 hours of overdosage with paracetamol.

Overdosage with paracetamol may cause hepatic cytolysis which can lead to hepatocellular insufficiency, gastrointestinal bleeding, metabolic acidosis, encephalopathy, disseminated intravascular coagulation, coma and death. Increased levels of hepatic transaminases, lactate deshydrogenase and bilirubin with a reduction in prothrombin level can appear 12 to 48 hours after acute overdosage. It can also lead to pancreatitis, acute renal failure and pancytopenia.

MANAGEMENT

Dicyclomine Hydrochloride: Treatment may include emetics, gastric lavage and symptomatic therapy if indicated.

Paracetamol: Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention.

Treatment involves gastric aspiration and lavage, preferably within 4 hours of ingestion.

Determinations of the plasma concentration of paracetamol are recommended.

Plasma concentration of paracetamol should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable).

Where paracetamol intoxication is suspected, intravenous administration of SH group donators such as N-acetylcysteine within the first 10 hours after ingestion is indicated. Although N-acetylcysteine is most effective if initiated within this period, it can still offer some degree of protection if given as late as 48 hours after ingestion; in this case, it is taken for longer.

Further measures will depend on the severity, nature and course of clinical symptoms of paracetamol intoxication and should follow standard intensive care protocols.

EFFECT ON ABILITY TO DRIVE AND/ OR OPERATE MACHINERY

None

Presentation: Strip of 10 tablets.

Storage: Store protected from light and moisture at a temperature not exceeding 30°. Keep out of reach of children.

Manufactured by: Windlas Biotech Limited (Plant-2), Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun -248110, Uttarakhand.

Marketed by: Sanofi India Ltd, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 400072

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Reference:

- Dicycloverine hydrochloride-CCSI-v1.1-LRC-24-May-2017.
- CCDS of Paracetamol v4 dated 08th July 2021