BUSCOGAST® PLUS TABLETS

Abridged Prescribing Information

COMPOSITION – Each film coated tablet contains – Hyoscine Butylbromide I.P. 10 mg, Paracetamol I.P. 325mg, Excipients q.s., Colour: Titanium Dioxide I.P.

THERAPEUTIC INDICATION – For spasmodic pain. Paroxysmal pain in diseases of the stomach or intestine spastic pain and functional disorders in the biliary and urinary tracts and female genital organs (e.g. dysmenorrhoea)

DOSAGE & ADMINISTRATION –
Tablets
Adult: 1 - 2 tablets 3 times daily. The total daily dose should not exceed 6 tablets.
The tablets should not be chewed but swallowed in whole with a sufficient amount of water.
Children from 10 years onward may use Buscogast® PLUS film-coated tablets, if required, but not suitable for children under 10 years of age. Do not exceed for more than 3 days without doctor's consultation.

SAFETY-RELATED INFORMATION
CONTRAINDICATIONS – patients who have demonstrated prior hypersensitivity to hyoscine butylbromide, or paracetamol or other components of the drug, myasthenia gravis, mechanical stenosis in the gastrointestinal tract, paralytical or obstructive ileus, megacolon, severe hepatocellular insufficiency (Child - Pugh C).

PREGNANCY & LACTATION – It is preferable to avoid BUSCOGAST® PLUS during pregnancy and lactation.

WARNINGS AND PRECAUTIONS - In case severe, unexplained abdominal pain persists or worsens, or occurs together with symptoms like fever, nausea, vomiting, changes in bowel movements, abdominal tenderness, decreased blood pressure, fainting or blood in stool, medical advice should immediately be sought. Liver damage may result on paracetamol overdosage.
Caution is needed in patients with glucose-6-phosphate-dehydrogenase deficiency, chronic alcohol use including recent cessation of alcohol intake, severe renal insufficiency, Gilbert's syndrome, Mild to moderate hepatocellular insufficiency (Child - Pugh A/B) and low glutathione reserves.
The blood count and renal and liver function should be monitored after prolonged use.
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 Buscogast® PLUS. Caution is advised in patients with underlying sensitivity to aspirin and/or to non-steroidal anti-inflammatory drugs (NSAIDs). Hepatotoxicity may occur with paracetamol even at therapeutic doses.
Abrupt discontinuation of analgesics after a prolonged use at high doses may induce withdrawal symptoms (e.g. headache, tiredness, nervousness).

ADVERSE REACTIONS: Immune system disorders- Uncommon: Skin reactions, sweating abnormal, Rare: blood pressure decreased including shock; Cardiac disorders- Rare: tachycardia; Gastrointestinal disorders- Uncommon: Dry mouth

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

Source: Buscogast Plus PI dated July 2019