

BUSCOGAST® TABLETS

Abridged Prescribing Information

COMPOSITION –

Each sugar-coated tablet contains – Hyoscine Butylbromide I.P. 10 mg, Excipients q.s.,
Colour: Titanium Dioxide I.P.

THERAPEUTIC INDICATION – Gastro-intestinal tract spasm, spasm and dyskinesia of the biliary system, genito-urinary tract spasm. For targeted relief from abdominal pain and cramps.

DOSAGE & ADMINISTRATION -

Adults and children over 6 years: 3 times daily 1 - 2 s.c.(sugar coated) tablets.
BUSCOGAST® should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

SAFETY-RELATED INFORMATION

CONTRAINDICATIONS – patients who have demonstrated prior hypersensitivity to hyoscine butylbromide or any other component of the product, myasthenia gravis, mechanical stenosis in the gastrointestinal tract, paralytical or obstructive ileus, megacolon

PREGNANCY & LACTATION – It is preferable to avoid BUSCOGAST® tablets 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. Because of the potential risk of anticholinergic complications, caution should be used in patients prone to narrow angle glaucoma as well as in patients susceptible to intestinal or urinary outlet obstructions and in those inclined to tachyarrhythmia.

INTERACTIONS -_The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, antipsychotics, quinidine, amantadine, disopyramide and other anticholinergics may be intensified by BUSCOGAST®. Concomitant treatment with dopamine antagonists may result in diminution of the effects of both drugs on the gastrointestinal tract. The tachycardic effects of beta-adrenergic agents may be enhanced by BUSCOGAST®.

ADVERSE REACTIONS:

Cardiac disorders: Tachycardia (Uncommon), Gastrointestinal disorders: dry mouth (Uncommon), Skin and subcutaneous tissue disorders: skin reactions, urticaria, pruritus, abnormal sweating (Uncommon), Renal and urinary disorders: Urinary retention (Rare)

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 400072

Source: Buscogast Tablets PI dated July 2019