

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

BUSCOGAST® AMPOULES

Abridged Prescribing Information

COMPOSITION - Each one ml ampoule contain - Hyoscine Butylbromide IP .20 mg, Excipients q.s.

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 adolescents over 12 years:* 1 - 2 ampoules of BUSCOGAST® (20 - 40 mg) may be administered by slow intravenous, intramuscular or subcutaneous injection several times daily but not more than 100 mg daily. *Infants and children:* In severe cases: 0.3 - 0.6 mg/kg bodyweight, to be administered by slow intravenous, intramuscular or subcutaneous injection several times daily but not more than daily dose of 1.5 mg/kg body weight.

SAFETY-RELATED INFORMATION

CONTRAINDICATIONS - patients who have demonstrated prior hypersensitivity to hyoscine butylbromide or any other component of the product, untreated narrow angle glaucoma, hypertrophy of the prostate with urinary retention, mechanical stenosis in the gastrointestinal tract, paralytical or obstructive ileus, megacolon, tachycardia, myasthenia gravis. By intramuscular injection, in patients being treated with anticoagulant drugs since intramuscular haematoma may occur. In these patients, the subcutaneous or intravenous routes may be used.

PREGNANCY & LACTATION – It is preferable to avoid BUSCOGAST® 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. Patients with undiagnosed and therefore untreated narrow angle glaucoma should seek urgent ophthalmological advice in case they develop a painful, red eye with loss of vision after the injection of BUSCOGAST®. In case of anaphylaxis reactions, patients receiving BUSCOGAST® by injection should be kept under observation. Caution is needed in patients with cardiac conditions submitted to parenteral treatment with BUSCOGAST® with monitoring.

ADVERSE REACTIONS: Eye disorders - Accommodation disorders, Cardiac disorders – Tachycardia, Gastrointestinal disorders - Dry mouth.

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

Source: Buscogast Ampoules PI dated July 2019