Contraindications:
BUSCOPAN is contraindicated in myasthenia gravis and megacolon. In addition, it should not be used in patients who have demonstrated prior sensitivity to hyoscine-N-butylbromide or any other component of the product.

Pregnancy and lactation:
Long experience has shown no evidence of ill-effects during human pregnancy. However, the usual precautions regarding the use of drugs in pregnancy, especially during the first trimester, should be observed. Safety during lactation has not yet been established. However, adverse effects on the new born have not been reported.

Interactions:
The anticholinergic effect of tricyclic antidepressants, antihistamines, quinidine, amantadine and disopyramide may be intensified by BUSCOPAN. Concomitant treatment with dopamine antagonists such as metoclopramide 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 BUSCOPAN.

Side Effects:
Anticholinergic side effects including xerostomia, dyshidrosis, tachycardia and potentially urinary retention may occur but are generally mild and self limited.

Special Precautions:
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.

Composition: 1 sugar-coated tablet contains 10.0 mg Hyoscine-N-butylbromide
Excipients: s.c. tablets: dibasic calcium phosphate, maize starch, starch soluble, aerosil 200, tartaric acid, stearic acid, polyvidone, saccharose, talc, acacia, titanium dioxide, polyethylene glycol 6000, carnauba wax, beeswax white.
Suppositories: Hard fat

Properties:
BUSCOPAN exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genito-urinary tracts. As a quarternary ammonium derivative, hyoscine-N-butylbromide does not enter the central nervous system. Therefore, anticholinergic side effects at the central nervous system do not occur. Peripheral anticholinergic action results from a ganglion-blocking action within the visceral wall as well as from an anti-muscarinic activity.

Pharmacokinetics
As a quaternary ammonium compound, hyoscine-N-butylbromide is highly polar and hence only partially absorbed following oral (8%) administration. The systemic availability was found to be less than 1%. Nevertheless, despite the briefly measurable low blood levels, relatively high local concentrations of radio-labelled hyoscine-N-butylbromide and/or its metabolites have been observed at the site of action: in the gastrointestinal tract, gall bladder, bile ducts, liver, and kidneys. Hyoscine-N-butylbromide does not pass the blood-brain barrier and its binding to plasma proteins is low. The total clearance, determined after i.v. administration, is 1.2 l/min, approximately half of the clearance is renal. The main metabolites found in urine bind poorly to the muscarinic receptor.

Indications:
Gastrointestinal tract spasm, spasm and dyskinesia of the biliary system, genito-urinary tract spasm.
**Dosage and Administration:**
Unless otherwise prescribed by the physician, the following dosages are recommended:

**Oral**
*Sugar-coated tablets:*
Adults and children over 6 years: 3 - 5 times daily
1 - 2 s.c. tablets
The sugar-coated tablets should be swallowed whole with adequate fluid.

**Overdosage:**
Since cases of poisoning with BUSCOPAN have not been reported so far, the following recommendations are based on theoretical considerations:

**Symptoms**
In the case of overdosage, anticholinergic symptoms as urinary retention, dry mouth, reddening of the skin, tachycardia, inhibition of gastrointestinal motility, and transient visual disturbances may occur.

**Therapy**
In the case of oral poisoning, gastric lavage with medicinal charcoal should be followed by magnesium sulfate (15%). Symptoms of BUSCOPAN overdosage respond to parasympathomimetics. For patients with glaucoma, pilocarpine should be given locally. If necessary, parasympathomimetics should be administered, e.g. neostigmine 0.5-2.5 mg i.m. or i.v. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis: intubation, artificial respiration. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

**Availability:**
Sugar coated tablet containing 10 mg

**Storage instructions:**
Store in a safe place below 30°C