Buscopan®

Boehringer Ingelheim

Composition
1 sugar-coated tablet contains
1 suppository contains
1 suppository for infants and
young children contains
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 quarternary ammonium compound, hyoscine-N-butylbromide is highly polar and hence only partially absorbed following oral (8%) or rectal (3%) administration. The systemic availability was found to be less than 1%. Nevertheless, despite the briefly measurable low blood levels, relatively high local concentrations of radiolabelled 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.

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.

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.

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.
Very rarely hypersensitivity reactions, particularly skin reactions and, in extremely rare cases, dyspnoea have been reported.

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.

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.

Rectal
Suppositories:
Adults and children over 6 years:
3–5 times daily 1–2 suppositories.

Paediatric suppositories:
Children over 1 year: 3–5 times daily 1 suppository.
Infants: 2–3 times daily 1 suppository.
The suppositories should be unwrapped and inserted into the rectum pointed end first.

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
Suppositories containing 10 mg
Paediatric suppositories containing 7.5 mg

Storage instructions
Store in a safe place below 30 °C
Suppositories: store below 25 °C

Date of package insert
December 1997

Manufacturer:
Boehringer Ingelheim Pharma GmbH & Co. KG
for
Boehringer Ingelheim International GmbH
Ingelheim am Rhein
Germany

This is a medicament
- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament
- The doctors and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children!

Council of Arab Health Ministers –
Union of Arab Pharmacists