SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hyoscine Butylbromide 20 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 mg hyoscine butylbromide.

Excipient with known effect:
Each film-coated tablet contains 130 mg lactose monohydrate equivalent to 123.50 mg of lactose (see section 4.4).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet.
(Tablet)

White to off-white round, biconvex, film-coated tablets with '20' debossed on one side and plain on other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hyoscine Butylbromide Tablets are indicated for the relief of spasm of the genito-urinary tract or gastro-intestinal tract and for the symptomatic relief of Irritable Bowel Syndrome.

4.2 Posology and method of administration

Posology

Adults: Two 10 mg tablets or one 20 mg tablet 4 times daily. For the symptomatic relief of Irritable Bowel Syndrome, the recommended starting dose is one 10 mg tablet 3 times daily, this can be increased up to two 10 mg tablets or one 20 mg tablet 4 times daily if necessary.

Children 6 - 12 years: One 10 mg tablet 3 times daily.

No specific information on the use of this product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

Hyoscine Butylbromide Tablets should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

Method of administration

For oral administration only.
Hyoscine Butylbromide Tablets should be swallowed whole with adequate water.

4.3 Contraindications

Hyoscine Butylbromide Tablets are contraindicated in:

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- myasthenia gravis
- mechanical stenosis in the gastrointestinal tract
- paralytical or obstructive ileus
- megacolon
- narrow angle glaucoma.

4.4 Special warnings and precautions for use

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.

Hyoscine Butylbromide Tablets should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery where it may further accelerate the heart rate. Due to the risk of anticholinergic complications, caution should be used in patients susceptible to intestinal or urinary outlet obstructions.

Because of the possibility that anticholinergics may reduce sweating, Hyoscine Butylbromide Tablets should be administered with caution to patients with pyrexia.
Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as Hyoscine Butylbromide Tablets in patients with undiagnosed and therefore untreated narrow angle glaucoma. Therefore, patients should seek urgent ophthalmological advice in case they should develop a painful, red eye with loss of vision whilst or after taking Hyoscine Butylbromide Tablets.

Lactose
This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, quinidine, amantadine, antipsychotics (e.g. butyrophenones, phenothiazines), disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by Hyoscine Butylbromide Tablets.

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 Hyoscine Butylbromide Tablets.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited data from the use of hyoscine butylbromide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). As a precautionary measure Hyoscine Butylbromide Tablets are not recommended during pregnancy.

Breast-feeding

There is insufficient information on the excretion of hyoscine butylbromide and its metabolites in human milk. A risk to the breastfeeding child cannot be excluded. Use of Hyoscine Butylbromide Tablets during breastfeeding is not recommended.

Fertility
No studies on the effects on human fertility have been conducted.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

4.8 Undesirable effects

Many of the listed undesirable effects can be assigned to the anticholinergic properties of Hyoscine Butylbromide Tablets.

Adverse events have been ranked under headings of frequency using the following convention:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

System Organ class	Frequency	Undesirable Effect
Immune system disorders	Not Known*	Anaphylactic shock, anaphylactic reactions, dyspnoea, other hypersensitivity
Cardiac disorders	Uncommon	Tachycardia
Gastrointestinal disorders	Uncommon	Dry mouth
Skin and subcutaneous tissue disorders	Uncommon	Skin reactions (e.g. urticaria, pruritus), abnormal sweating
	Not Known*	Rash, erythema
Renal and urinary disorders	Rare	Urinary retention

* This adverse reaction has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than uncommon (3/1,368) but, might be lower. A precise frequency estimation is not possible as the

adverse drug reaction did not occur in a clinical trial database of 1,368 patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms:

Serious signs of poisoning following acute overdosage have not been observed in man. In the case of overdosage, anticholinergic effects such as urinary retention, dry mouth, reddening of the skin, tachycardia, inhibition of gastrointestinal motility and transient visual disturbances may occur, and Cheynes-Stokes respiration has been reported.

Therapy:

In the case of oral poisoning, gastric lavage with medicinal charcoal should be followed by magnesium sulfate (15%). Symptoms of Hyoscine Butylbromide Tablets overdosage respond to parasympathomimetics. For patients with glaucoma, pilocarpine should be given locally. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis, intubation and artificial respiration should be considered. Catheterisation may be required for urinary retention.

In addition, appropriate supportive measures should be administered as required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds.

ATC code: A03BB01.

Mechanism of action

Hyoscine Butylbromide Tablets exert a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genito-urinary tracts. As a quaternary ammonium derivative, hyoscine 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.

5.2 Pharmacokinetic properties

Absorption

As a quaternary ammonium compound, hyoscine butylbromide is highly polar and hence only partially absorbed following oral (8%) or rectal (3%) administration. After oral administration of single doses of hyoscine butylbromide in the range of 20 to 400 mg, mean peak plasma concentrations between 0.11 ng/ml and 2.04 ng/ml were found at approximately 2 hours. In the same dose range, the observed mean AUC_{0-tz}-values varied from 0.37 to 10.7 ng h/ml. The median absolute bio-availabilities of different dosage forms, i.e. coated tablets, suppositories and oral solution, containing 100 mg of hyoscine butylbromide each were found to be less than 1%.

Distribution

Because of its high affinity for muscarinic receptors and nicotinic receptors, hyoscine butylbromide is mainly distributed on muscle cells of the abdominal and pelvic area as well as in the intramural ganglia of the abdominal organs. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 4.4%. Animal studies demonstrate that hyoscine butylbromide does not pass the blood-brain barrier, but no clinical data to this effect is available. Hyoscine butylbromide (1 mM) has been observed to interact with the choline transport (1.4 nM) in epithelial cells of human placenta in vitro.

Biotransformation and elimination

Following oral administration of single doses in the range of 100 to 400 mg, the terminal elimination half-lives ranged from 6.2 to 10.6 hours. The main metabolic pathway is the hydrolytic cleavage of the ester bond. Orally administered hyoscine butylbromide is excreted in the faeces and in the urine. Studies in man show that 2 to 5% of radioactive doses is eliminated renally after oral, and 0.7 to 1.6% after rectal administration. Approximately 90% of recovered radioactivity can be found in the faeces after oral administration. The urinary excretion of hyoscine butylbromide is less than 0.1% of the dose. The mean apparent oral clearances after oral doses of 100 to 400 mg range

from 881 to 1420 L/min, whereas the corresponding volumes of distribution for the same range vary from 6.13 to 11.3 x 10^5 L, probably due to very low systemic availability. The metabolites excreted via the renal route bind poorly to the muscarinic receptors and are therefore not considered to contribute to the effect of the hyoscine butylbromide.

5.3 Preclinical safety data

In limited reproductive toxicity studies hyoscine butylbromide showed no evidence of teratogenicity in rats at 200 mg/kg in the diet or in rabbits at 200 mg/kg by oral gavage or 50 mg/kg by subcutaneous injection. Fertility in the rat was not impaired at doses of up to 200 mg/kg in the diet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Lactose monohydrate,
Cellulose, microcrystalline,
Povidone K-30,
Magnesium stearate.

Film-coating:
Polyvinyl alcohol (E1203), titanium dioxide (E171), talc (E553b), polyethylene glycol (E1521) and lecithin (E422).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVdC-Alu blister containing packs of 28, 56, 100 and 500 tablets are available.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Morningside Healthcare Ltd.
Unit C, Harcourt Way
Leicester, LE19 1WP, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20117/0349

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/08/2026

10 DATE OF REVISION OF THE TEXT

24/08/2026