SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of medicinal product
Hyoscine Butylbromide Tablets BP 10 mg

2. Qualitative and Quantitative composition:
Composition:
Each Sugar Coated Tablets Contains:
Hyoscine Butylbromide BP…… 10 mg
Excipients…… QS
Approved Colour Used

Excipients with known effect:

Each 10 mg hyoscine Butylbromide tablet contains 0.20mg Lactose

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form: Tablets

A white coloured, circular, biconvex sugar-coated tablets.

4. Clinical Particulars

4.1 Therapeutic indication
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
Relief of spasm of gastrointestinal tract
Adults and children over 12 years: Two tablets (20 mg) four times daily.
For the symptomatic relief of Irritable Bowel Syndrome
Adults and children over 12 years: The recommended starting dose is 1 tablet up to three times daily, this can be increased up to 2 tablets four times daily if necessary.
If symptoms do not improve or if they worsen after 2 weeks of treatment a doctor should be consulted.
Tablets should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.
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.

Method of administration
For oral use.

4.3 Contraindication

- Hypersensitivity
- myasthenia gravis
- mechanical stenosis in the gastrointestinal tract
- paralytical or obstructive ileus
- megacolon
- narrow angle glaucoma.

4.4 Special Warning & 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 be sought immediately.

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 Pregnancy and lactation

Pregnancy
There is limited data from the use of hyoscine butylbromide in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity
Breastfeeding
There is insufficient information on the excretion of hyoscine butylbromide and its metabolites in human milk.
As a precautionary measure, it is preferable to avoid the use of Buscopan 10mg Coated Tablets during pregnancy and lactation.
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 visual accommodation disturbances patients should not drive or operate machinery if affected.

4.8 Undesirable effects

Anaphylactic shock, anaphylactic reactions, dyspnoea, other hypersensitivity, Dry mouth, Skin reactions (e.g. urticaria, pruritus), abnormal sweating, Urinary retention

Section 4.8 Reporting of adverse effects
Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board,Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

4.9 Overdose
Symptoms
Serious signs of poisoning following acute overdosage have not been observed in man. In the case of overdosage, anticholinergic symptoms 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 sulphate (15%). Symptoms of Buscopan 10mg Coated 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Belladonna alkaloids, semisynthetic quaternary ammonium compounds

ATC code: A03BB01
Hyoscine butylbromide exerts 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 AUC0-tz-values varied from 0.37 to 10.7 ng h/mL. The median absolute bioavailabilities 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 105 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

- Hyoscine Butyl bromide
- Dibasic calcium phosphate
- Microcrystalline cellulose
- Maize starch
- Gelatin
- Methyl paraben
- Propyl paraben
- Purified Talc
- Magnesium stearate
- Lactose
- Croscarmellose sodium
- Sucrose
- Gelatin
- Gum acacia
- Titanium Dioxide
- Calcium carbonate
- Purified talc
- Bee wax

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3years

6.4 Special precautions for storage
Store in a cool and dry place below 30°C

6.5 Nature and contents of container
Alu PVC blister 10 x 10 tablets in a carton along with insert

6.6 Special precautions for disposal
No special requirements.

7.Marketing Authorisation Holder:
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8. MARKETING AUTHORISATION NUMBER

NA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

NA

10. DATE OF REVISION OF THE TEXT

01/04/2026