Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

BISPANOL TABLETS

2. Qualitative and quantitative composition

Each tablet contains hyoscine butylbromide 10 mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Coated Tablets.

Small, off-white, biconvex, sugar-coated tablet, free from visible impurities.

4. Clinical particulars

4.1 Therapeutic indications

Bispanol Tablets are indicated for the relief of spasm of the genitourinary tract or gastro-intestinal tract and for the symptomatic relief of irritable bowel syndrome.

4.2 Posology and method of administration

Bispanol 10 mg Tablets are for oral administration only.

Bispanol 10 mg Tablets should be swallowed whole with adequate water.

Adults: 2 tablets four times daily. For the symptomatic relief of irritable bowel syndrome, the recommended starting dose is 1 tablet three times daily, this can be increased up to 2 tablets four times daily if necessary.

Children 6 - 12 years: 1 tablet three 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.

Bispanol 10 mg Tablets should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

4.3 Contraindications

Bispanol 10 mg Tablets are contraindicated in:

- patients who have demonstrated prior hypersensitivity to hyoscine butyl bromide or any other component of the product

- myasthenia gravis

- mechanical stenosis in the gastrointestinal tract

- paralytical or obstructive ileus

- megacolon

- narrow angle glaucoma

4.4 Special warnings and precautions for use

Bispanol 10 mg Tablets should be used with caution in conditions characterized 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, Bispanol should be administered with caution to patients with pyrexia.

Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as Bispanol 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 Bispanol.

As the tablet coat contains sucrose patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Bispanol Tablets.

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 Bispanol.

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 Bispanol.

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. As a precautionary measure Bispanol is not recommended during pregnancy.

Lactation

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 Bispanol 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 BISPANOL.

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

Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to <1/100); rare (≥ 1/10000 to <1/1000); very rare (<1/10000); not known (cannot be estimated from the available data).

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

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 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 Bispanol overdosage respond to parasympathomimetic. 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. Catheterization may be required for urinary retention.

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC code: A03BB01

Bispanol exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genitourinary tracts. As a quaternary ammonium derivative, hyoscine butyl bromide 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 butyl bromide 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 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*.

Metabolism 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

Lactose monohydrate, maize starch, Potassium sorbate, Sodium benzoate, magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 30°C in a dry place. Protect from light.

7. Marketing Authorization Holder

Regal Pharmaceuticals Ltd

Plot No: 7879/18, Off Baba Dogo Road,

Ruaraka-Nairobi Kenya.

8. Marketing authorization number(s)

H91046-398

9. Date of first authorization/renewal of the

authorization
15/01/2026

10. Date of revision of the text
15/01/2026