SmPC (Summary of Product Characteristics)

Legal Category

POM: Over the Counter

Summary of Product Characteristics for Pharmaceutical Products (SmPC)

1. Name of the medicinal product

BUSCOKRIS ELIXIR (Hyoscine Butylbromide 5.0 mg elixir)

2. Qualitative and quantitative composition

Each 5.0 ml contains:

Hyoscine Butylbromide BP 5.0mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid elixir

4. Clinical particulars

4.1 Therapeutic indications

Buscokris elixir is 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

Buscokris elixir is for oral administration only. As directed by physician.

Adults: 2 tablets four times daily. For the symptomatic relief of Irritable Bowel Syndrome, the recommended starting dose is 10 ml three times daily, this can be increased up to 20 ml four times daily if necessary. Children 6 - 12 years: 10 ml 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.

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

4.3 Contraindications

Buscokris elixir is contraindicated in:

- patients who have demonstrated prior hypersensitivity to hyoscine butylbromide 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

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. Buscokris elixir 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, hyoscine butylbromide 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 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.

As the elixir contains glucose patients with rare hereditary problems of glucose-galactose malabsorption should not take Buscokris elixir.

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 Buscokris. 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 (salbutamol) may be enhanced by Buscokris.

4.6 Fertility, pregnancy and lactation Pregnancy

There are limited data from the use of hyoscine butylbromide in pregnant women. As a precautionary measure Hyoscine butylbromideis 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 Hyoscine butylbromide 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. 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

* 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:

Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System.

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 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

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.

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 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

None

6. Pharmaceutical particulars

6.1 List of excipients

Refined Sugar, Methyl Paraben, Propyl Paraben, Sorbitol 70%, Sodium Saccharin, Sodium Chloride, Citric Acid Monohydrate, Sodium Citrate, Flavour Menthol, Flavour Banana, Flavour Vanilla, Purified Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 Years.

6.4 Special precautions for storage

Store in a cool, dry place below 30°C.

6.5 Nature and contents of container

60 ml amber PET Bottle provided with a measuring cup.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. Marketing authorization holder

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State, NIGERIA.

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