Summary of Product Characteristics

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1. Name of the medicinal product

Hyoscine Butyl bromide Tablets BP 10mg

2. Qualitative and quantitative composition

Each uncoated tablet contains:
Hyoscine Butyl Bromide BP 10mg
For the full list of excipients, see section 6.1

3. Pharmaceutical form

Tablets

White to off- white, round, flat tablets with bevelled edges having score line on one side

4. Clinical particulars

4.1. Therapeutic indications

Hyoscine Butyl Bromide Tablet BP 10mg is indicated in 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

Adults

Moderately severe infection, 150-300 mg every six hours; severe infection, 300- 450 mg every six hours.

Elderly:

The half-life, volume of distribution and clearance, and extent of absorption after administration of clindamycin hydrochloride are not altered by increased age. Analysis of data from clinical studies has not revealed any age-related increase in toxicity. Dosage requirements in elderly patients, therefore, should not be influenced by age alone.

Paediatric population:

Clindamycin hydrochloride capsules should only be used for children who are able to swallow capsules. Doses of 12-25 mg/kg/day six hourly depending on the severity of the infection.

The use of whole capsules may not be suitable to provide the exact mg/kg doses required for the treatment of children.

Dosage in Renal /Hepatic Impairment: Clindamycin dosage modification is not necessary in patients with renal or hepatic insufficiency.

Note: In cases of beta-haemolytic streptococcal infection, treatment with Clindamycin should continue for at least 10 days to diminish the likelihood of subsequent rheumatic fever or

glomerulonephritis.

Method of administration

Oral

Clindamycin capsules should always be taken with a full glass of water. Absorption of Clindamycin capsules is not appreciably modified by the presence of food.

4.3. Contraindications

Hyoscine Butylbromidemg Tablets should not be administered to patients with myasthenia gravis, megacolon and narrow angle glaucoma. In addition, they should not be given to patients with a known hypersensitivity to hyoscine butylbromide or any other component of the product.

4. 4. Special warnings and special 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 10 mg 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.

As the tablet coat contains sucrose (41.2 mg), patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Hyoscine Butylbromide tablets 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 Hyoscine Butylbromide.

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.

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 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 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 Butyl bromide. 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

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

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.

5.0. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: anti-spasmodic

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. Pharmacokinetics 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.

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 nM) 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 are 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

Calcium Hydrogen Phosphate, Maize Starch, Lactose, Microcrystalline Cellulose, Methyl hydroxy benzoate, Propyl hydroxy benzoate, Purified Talc, Magnesium Stearate, Sodium Starch Glycolate (Type A), Colloidal Anhydrous Silica and Purified Water.

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place. Protect from light

6.5. Nature and contents of container

Pack size available: Blister Tablets 10 x 10

6.6 Instructions for use and handling and disposal

No special requirements for disposal.

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

7.0 Marketing Authorisation Holder

Medicamen Biotech Limited

SP-1192 A&B, PHASE - IV,

Industrial Area,

Bhiwadi - 301 019

Distt. Alwar,

Rajasthan, India.

8.0 Number(S) in the national register of finished Pharmaceutical Products

Registration No; 06917/3483/NMR/2017

9.0 Date Of First Authorisation/Renewal Of The Authorisation

Approval date; 07-12-2021

10.0 Date of Revision of The Text

July 2024