Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Buscopan 10 mg Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg hyoscine butylbromide.

Excipient(s) with known effect: Sucrose (41.2mg per tablet)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet
Round, white, biconvex sugar-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Buscopan 10mg Coated Tablets are indicated for the relief of spasm of the gastrointestinal 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.

Buscopan 10mg Coated 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.

Paediatric population
Buscopan 10mg Coated Tablets are not recommended for use in children under 12 years of age.

Method of administration
Oral use.
Buscopan 10mg Coated Tablets should be swallowed whole with adequate water.

4.3 Contraindications

Buscopan 10 mg Coated Tablets are contraindicated in patients with:
- 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 be sought immediately.

Buscopan 10mg Coated 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 obstruction.

Because of the possibility that anticholinergics may reduce sweating, Buscopan 10mg Coated 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 Buscopan 10mg Coated 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 Buscopan 10mg Coated 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 Buscopan 10mg Coated Tablets.

Before taking Buscopan 10mg Coated Tablets a doctor should be consulted if any of the following apply:
- if this is the first time the patient has symptoms of Irritable Bowel Syndrome
- the patient is 40 years or over and it is some time since the last episode of IBS / abdominal cramps or the symptoms are different this time
- the patient has recently passed blood from the bowel
- the patient is feeling sick or vomiting
- the patient has lost his / her appetite or lost weight
- the patient looks pale and is feeling tired
- the patient is suffering from severe constipation
- the patient has a fever
- the patient has recently travelled abroad
- the patient has abnormal vaginal bleeding or discharge
- the patient has difficulty or pain passing urine

If symptoms do not improve or if they worsen after 2 weeks of treatment a doctor should be consulted.

<u>Paediatric population</u>
Buscopan 10mg Coated Tablets are not recommended for use in children under 12 years of age.

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. phenothiazines, butyrophenones), disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by Buscopan 10mg Coated 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 Buscopan 10mg Coated Tablets.

4.6 Fertility, 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 (see section 5.3).

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

Many of the listed undesirable effects can be assigned to the anticholinergic properties of hyoscine butylbromide.
Anticholinergic side effects of Buscopan 10 mg Coated Tablets are generally mild and self-limited.

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 available data)

Immune system disorders
Not known*: anaphylactic shock, anaphylactic reactions, dyspnoea, other hypersensitivity.

Cardiac disorders
Uncommon: tachycardia

Gastrointestinal disorders
Uncommon: dry mouth, constipation

Eye disorders
Not known: Visual accommodation disturbances

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 HPRA Pharmacovigilance,
Website: www.hpra.ie.

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.

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

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 $AUC_{0\text{-}tz}$-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 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

Hyoscine butylbromide was neither embryotoxic nor teratogenic at oral doses of up to 200 mg/kg in the diet (rat) or 200 mg/kg by gavage or 50 mg/kg s.c. (rabbit). Fertility was not impaired at doses of up to 200 mg/kg p.o..

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Hydrogen Phosphate, anhydrous
Maize Starch
Starch, soluble
Silica, Colloidal Anhydrous
Tartaric acid
Stearic/Palmitic acid
Sucrose
Talc
Acacia
Titanium Dioxide (E171)
Macrogol 6000
Carnauba Wax
Beeswax, White
Povidone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

PVC-aluminium blister packs of 20, 40 and 60 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare France SAS T/A Sanofi
82 Avenue Raspail
94250 Gentilly
France

8 MARKETING AUTHORISATION NUMBER

PA23180/016/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1979
Date of last renewal: 1st April 2009

10 DATE OF REVISION OF THE TEXT

June 2024