

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	BUSCOREN TABLETS (Hyoscine Butylbromide Tablets 10mg)
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1.5 Product Information: BUSCOREN TABLETS

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: BUSCOREN TABLETS

Strength:

Hyoscine butylbromide 10mg

Pharmaceutical form: Tablet

2. Qualitative and Quantitative composition:

Qualitative composition:

Sr. No.	Ingredient	Specification	Uses
1.	Hyoscine butylbromide	Ph. Eur	Active
2.	Microcrystalline cellulose (MCC102)	BP	Diluents
3.	Sodium starch glycollate	BP	Disintegrant
4.	Colloidal Silicon Dioxide (Aerosil)	USP	Glidant
5.	Magnesium stearate	BP	Lubricant
6.	Hydroxy propyl methyl cellulose	USP	Polymer
7.	Isopropyl alcohol	BP	Solvent
8.	Methylene chloride	BP	Solvent
9.	Maize starch	BP	Dusting powder
10.	Purified Talc	BP	Dusting powder
11.	Calcium Carbonate	BP	Dusting powder
12.	Gum Acacia	BP	Sub Coating
13.	Gelatin	BP	Sub Coating
14.	Purified Talc	BP	Sub Coating
15.	Sucrose	BP	Sub Coating
16.	Titanium dioxide	BP	Pigment
17.	Sucrose	BP	Colour Coat
18.	Titanium dioxide	BP	Pigment
19.	Novoglow	IH	Polishing
20.	Isopropyl alcohol	BP	Solvent
21.	Methylene chloride	BP	Solvent

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Quantitative composition:

Name of active ingredient(s)	Quantity per Tablet in mg.	Unit of measure	Reference/ monograph standard
Hyoscine butylbromide	10.000	mg	Ph. Eur.
Name Excipient(s)			
Micro Crystalline Cellulose (MCC102)	73.000	mg	BP
Sodium Starch Glycollate	10.000	mg	BP
Colloidal silicon dioxide (Aerosil)	5.000	mg	USP
Magnesium stearate	2.000	mg	BP
Hydroxy propyl methyl cellulose	2.400	mg	USP
Isopropyl alcohol	6.000	µl	BP
Methylene chloride	10.000	µl	BP
Maize starch	2.500	mg	BP
Purified Talc	5.000	mg	BP
Calcium carbonate	10.000	mg	BP
Gum Acacia (for sub coat)	3.000	mg	BP
Gelatin (for sub coat)	0.600	mg	BP
Purified Talc (for sub coat)	12.000	mg	BP
Sucrose (for sub coat)	60.000	mg	BP
Titanium dioxide (for sub coat)	0.900	mg	BP
Sucrose (for colour coat)	36.000	mg	BP
Colour Titanium dioxide (for colour coat)	0.336	mg	BP
Novo Glow (for polishing)	1.250	mg	IH
Isopropyl alcohol	6.000	µl	BP
Methylene Chloride	10.000	µl	BP

3. Pharmaceutical form: Tablet

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4. Clinical particular's:

4.1 Therapeutic indication:

Buscoren 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:

Buscoren Tablets are for oral administration only.

Buscoren 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.

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

Method of Administration: Oral route.

4.3 Contraindication:

Buscoren 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 warning and precaution 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.

Buscoren 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,

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caution should be used in patients susceptible to intestinal or urinary outlet obstructions.

Because of the possibility that anticholinergics may reduce sweating, Buscoren should be administered with caution to patients with pyrexia.

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

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

If any of the following apply to you do not take Buscoren Tablets. It may not be the right treatment for you. See your doctor as soon as possible.

- Aged 40 years or over
- Have passed blood from the bowel
- Are feeling sick or vomiting
- Have lost your appetite or lost weight
- Are looking pale and feeling tired
- Are suffering from severe constipation
- Have a fever
- Have recently travelled abroad
- Have abnormal vaginal bleeding or discharge
- Have difficulty or pain passing urine

Consult your doctor if you have developed new symptoms, or if your symptoms worsen, or if they do not improve after 2 weeks of treatment.

4.5 Interactions with other medicinal products and other forms of interactions:

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 Buscoren.

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 Buscoren.

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Additional information on special populations:

Not Applicable

Paediatric population:

Not Applicable

4.6 Fertility, pregnancy and lactation:

As a precautionary measure Buscoren is not recommended during pregnancy and breast-feeding.

4.7 Effects on ability to drive and use machines:

Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

4.8 Undesirable effects:

Like all medicines, Buscoren Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Stop taking your medicine and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- Allergic reactions such as skin reactions e.g. nettle rash, itching (affects fewer than 1 in 100 people), rash, redness of the skin
- Severe allergic reactions (anaphylactic shock) such as difficulty breathing, feeling faint or dizzy (shock)
- Painful red eye with loss of vision

Other side effects

- Dry mouth (affects fewer than 1 in 100 people)
- Small blisters on hands and feet (affects fewer than 1 in 100 people)
- Increased heart rate (affects fewer than 1 in 100 people)
- Being unable to pass water (urine) (affects fewer than 1 in 1,000 people)

4.9 Overdose and Treatment:

Symptoms:

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.

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Therapy:

In the case of oral poisoning, gastric lavage with medicinal charcoal should be followed by magnesium sulfate (15%). Symptoms of Buscoren over dosage 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. Catheterisation may be required for urinary retention.

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

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Buscoren 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-tz}-values varied from 0.37 to 10.7 ng h/mL. The median absolute bioavailabilities¹ of different dosage forms, i.e. 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

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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 stated.

6. Pharmaceutical Particulars:

6.1 List of excipients

Buscopen tablet contains the following excipients:

Microcrystalline cellulose (MCC102) BP, Sodium starch glycollate BP, Colloidal silicon dioxide (Aerosil) USP, Magnesium stearate BP, Hydroxy propyl methyl cellulose USP, Isopropyl alcohol BP, Methylene chloride BP, Maize starch BP, Purified Talc BP, Calcium carbonate BP, Gum Acacia BP, Gelatin BP, Sucrose BP, Titanium dioxide BP, Novoglow IH

6.2 Incompatibilities

None known

6.3 Shelf life

24 Months

6.4 Special precaution for storage

Store in cool & dry place. Below 30°C.

6.5 Nature and contents of container

10 tablets are packed in Aluminium/PVC blister; such ten blisters are packed in a unit carton along with literature insert.

1000 Tablets packed in polythene bag and contained in HDPE Container with leaflet.

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6.6 Special precautions for disposal

No special precaution.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES:

Marketing Authorization Holder:

Rene Industries Ltd

Address : PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

Manufactured by:

Rene Industries Ltd

Address : PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

8. MARKETING AUTHORISATION NUMBER:

Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION:

Not Applicable

10. DATE OF REVISION OF THE TEXT:

Not Applicable

11. DOSIMETRY (IF APPLICABLE):

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE):

Not Applicable