Professional Information

SCHEDULING STATUS: S1

1.NAME OF MEDICINE:
SCOPEX TABLETS

Strength
Hyoscine-N-butylbromide 10 mg per tablet

Pharmaceutical form:
Film-coated tablet

2.QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each film-coated tablet contains:
Hyoscine-N-butylbromide 10 mg
Preservative:
Nipastat/Salistat (total parabens) 126 % *m*/*m* (in tablet core)
Contains sugars:
Lactose 32 mg
For a full list of excipients see section 6.1

3.PHARMACEUTICAL FORM
Tablets
White, round, biconvex, film-coated tablets.

4.CLINICAL PARTICULARS
4.1.Therapeutic indications:
Hyoscine butylbromide is used in the treatment of conditions associated with gastrointestinal spasm.

4.2 Posology and method of administration
Two tablets (20 mg) four times daily.

4.3 Contraindications:
•**SCOPEX TABLETS** should not be used in patients with prostatic enlargement, paralytic ileus or pyloric stenosis, closed-angle glaucoma or with a narrow angle between the iris and the cornea.
•Due to the risk of provoking hyperpyrexia it should not be given to patients, especially children where the ambient temperature is high.
•**SCOPEX TABLETS** should not be given to patients with myasthenia gravis unless it is given to reduce adverse muscarinic effects of an anticholinesterase agent.
•Hyoscine Butylbromide is contraindicated in patients who have tachycardia, hypotension, anaphylaxis and cardiac diseases or history of cardiac disease or hypertension.

4.4 Special warnings and precautions for use:
Contains lactose. Patients with rare hereditary conditions such as galactose intolerance e.g. galactosemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **SCOPEX TABLETS**.
Contains lactose which may have an effect on the glycemic control of patients with diabetes mellitus.
Use with caution in children, geriatric patients, patients with diarrhoea, fever, and in conditions characterised by tachycardia. Care is required in patients with acute myocardial infarction and in patients with hypertension. In patients with ulcerative colitis its use may lead to ileus or megacolon, and its effects on lower oesophageal sphincter may exacerbate reflux.

4.5 Interaction with other medicines and other forms of interaction
The effects of hyoscine butylbromide may be enhanced by the concomitant administration of other medicines with antimuscarinic properties, such as amantadine, some antihistamines, butyrophenones, phenothiazines and tricyclic antidepressants. The absorption of other medicines may also be affected due to the reduction in gastric motility.
The use of **SCOPEX TABLETS** may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

4.6 Fertility, pregnancy and lactation
Safety and/efficacy have not been established.

4.7 Effects on ability to drive and use machine
Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decisions could lead to accidents.

4.8 Undesirable effects

Frequency	System organ class	Undesirable effects
Less frequent	Gastrointestinal disorders	Dryness of the mouth with difficulty in swallowing and talking, thirst, vomiting, reduction in the tone and motility of the gastrointestinal tract leading to constipation.
	Blood and lymphatic system disorders	Postural hypotension and impotence
	Skin and subcutaneous tissue disorders	Flushing and dryness of the skin
	Cardiac disorders	Transient bradycardia, tachycardia, with palpitations and arrhythmias
	Renal and urinary disorders	Impairment of renal function, difficulty in micturition
Frequency not known	Respiratory, thoracic and mediastinal disorders	Reduced bronchial secretions
	Eye disorders	Mydriasis (dilation of the pupils), cyclopegia (loss of accommodation), Photophobia
	Psychiatric disorders	Confusion, giddiness and staggering may occur.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 .
May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

4.9 Overdose
Toxic doses cause tachycardia, rapid respiration, hyperpyrexia, and central nervous system stimulation marked by restlessness, confusion, excitement, paranoid and psychotic reactions, hallucinations and delirium and occasionally seizures or convulsions. A rash may appear on the face or upper trunk.
In case of oral overdosage the stomach should be emptied by aspiration and lavage or by emesis.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamics properties
A.5.4.2 Cholinolytics (anticholinergics) General
Mechanism of action:
Hyoscine butylbromide is a quaternary ammonium anticholinergic agent the peripheral effects of which are similar to those of atropine, but weaker and of shorter duration.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Chloroform
Lactose
Magnesium stearate
Maize starch
Opadry II White
Opaglos NA- 7150
Purified talc

6.2 Incompatibilities
Not applicable

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store in airtight container at or below 25 °C. Protect from light.

6.5 Nature and contents of container
Polypropylene securitainers with white, LDPE closures containing 10 tablets. Blisters using PVC film & printed aluminium foil of 10 tablets.

7.HOLDER OF THE CERTIFICATE OF REGISTRATION
Adcock Ingram Limited
1 New Road
Erand Gardens,
Midrand, 1685
Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER
C674 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION
Old Medicine

10. DATE OF REVISION OF THE TEXT
08 September 2021

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