SCHEDULING STATUS: **S1**

1. NAME OF THE MEDICINE

SCOPEX SYRUP, 5 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of syrup contains:

Hyoscine butylbromide	5,00 mg
Preservative:	
Sorbic acid	0,08 % *m/v*
Contains Sweeteners:	
Sodium saccharin 500	2,50 mg
Sodium Cyclamate	10,00 mg
Contains Sugars:	
Glycerol (Glycerin)	250,00 mg
Sorbitol 70% solution	500,00 mg

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

A clear, colourless syrup with an odour and taste of banana with a bitter after taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

SCOPEX SYRUP is used in the treatment of conditions associated with gastrointestinal spasm.

4.2 Posology and method of administration

Posology:

The initial oral dose must be the lowest recommended for age.

Children older than 1 year up to 3 years: 5 to 10 ml three times daily.

Children older than 3 years up to 6 years: 10 ml three times daily.

Children older than 6 years up to 12 years: 10 to 20 ml three times daily.

Children older than 12 years and adults: 20 ml four times daily.

Paediatric population:

Babies older than 1 month up to 3 months: 2,5 ml three times daily.

Infants older than 3 months up to 1 year: 2,5 to 5 ml three times daily.

Method of administration

Oral.

Shake the bottle before use.

4.3 Contraindications:

SCOPEX SYRUP should not be used in patients with:

- Myasthenia gravis
- Closed angle glaucoma
- Narrow angle between the iris and the cornea
- A high ambient temperature, especially in children
- Porphyria
- Intestinal obstruction or ileus.

SCOPEX SYRUP should not be used in patients who have experienced prior hypersensitivity to hyoscine butylbromide or any of the excipients listed in Section 6.1.

Hyoscine butylbromide is contraindicated in patients who have tachycardia, hypotension, anaphylaxis and cardiac diseases or history of cardiac disease or hypertension.

SCOPEX SYRUP should not be used during pregnancy and lactation.

4.4 Special warnings and precautions for use:

DO NOT EXCEED THE RECOMMENDED DOSE.

SCOPEX SYRUP should be used with care in the following:

General disorders:

- Fever

Cardiac disorders:

- tachycardia
- myocardial infarction

Gastrointestinal disorders:

- paralytic ileus
- pyloric stenosis
- ulcerative colitis
- exacerbated reflux
- diarrhoea

Renal and urinary disorders:

- prostatic enlargement
- impaired kidney function

Disorders of metabolism:

- impaired metabolic function

Vascular disorders:

- hypertension

Hepato-biliary disorders:

- impaired liver function

Contains glycerol and sorbitol and may have a laxative effect.
Patient with the rare hereditary condition of sorbitol intolerance should not take SCOPEX SYRUP.

4.5 Interaction with other medicines and other forms of interaction

The effects of SCOPEX SYRUP 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.

4.6 Fertility, pregnancy and lactation

SCOPEX SYRUP should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

The effect on the ability to drive and use machine has not been established.

4.8 Undesirable effects

Frequency	System organ class	Undesirable effects
Less frequent	Cardiac disorders	• Transient bradycardia • Tachycardia • Palpitations, arrhythmias
	General disorders	• Dryness of the mouth • Difficulty in swallowing and talking • Thirst
	Skin disorders and subcutaneous tissue disorders	• Flushing • Dryness of the skin
	Renal and urinary disorders	• Difficulty in micturition
Frequency not known	Gastrointestinal disorders	• Reduction in the tone and motility of the gastrointestinal tract leading to constipation.
	Eye disorders	• Mydriasis (Dilatation of the pupils) • Cyclopegia (Loss in accommodation) • Photophobia
	Respiratory disorders	• Reduced bronchial secretions

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

In toxic doses anticholinergic effects predominate. These include tachycardia, hyperpyrexia, restlessness, confusion, excitement, hallucinations and delirium. A flushing of the face and upper trunk may be a prominent feature.

Overdose may cause postural hypotension. Toxic doses may cause non-depolarising neuromuscular block.

Treatment is symptomatic and supportive.

5. PHARMACEUTICAL PROPERTIES

5.1 Pharmacodynamic properties

A 11.2 Gastrointestinal antispasmodics and cholinolytics (anticholinergics).

Mechanism of action:

Hyoscine butylbromide is a quaternary ammonium derivative that acts at the parasympathetic ganglia in the walls of the viscera where it exerts a specific antispasmodic action on the smooth muscle of the gastrointestinal, biliary and urinary tracts.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Banana flavour LR 4186

Hydrochloric acid 32%

Hydroxypropyl methyl cellulose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 ˚C.

Protect from light.

Keep well closed.

6.5 Nature and contents of container

100 Amber glass bottle with a white polypropylene cap.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand,1685
Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER(S)

36/11.2/0327

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 May 2004

10. DATE OF REVISION OF THE TEXT

09 June 2021

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Botswana: S3 BOT1703136