**SCHEDULING STATUS:** **S1**

## 1. NAME OF THE MEDICINE

SCOPEX TABLETS, 10 mg, film-coated tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film-coated tablet contains:

Hyoscine butylbromide 10 mg

Preservative:

Paraben Blend 0,120 % *m/m*

Contains sugar:

Lactose 32 mg

For a full list of excipients see section 6.1

## 3. PHARMACEUTICAL FORM

Film-coated tablets.

A white, round, biconvex, coated tablet, odourless.

## 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.

**Method of administration**

To be taken orally.

### 4.3 Contraindications

- Hypersensitivity to the hyoscine butylbromide or to any of the excipients (see section 6.1).
- 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 depressant.

### 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. |
| | 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. |
| | Blood and lymphatic system disorders | Postural hypotension and impotence. |

**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 requested to report any suspected adverse drug reactions to SAHPRA via Med Safety APP (Medsafety x SAHPRA) and eReporting platform (who-umc.org), found on SAHPRA website.

Suspected adverse reactions 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 or by emesis.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic 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

**Tablet core**:

Lactose,

Magnesium stearate,

Maize starch,

Paraben blend,

Purified talc.

**Coating:**

Opadry II White 85F18422,

Opaglos NA- 7150,

### 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

White polypropylene securitainers with white, LDPE closures containing 10 tablets, blisters using PVC film & printed aluminium foil of 10 tablets.

## 7. HOLDER OF 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

20 January 2025

Botswana: S2 B9323925

Namibia: NS1 14/11.2/0140