PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

SCOPEX SYRUP, each 5 ml of syrup contains:

Hyoscine butylbromide 5 mg

Contains Sweetener:

Sodium saccharin 500	**2, 50 mg**
Sodium Cyclamate	**10, 00 mg**

Contains Sugars:

Glycerol (Glycerin)	**250, 00 mg**
Sorbitol 70% solution	**500, 00 mg**

Read all of this leaflet carefully because it contains important information for you.

SCOPEX SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **SCOPEX SYRUP** carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Do not share **SCOPEX SYRUP** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What **SCOPEX SYRUP** is and what it is used for
2. What you need to know before you take **SCOPEX SYRUP**
3. How to take **SCOPEX SYRUP**
4. Possible side effects
5. How to store **SCOPEX SYRUP**
6. Contents of the pack and other information

Date of approval: 09 June 2021

PATIENT INFORMATION LEAFLET

1. WHAT SCOPEX SYRUP IS AND WHAT IT IS USED FOR

SCOPEX SYRUP contains hyoscine butylbromide which belongs to a group of medicines referred to as gastrointestinal antispasmodics and cholinolytics (anticholinergics).

SCOPEX SYRUP is used in the treatment of conditions associated with gastrointestinal spasm (stomach cramps).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SCOPEX SYRUP

Do not take SCOPEX SYRUP

- If you are hypersensitive (allergic) to hyoscine butylbromide or any of the other ingredients of **SCOPEX SYRUP** (listed in section 6).
- if you have weakness and rapid fatigue of the muscles
- if you have closed angle glaucoma (eye problems)
- if you have narrow angle between the iris and the cornea (eye problems increasing pressure in the eye)
- if you have a high ambient temperature, especially in children
- if you suffer from liver disorder (porphyria)
- if you have bowel blockage and/or the bowel does not function properly.
- If you have tachycardia, low blood pressure, severe allergic reactions and heart disease or history of heart disease or hypertension
- During pregnancy and lactation.

Warnings and precautions

Take special care with **SCOPEX SYRUP**:

- As it contains sorbitol and may have a laxative effect.
- **SCOPEX SYRUP** contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take **SCOPEX SYRUP.**

Use in children and adolescents

DO NOT EXCEED THE RECOMMEND DOSE.

Other medicines and SCOPEX SYRUP

Always tell your health care provider if you are taking any other medicine.

The effects of **SCOPEX SYRUP** may be enhanced by the concomitant administration of other medicines which relax smooth muscles, decrease secretion of saliva, sweat and dilate the pupil of the eye 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.

SCOPEX SYRUP with food and drinks

No known interactions with food and drinks.

Pregnancy and breastfeeding

SCOPEX SYRUP should not be used during pregnancy and lactation.

The effect of **SCOPEX SYRUP** on fertility has not yet been recorded.

Driving and using machinery

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

3. HOW TO TAKE SCOPEX SYRUP

Always take **SCOPEX SYRUP** exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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

- 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.
- 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.

Shake the bottle before use.

If you take more SCOPEX SYRUP than you should:

- In toxic doses reduced smooth muscle spasms predominate. These include tachycardia (rapid heartbeat), hyperpyrexia (high fever), restlessness, confusion, excitement, hallucinations and delirium.
- A flushing of the face and upper trunk may be a prominent feature.
- Overdose may cause low blood pressure that happens when standing up from sitting or lying down (postural hypotension) and non-depolarising neuromuscular block.
- Treatment is symptomatic and supportive.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. POSSIBLE SIDE EFFECTS

SCOPEX SYRUP can have side effects.

Not all side effects reported for **SCOPEX SYRUP** are included in this leaflet. Should your general health worsen or if you experience any undesirable effects while taking **SCOPEX SYRUP**, please consult your health care provider for advice.

Side effects include:

<u>Less frequent side effects</u>

- Dryness of the mouth, Difficulty in swallowing and talking, thirst.
- Slow heart beat or abnormal rapid heart rate (tachycardia, palpitations, and arrhythmias).
- Flushing and dryness of the skin.
- Difficulty micturition (difficulty in passing urine).

<u>Frequency not known side effects</u>

- Dilatation of the pupils, loss in accommodation and photophobia.
- Reduced bronchial secretions.
- Reduction in the tone and motility of the gastrointestinal tract leading to constipation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **SCOPEX SYRUP.** You may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. HOW TO STORE SCOPEX SYRUP

Store all medicines out of reach of children.

Store at or below 25 ˚C.

Protect from light. Keep well closed.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SCOPEX SYRUP contains

The active substance is Hyoscine butylbromide.

Each 5 ml of syrup contains

Hyoscine butylbromide	5 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

Other excipients:

Banana flavour LR 4186, hydrochloric acid 32%, hydroxypropyl methyl cellulose.

What SCOPEX SYRUP looks like and contents of the pack

A clear, colourless syrup with an odour and taste of banana with a bitter after taste in a 100 ml amber glass bottle with a white polypropylene cap.

PATIENT INFORMATION LEAFLET

Holder of Certificate of Registration

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