PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BUTYRONEX 20 mg/mL solution for injection

hyoscine butylbromide

Sugar free.

Read all of this leaflet carefully before you are given BUTYRONEX 20 mg/mL.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.

What is in this leaflet

1. What BUTYRONEX is and what it is used for
2. What you need to know before you receive BUTYRONEX
3. How BUTYRONEX ampoules will be given
4. Possible side effects
5. How to store BUTYRONEX
6. Contents of the pack and other information.

1. What BUTYRONEX is and what it is used for

Each 1 mL BUTYRONEX contains 20 mg hyoscine butylbromide.

It belongs to a group of medicines called antispasmodics.

BUTYRONEX ampoules are used to relieve cramps in the muscles of your stomach and gut (intestine).

2. What you need to know before you receive BUTYRONEX

Do not receive BUTYRONEX:

- if you are hypersensitive (allergic) to hyoscine butylbromide or any of the other ingredients of BUTYRONEX (listed in section 6)
- if you have porphyria (metabolism disorder affecting the skin or nervous system)
- if you have difficulty or pain passing water (urine) such as men with prostate problems
- if you have any obstruction of the gastrointestinal tract, such as paralytic ileus (small bowel not working properly), pyloric stenosis (narrowing of the muscular outlet of the stomach) and other mechanical stenosis (abnormal narrowing or blockage) of the stomach or gut
- if you have closed angle glaucoma (increased pressure in the eye)
- if you have myasthenia gravis (muscle weakness problem)
- if you have a fever
- if you have an enlarged bowel (megacolon)
- if you have ulcerative colitis (bloody diarrhoea, stomach pain and cramps)
- if you have changes in the way your heart beats (beating faster)
- intramuscularly if you are using any medicine to stop blood from clotting (anticoagulant)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with BUTYRONEX

Consult your doctor, pharmacist or health care provider before receiving BUTYRONEX ampoules if you have unexplained pain in your stomach which persists, worsens or occurs with:

- fever
- nausea (feeling sick)
- vomiting (being sick)
- changes in your bowel movements
- tenderness in your stomach area
- low blood pressure (dizziness or light-headedness)
- feeling faint
- frequent/loose watery stools (diarrhoea)
- blood in your stools.

BUTYRONEX ampoules can cause fast irregular heartbeats (tachycardia), low blood pressure (hypotension), an overactive thyroid gland which can cause increased appetite, weight loss or sweating (hyperthyroidism) or a severe allergic reaction (anaphylaxis). Take therefore special care if you have any heart condition such as:

- heart failure
- coronary heart disease
- dysrhythmia
- high blood pressure
- heart surgery.

If any of the above apply to you, you should be monitored. Emergency equipment and personnel trained in its use must be readily available.

Consult your doctor urgently if you experience any pain, redness or vision loss in your eye after receiving BUTYRONEX.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or other health care provider before receiving BUTYRONEX injection.

Children and adolescents

BUTYRONEX is not indicated for use in children under 12 years of age.

Other medicines and BUTYRONEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

BUTYRONEX ampoules may cause an interaction when used together with:

- antidepressants (used to treat depression)
- antihistamines (used to treat hay fever and other allergies)
- quinidine or disopyramide (used to control your heartbeat)

- amantadine (used for Parkinson's disease and flu)
- tiotropium, ipratropium or atropine-like medicines (used for breathing problems)
- metoclopramide (used to treat nausea).

BUTYRONEX with alcohol

Alcohol should be avoided if you receive BUTYRONEX.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving BUTYRONEX.

You should not be given BUTYRONEX ampoules if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

Driving and using machines

BUTYRONEX may cause visual disturbances or dizziness. If this happens to you, wait until your sight returns to normal or you stop feeling dizzy before driving a vehicle or performing any tasks requiring your attention.

BUTYRONEX ampoules contain sodium chloride:

BUTYRONEX ampoules contain sodium chloride. The amount of sodium in a 1 mL ampoule is less than 1 mmol (23 mg), the total amount of sodium if you are given five ampoules in 24 hours is less than 1 mmol (23 mg) this means that your medicine is essentially sodium free.

3. How BUTYRONEX ampoules will be given

BUTYRONEX ampoules are usually given by a doctor, nurse or health care provider.

Your doctor will decide on the appropriate dosage for you.

BUTYRONEX ampoules will be given to you into a muscle (intramuscular) or into a vein (slow intravenous).

You will not be expected to give yourself BUTYRONEX ampoules, it will be given to you by a person who is qualified to do so.

If you receive more BUTYRONEX than you should

Since a health care provider will administer BUTYRONEX ampoules, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms of the overdosage.

If you forget to receive BUTYRONEX ampoule

Since a health care provider will administer BUTYRONEX ampoules, it is unlikely that the dose will be missed.

4. Possible side effects

BUTYRONEX can have side effects.

Not all side effects reported for BUTYRONEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving BUTYRONEX, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving BUTYRONEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing and shock.
- Rash or itching.
- Fainting (lose consciousness).

These are all very serious side effects. If you have them, you may have had a serious reaction to BUTYRONEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Painful red eyes with loss of vision, you may have an eye problem called glaucoma and need

urgent medical attention.

- Fast or slow irregular heart rate or changes in the way the heart beats.
- Problems emptying your bladder.

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring frequently:

- Disorientation, a serious change in mental abilities (delirium), somnolence (sleepiness).
- Eye disorders.
- Dizziness.
- Dry mouth, constipation.

Side effects occurring with an unknown frequency:

- Difficulty in movement or walking (staggering).
- Increased sensitivity to light (photophobia).
- Sensation of whirling and a tendency to fall or stagger (giddiness).
- Difficulty in swallowing, thirst, vomiting, pain behind the breastbone or inside the chest, due to increased gastric reflux.
- Dryness of the skin.
- Urinary urgency (a sudden, strong need to urinate).
- Pain at the place you had the injection may occur if you have been given BUTYRONEX ampoules into a muscle.
- Dilatation of the pupil of the eye (mydriasis).
- Low blood pressure (dizziness, light-headedness), flushing.
- Abnormal sweating or reduced sweating, small, intensely itchy blisters on the palms of hands or soles of feet.

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, pharmacist or nurse. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BUTYRONEX.

5. How to store BUTYRONEX

- Store at or below 25 °C.
- Protect from light and excessive heat.
- Keep ampoules in original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BUTYRONEX contains

The active substance is hyoscine butylbromide.

Other ingredients are sodium chloride and water for injection.

What BUTYRONEX looks like and contents of the pack

A clear, colourless solution.

1 mL clear Fiolax® (USP type 1) ampoule with a white OPC dot or

1 mL clear NEG (USP type 1) ampoule with a yellow OPC dot.

Pack size: Carton box containing 10 x 1 mL ampoules.

Holder of Certificate of Registration:

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Unit 6, Ground Floor

10 Church Street

Durbanville

7551

Tel: 087 551 3245

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