PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BUSCOPAN® 20 mg/1 ml

Ampoules

Hyoscine butylbromide

Read all of this leaflet carefully before you are given BUSCOPAN 20 mg/1 ml ampoules.

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

What is in this leaflet

1. What BUSCOPAN 20 mg/1 ml ampoules is and what it is used for
2. What you need to know before you use BUSCOPAN 20 mg/1 ml ampoules
3. How to use BUSCOPAN 20 mg/1 ml ampoules
4. Possible side effects
5. How to store BUSCOPAN 20 mg/1 ml ampoules
6. Contents of the pack and other information

1. What BUSCOPAN 20 mg/1 ml ampoules are and what they are used for

Hyoscine butylbromide belongs to a group of medicines called antispasmodics (medicines that relax the cramping muscles of your stomach and bowel).

BUSCOPAN 20 mg/1 ml ampoules are used in the treatment of conditions associated with

gastrointestinal spasm, that is, to relieve cramps in the muscles of the stomach and gut.

2. What you need to know before you use BUSCOPAN 20 mg/1 ml ampoules

BUSCOPAN 20 mg/1 ml ampoules should not be administered to you:

- if you are hypersensitive (allergic) to hyoscine butylbromide or any of the other ingredients (listed in section 6).
- If you have closed angle glaucoma (an eye problem with increased pressure in the eye)
- If you have an enlarged prostate
- If you have urine retention (a desire to urinate with the inability to do so) due to any urethral or prostate disease
- If you have pyloric stenosis (narrowing of the muscular outlet of the stomach) and other mechanical stenoses (abnormal narrowings)/blockages of the stomach or gut.
- if you have a condition where the bowel is blocked and does not work properly (paralytic or obstructive ileus)
- if you have a very enlarged bowel (megacolon)
- If you have tachycardia (fast heartbeat)
- if you have myasthenia gravis (a very rare muscle weakness problem)
- If you have porphyria (disturbances of metabolism that can be seen as disorders of the skin or other organs)
- If you have a fever
- If you take anticoagulants (medicine used to prevent blood clots), tell your doctor, pharmacist or other healthcare professional as the injection should then be given under the skin or into a vein.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Tell your doctor, pharmacist or other health care provider before being given BUSCOPAN 20 mg/1 ml ampoules:

- If you have abnormal liver or kidney function
- If you have any heart problems
- If you have a predisposition to intestinal or urinary blockages.

Contact your doctor immediately if you have severe, unexplained abdominal (belly) pain that persists or worsens or occurs together with fever, nausea (feeling sick), vomiting, changes in your bowel movements, abdominal (belly) tenderness, low blood pressure, fainting or blood in your bowel movements.

If you experience painful red eyes with loss of vision after having BUSCOPAN 20 mg/1 ml ampoules, tell your doctor immediately. You may have an eye problem called glaucoma and need urgent medical attention.

After parenteral administration of BUSCOPAN 20 mg/1 ml ampoules, that is, by injection, cases of anaphylaxis (a severe type of allergic reaction) including episodes of shock have been observed. Patients receiving BUSCOPAN 20 mg/1 ml ampoules by injection should be kept under observation.

Contact your doctor immediately as you may need urgent medical attention if you experience anaphylactic reaction and shock – this is a severe type of allergic reaction. The itchy rash may spread all over the body, as well as swelling. You may have difficulty in breathing and may lose consciousness.

Other medicines and BUSCOPAN 20 mg/1 ml ampoules

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

BUSCOPAN 20 mg/1 ml ampoules can interfere with some other medicines, in particular:

Antihistamines – used to treat hayfever and other allergies.

Tricyclic or tetracyclic antidepressant medicines – used to treat depression.

Quinidine or disopyramide – used to control your heartbeat.

Amantadine – used for Parkinson's disease and flu.

Antipsychotic medicines such as butyrophenones or phenothiazines – used to treat severe mental illness such as schizophrenia

Tiotropium, ipratropium or atropine-like medicines – medicines inhaled to treat breathing problems.

Dopamine antagonists such as metoclopramide for feeling nauseous.

Beta-adrenergic medicines such as salbutamol for asthma.

Pregnancy and breastfeeding

Do not use BUSCOPAN 20 mg/1 ml ampoules if you are pregnant, likely to get pregnant or are breast-feeding.

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 taking this medicine.

Driving and using machines

Some people may have temporary blurring of vision while using BUSCOPAN 20 mg/1 ml ampoules. If this happens to you, wait until your vision returns to normal before driving or using any tools or machines.

3. How to use BUSCOPAN 20 mg/1 ml ampoules

Adults and adolescents over 12 years of age:

Your doctor will decide on the appropriate dosage for you.

BUSCOPAN 20 mg/1 ml ampoules are given by injection.

You will not be expected to give yourself BUSCOPAN 20 mg/1 ml ampoules. It will be given to you by a person who is qualified to do so.

If you get more BUSCOPAN 20 mg/1 ml ampoules than you should:

Since a health care provider will administer BUSCOPAN 20 mg/1 ml ampoules, he / she will control the dosage. However, in the event of overdosage, your doctor will take appropriate actions.

If you forget to use BUSCOPAN 20 mg/1 ml ampoules

Since a health care provider will administer BUSCOPAN 20 mg/1 ml ampoules, it is unlikely that the dose will be missed.

4. Possible side effects

BUSCOPAN 20 mg/1 ml ampoules can have side effects.

Not all side effects reported for BUSCOPAN 20 mg/1 ml ampoules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BUSCOPAN 20 mg/1 ml ampoules, please consult your health care provider for advice.

If you get any of the side effects described below stop using BUSCOPAN 20 mg/1 ml ampoules and tell your doctor immediately. You may need urgent medical attention.

If any of the following happens, stop using BUSCOPAN 20 mg/1 ml ampoules and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Anaphylactic reaction and shock – this is a severe type of allergic reaction. The itchy rash may spread all over the body, as well as swelling. You may have difficulty in breathing and may lose consciousness.
- Allergic reactions – the signs may include skin rash and itching, wheezing and shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BUSCOPAN 20 mg/1 ml ampoules. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you experience painful red eyes with loss of vision after having BUSCOPAN 20 mg/1 ml ampoules, tell your doctor immediately. You may have an eye problem called glaucoma and need urgent medical attention.
- Slowing of the heart rate followed by increased heart rate with faster or irregular heartbeats, also called palpitations, and changes in the way the heart beats.
- Problems emptying the bladder.

These are all serious side effects. You may need urgent medical attention.

- Other side effects that do not normally need medical treatment:
- Dry mouth with difficulty swallowing, thirst, constipation, vomiting, heartburn.
- Dryness of the skin.
- Dizziness and staggering.
- A decrease in blood pressure.
- Flushing.

- Blurring of vision

If any of these side effects become troublesome, please consult your doctor, pharmacist or other healthcare professional.

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:

- The Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or
- The Pharmacovigilance Unit at CFAO at chcsa-za-safety@cfao.com.

By reporting side effects, you can help provide more information on the safety of BUSCOPAN 20 mg/1 ml ampoules.

5. How to store BUSCOPAN 20 mg/1 ml ampoules

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BUSCOPAN 20 mg/1 ml ampoules contain:

The active substance is hyoscine butylbromide.

Each ampoule contains hyoscine butylbromide 20 mg.

The other ingredients are sodium chloride, water for injection.

What BUSCOPAN 20 mg/1 ml ampoules look like and contents of the pack:

A clear colourless solution in 1 ml glass ampoules.

Boxes containing 5 BUSCOPAN ampoules (20 mg/ml).

Holder of Certificate of Registration:

CFAO Healthcare South Africa (Pty) Ltd.

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