

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S3****GLYCOSTOM 0,2 mg/ml solution for injection****Glycopyrronium bromide****Sugar free****Read all of this leaflet carefully before you are given GLYCOSTOM**

- 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 GLYCOSTOM is and what it is used for
2. What you need to know before you receive GLYCOSTOM
3. How to use GLYCOSTOM
4. Possible side effects
5. How to store GLYCOSTOM
6. Contents of the pack and other information

1. What GLYCOSTOM is and what it is used for

GLYCOSTOM contains the active substance glycopyrronium bromide.

Glycopyrronium Bromide belongs to a group of medicines called anticholinergic medicines.

GLYCOSTOM may be used:

- To protect against some of the unwanted effects of medicines such as neostigmine or pyridostigmine, which are used to reverse the effects of certain types of muscle-relaxing

medicines (called non-depolarising muscle relaxants).

- Before an operation, to reduce saliva and other secretions and to reduce the acidity of the stomach contents.
- Before or during an operation, to reduce or prevent slowing of the heartbeat during surgery.

2. What you need to know before you receive GLYCOSTOM

GLYCOSTOM should not be administered to you:

- If you are hypersensitive (allergic) to glycopyrronium bromide or any of the other ingredients of GLYCOSTOM (listed in section 6).
- If you have glaucoma (increased pressure in the eye).
- If you suffer from myasthenia gravis (a disorder that causes extreme muscle weakness and fatigue).
- If you have an enlarged prostate.
- If you have stomach or bowel problems.
- If you suffer from a prolonged QT interval (irregular heart rhythm) should avoid the combination use of neostigmine plus GLYCOSTOM.

Warnings and precautions

Special care should be taken with GLYCOSTOM:

- if you have a condition characterised by rapid heartbeat (including over-active thyroid, heart failure or heart surgery);
- if you have a history of high blood pressure, coronary artery disease or irregular heartbeats;
- if you are receiving inhalation anaesthesia (to put you asleep before an operation) as it may cause a change in your normal heart rhythm;

- if you have gastric reflux (a condition in which the liquid stomach contents backs up (regurgitates) into the gullet);
- if you have diarrhoea;
- if you have ulcerative colitis (a chronic inflammation of the large intestine (colon) which can cause abdominal pain, diarrhoea and bleeding from the back passage);
- if you have a high temperature (as the medicine will inhibit sweating).
- avoid repeated or large doses if you suffer from renal impairment (kidney problems), and your doctor may adapt the dose accordingly.

Other medicines and GLYCOSTOM

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

Medicines which may interact with GLYCOSTOM include:

- Cyclopropane anaesthesia (simultaneous use can result in irregular heart rhythm);
- Other medicines with antimuscarinic effects. The simultaneous use of two or more of these may increase the risk of side effects such as dry mouth, urinary retention, and constipation. Concurrent use can also lead to confusion in the elderly);
- Medicine for depression known as tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs).
- Clozapine which is used to treat severe mental disorders.
- Strong pain relievers such as nefopam.
- Slow-dissolving digoxin tablets, disopyramide (used to treat heart problems);
- Domperidone or metoclopramide (used to treat nausea and vomiting);
- Ketoconazole (used to treat fungal infections);
- Amantadine, levodopa (used to treat Parkinson's disease);
- Memantine (used to treat Alzheimer's disease).

Pregnancy, breastfeeding and fertility

The safety of GLYCOSTOM during pregnancy and whilst breastfeeding has not been established.

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 GLYCOSTOM.

Driving and using machines

After having GLYCOSTOM you should not drive or operate machines because this medicine can cause blurred vision, dizziness and other effects that may affect your ability to do so. Do not drive or use machinery until these effects have gone.

GLYCOSTOM contains sodium

This injection contains less than 1 mmol (23 mg) of sodium per ml, that is to say essentially 'sodium-free'.

3. How to use INTESTRONIUM

Do not share medicines prescribed for you with any other person.

GLYCOSTOM is given by injection into a muscle (intramuscularly) or into a vein (intravenously).

You will not be expected to give yourself GLYCOSTOM. It will be given to you by a person who is qualified to do so.

The usual dose in adults and children:

The individual dose will be decided by the doctor.

If you receive more GLYCOSTOM than you should

Since a health care provider will administer GLYCOSTOM, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of GLYCOSTOM

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

4. Possible side effects

GLYCOSTOM can have side effects.

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

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

- swelling mainly of the face, lips or throat which makes it difficult to swallow or breathe,
- itching and rashes.

These are all very serious side effects. If you have them, you may have had a serious reaction to GLYCOSTOM. 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:

- increased or decreased heartbeat, irregular heartbeat,
- mental excitement (may occur more frequently in the elderly).

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

Tell your doctor if you notice any of the following:

Frequent

- drowsiness
- visual disturbances

Less frequent

- mental confusion, nervousness, sleeplessness,
- headache, drowsiness, dizziness, giddiness, loss of taste
- blurred vision, light sensitivity, a feeling of pressure in the eye
- reduced bronchial secretions
- nausea (feeling sick), vomiting, constipation, bloated feeling, dry mouth
- decreased sweating, flushing, dryness of the skin
- difficulty in passing urine, impotence
- suppression of lactation (breast milk becomes less)
- weakness

Frequency unknown

- hypersensitivity
- swelling of the face
- nasal stuffiness
- feeling of discomfort

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 to SAHPRA 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 GLYCOSTOM.

5. How to store GLYCOSTOM

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not use after the expiry date stated on the label or 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 GLYCOSTOM contains

- The active substance is glcopyrronium bromide.
Each 1 ml of GLYCOSTOM contains 0,2 mg glycopyrronium bromide.
- The other ingredients are sodium chloride, hydrochloric acid, water for injection.

What GLYCOSTOM looks like and contents of the pack

A clear, colourless solution free from visible particles and visual fibers.

GLYCOSTOM is presented in 1 ml glass ampoules with a green dot.

Pack size: 10 x 1 ml ampoules per cardboard carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

<https://www.pharmaq.co.za>