

Applicant/HCR	:	Umsebe Healthcare	V5 (10.05.2024)
Product name, strength and dosage form	:	Cholstyq, 0,5 mg/ml glycopyrronium bromide and 2,5 mg/ml neostigmine metilsulfate, solution for injection	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Cholstyq **Solution for injection**

Glycopyrronium bromide and Neostigmine metilsulfate

Each 1 ml of the solution for injection contains 3 mg (0,13 mmol) sodium.

Read all of this leaflet carefully before you are given Cholstyq

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

What is in this leaflet

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

1. What Cholstyq is and what it is used for

Cholstyq contains two active ingredients:

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- Neostigmine metilsulfate belongs to a group of medicines called cholinesterase inhibitors. It has the effect of reversing the action of certain muscle-relaxing medicines.
- Glycopyrronium bromide belongs to a group of medicines called anticholinergic agents. Its purpose is to block some of the unwanted effects that may occur with neostigmine metilsulfate, such as slowing the heart rate or excess production of saliva.

Glycopyrronium bromide and neostigmine metilsulfate Injection is used at the end of an operation to reverse the effects of some of the medicines used during surgery, such as anaesthetics and muscle relaxants.

2. What you need to know before you are given Cholstyq

Cholstyq should not be given to you:

- if you are hypersensitive (allergic) to glycopyrronium bromide or neostigmine metilsulfate or any of the other ingredients of Cholstyq (listed in section 6).
- if you have a blockage in your stomach, intestine or urinary passages, such as bladder or kidneys.
- if you are also receiving another muscle relaxant of the depolarising muscle relaxant group during an operation, such as suxamethonium.

Warnings and precautions

Tell your doctor or healthcare professional before you are given Cholstyq:

- if you suffer from asthma or attacks of wheezing.
- if you suffer from glaucoma (increased pressure in the eye).
- if you have had a recent operation on the intestines (gut).
- if you suffer from increased body temperature (especially children), as Cholstyq may prevent you from sweating.
- if you have high or low blood pressure.

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- if you suffer from cardiac dysrhythmia (irregular heartbeats) or slow heart rate.
- if you suffer from heart failure or heart disease.
- if you suffer from myasthenia gravis (a condition of muscle weakness).
- if you have an enlarged prostate gland.
- if you suffer from obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus).
- if you have a stomach ulcer.
- if you have an overactive thyroid gland.
- if you are suffering from epilepsy or Parkinsonism (a disorder in the brain causing muscle stiffness and shaking).
- if you suffer from vagotonia (hyperexcitability of the vagus nerve that adversely affects the function of the blood vessels, stomach and muscles).
- if you suffer from kidney problems.

Other medicines and Cholstyq

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

Tell your doctor if you are taking/using, have recently taken/used, or might take/use any other medicines:

- suxamethonium, a muscle relaxant usually given during operations.
- medicines to treat depression (e.g. tricyclic antidepressants, monoamine oxidase inhibitors).
- medicines used to treat mental illness (e.g. clozapine).
- medicines used to relieve the pain (e.g. nefopam).
- amantadine which is used to treat Parkinson's disease or viral infections.

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- aminoglycosides (antibiotics used to treat infections, e.g. gentamycin, neomycin, streptomycin).
- clindamycin and colistin (antibiotics used to treat infections).
- inhalation anaesthetics before an operation (e.g. halogenated inhalation anaesthetics).
- beta-blocking medicines used to treat high blood pressure or to control your heartbeat (e.g. atenolol, bisoprolol, propranolol).
- quinidine (used for the treatment of irregular heartbeat).
- methylprednisone (a corticosteroid used to decrease your immune system's response to various diseases to reduce symptoms such as swelling, pain and allergic-type reactions).

Pregnancy, breastfeeding and fertility

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 being given Cholstyq.

Driving and using machines

This medicine may cause your eyesight to become weak and this could interfere with your ability to drive or operate machinery safely. Ask your doctor for advice before you drive or operate machinery.

Cholstyq contains sodium

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

If you have any further questions on the use of Cholstyq, ask your doctor or pharmacist.

3. How Cholstyq will be given

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

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

Your doctor will decide the correct dose for you depending on your circumstances. Your dose may be calculated according to your weight. The injection is usually given over a period of 10 to 30 seconds and may need to be repeated depending on your response.

Children:

Your doctor will administer a specific dose based on body weight.

If you are given more Cholstyq than you should

Since a health care provider will administer Cholstyq, he / she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

4. Possible side effects

Cholstyq can have side effects.

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

If any of the following happens, stop taking / using Cholstyq and tell your doctor immediately or go to the casualty department at your nearest hospital:

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- Swelling of the face, lips or throat which makes it difficult to swallow or breathe, rash, itching, hives and dizziness. This could be a sign of an angioedema or a severe allergic reaction.

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

The following side effects have also been reported but their frequency is not known:

- Slow heart rate (bradycardia)
- An awareness of strong, thumping heart beats (palpitation) or irregular heart beats
- Reduced secretion in the lung
- Difficulty in passing urine
- Sudden urge to urinate
- Difficulty in passing stools (constipation)
- Nausea (feeling sick), vomiting (being sick)
- Increased secretions of the stomach
- Stomach cramps
- Bloating feeling
- Eating disorder (anorexia)
- Loss of taste
- Dry mouth
- Excessive secretion of saliva
- Inhibition/decreased sweating
- Dryness of the skin
- Reddening of the skin (flushing)
- Confusion and/or excitement (especially in the elderly)
- Dizziness

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- Nervousness
- Drowsiness
- Weakness
- Muscle cramps or twitches
- Insomnia
- Headache
- Eye disorder (glaucoma)
- Increased pressure in the eyes
- Light sensitivity of the eyes
- Dilated pupils
- Blurred vision
- Impotence
- Reduced breastmilk production

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 “**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 Cholstyq.

5. How to store Cholstyq

Store at or below 30 °C.

Do not freeze.

Cholstyq has to be used immediately after first opening.

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For single use only.

Keep out of the sight and reach of children.

Do not use after the expiry date, which is stated on the carton and ampoule. The expiry date refers to the last day of that month.

Cholstyq should not be administered if noticed that the solution is not clear and free from particles.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Cholstyq contains

The active substances are glycopyrronium bromide and neostigmine metilsulfate.

Each glass ampoule contains 1 ml of solution, which contains the two active ingredients glycopyrronium bromide 0,5 mg/ml and neostigmine metilsulfate 2,5 mg/ml.

The other ingredients are citric acid, disodium phosphate dodecahydrate, sodium hydroxide and water for injections.

What Cholstyq looks like and contents of the pack

Cholstyq is a clear, colourless solution, practically free of visible particles. Cholstyq is presented in 2 ml (filled to 1 ml) Type I clear colourless glass ampoules. Ampoules are packed into outer cardboard cartons in pack sizes of 10.

Holder of Certificate of Registration

Umsebe Healthcare

506 Sunclare Building

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South Africa

Name of Manufacturer: Sintetica SA

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Access to the corresponding Professional Information

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