Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using GLYCONEO 0.5/2.5?

GLYCONEO 0.5/2.5 contains the active ingredients glycopyrronium bromide (glycopyrrolate) and neostigmine methylsulfate. GLYCONEO 0.5/2.5 is used at the end of an operation to reverse the effects of some of the medicines used during surgery such as anesthetics and muscle relaxants.

For more information, see Section 1. Why am I using GLYCONEO 0.5/2.5? in the full CMI.

2. What should I know before I use GLYCONEO 0.5/2.5?

Do not use if you have ever had an allergic reaction these ingredients; glycopyrronium bromide (glycopyrrolate), neostigmine methylsulfate, dibasic sodium phosphate dodecahydrate, citric acid and sodium hydroxide.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use GLYCONEO 0.5/2.5? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GLYCONEO 0.5/2.5 and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use GLYCONEO 0.5/2.5?

GLYCONEO 0.5/2.5 will be given to you by injection by a doctor or a specially trained nurse.

Your doctor will know how much GLYCONEO 0.5/2.5 you should be given. The need for more doses will depend on how well your body responds to the treatment. The doctor will decide how many injections you receive, and how often you should receive them

More instructions can be found in Section 4. How do I use GLYCONEO 0.5/2.5? in the full CMI.

5. What should I know while using GLYCONEO 0.5/2.5?

Things you should do	• Remind any doctor, dentist, pharmacist, or any healthcare professional you visit that you are using GLYCONEO 0.5/2.5.
Things you should not do	Do not participate in physical exercise or stay in a warm environment as it may reduce your ability to sweat and can therefore cause overheating.
Driving or using machines	• Ask your doctor for advice before you drive or operate machinery as GLYCONEO 0.5/2.5 may cause side effects such as drowsiness and blurred vision.
Drinking alcohol	• Tell your doctor if you will be drinking alcohol, as GLYCONEO 0.5/2.5 is known to cause drowsiness
Looking after your medicine	• GLYCONEO 0.5/2.5 should be stored in the pharmacy or on the ward in a cool dry place, protected from light where the temperature stays below 25°C

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

All medicines have side effects. If they do occur, they are usually minor and temporary.

Common and usually mid Side Effects: sweating or unable to sweat, feeling sick or vomiting, dry mouth or increased saliva or mucous production, dry and/or itchy skin and constipation, diarrhoea, fever and muscle weakness, muscle cramps or twitching. Serious Side Effects which require immediate medical attention are:

- rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- cold sweat, nausea, lightheadedness, discomfort in the chest or other areas of the upper body, e.g., pain or discomfort in one
 or both arms, the back, neck, jaw, or stomach.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Active ingredient(s): Glycopyrronium bromide (glycopyrrolate) - Neostigmine methylsulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using GLYCONEO 0.5/2.5. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GLYCONEO 0.5/2.5.

Where to find information in this leaflet:

1.Why am I using GLYCONEO 0.5/2.5?

2. What should I know before I use GLYCONEO 0.5/2.5?

3. What if I am taking other medicines?

4.How do I use GLYCONEO 0.5/2.5?

5. What should I know while using GLYCONEO 0.5/2.5?

6. Are there any side effects?

7.Product details

1. Why am I using GLYCONEO 0.5/2.5?

GLYCONEO 0.5/2.5 contains the active ingredient glycopyrronium bromide (glycopyrrolate) and neostigmine methylsulfate,

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

GLYCONEO 0.5/2.5 is used at the end of an operation to reverse the effects of some of the medicines used during surgery such as anesthetics and muscle relaxants.

2. What should I know before I use GLYCONEO 0.5/2.5?

Warnings

Do not use GLYCONEO 0.5/2.5 if:

- you are allergic to Glycopyrronium bromide (glycopyrrolate) - Neostigmine methylsulfate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- At the same time you are receiving suxamethonium, a muscle relaxant usually given during operations.
- If you have blockage of the intestines or urinary tract.

Check with your doctor if you:

Have/had any other medical conditions including:

- recent surgery involving the intestine or bladder
- other intestinal or bladder problems
- asthma
- glaucoma
- heart disease or other heart problems
- epilepsy

- low or high blood pressure
- Parkinson's disease
- stomach ulcer or bowel problems
- hiatus hernia
- kidney problems
- Addison's disease
- an overactive thyroid gland
- difficulty urinating, or enlarged prostate
- myasthenia gravis, a muscle weakness disorder
- nerve or brain disorder, brain damage, or Down's Syndrome.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed

Do not use GLYCONEO 0.5/2.5 if you are pregnant or intend to be pregnant.

The safety of the use of this medicine in women who are pregnant or may become pregnant has not been established. GLYCONEO 0.5/2.5 is not recommended for use during pregnancy unless you and your doctor have discussed the risks and benefits involved.

Do not breast-feed if you are using this medicine

The active ingredient in GLYCONEO 0.5/2.5 passes into breast milk and there is a possibility that your baby may be affected.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with GLYCONEO 0.5/2.5 and affect how it works.

Medicines that may interfere with GLYCONEO 0.5/2.5:

- corticosteroids
- antibiotics
- lithium
- chloroquine, hydroxychloroquine, quinine
- medicine for heart problems including betablockers
- medicines to treat depression (e.g., tricyclic antidepressants, MAOI's)
- medicines used to treat mental illness (e.g., clozapine)
- medicines used to relieve pain (e.g., nefopam)
- amantadine, which is used to treat Parkinson's disease or viral infections
- sugammadex or suxamethonium, muscle relaxants usually given during operations.

The above medicines may be affected by GLYCONEO 0.5/2.5 or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given GLYCONEO 0.5/2.5.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GLYCONEO 0.5/2.5.

4. How do I use GLYCONEO 0.5/2.5?

How much to take /use

Your doctor will know how much GLYCONEO 0.5/2.5 you should be given.

The need for more doses will depend on how well your body responds to the treatment. Your doctor will decide how many injections you need, and how often you should receive them.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

This depends on your condition and whether you are taking any other medicines. If you receive the wrong dose, GLYCONEO 0.5/2.5 may not work as well and your problem may not improve.

When to take / use GLYCONEO 0.5/2.5

GLYCONEO 0.5/2.5 is used at the end of an operation to reverse the effects of some of the medicines used during surgery such as anesthetics and muscle relaxants.

Ask your doctor if you have any questions about why it has been prescribed for you.

GLYCONEO 0.5/2.5 is only available with a doctor's prescription

How the GLYCONEO 0.5/2.5 is given

GLYCONEO 0.5/2.5 will be given to you by injection by a doctor or a specially trained nurse

If you use too much GLYCONEO 0.5/2.5

As GLYCONEO 0.5/2.5 is given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, symptoms of an overdose may include nausea, vomiting, muscle cramps, sweating, increased saliva and changes in heart rate.

You should immediately:

Tell you doctor or nurse if you think that you or anyone else may have been given too much GLYCONEO 0.5/2.5. They have information on how to recognise and treat an overdose.

5. What should I know while using GLYCONEO 0.5/2.5?

Things you should do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using GLYCONEO 0.5/2.5. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are being given this medicine.

Call your doctor straight away if you notice any of the following:

- rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- cold sweat, nausea, lightheadedness, discomfort in the chest or other areas of the upper body, e.g. pain or discomfort in one or both arms, the back, neck, jaw or stomach.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some patients.

Remind any doctor, dentist or pharmacist or other medical personnel you visit that you are using GLYCONEO 0.5/2.5.

Things you should not do

Elderly:

Be careful if you are elderly or unwell.

Some people may experience side effects such as drowsiness, or blurred vision, which may increase the risk of a fall

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GLYCONEO 0.5/2.5 affects you.

GLYCONEO 0.5/2.5 may cause dizziness and blurred vision in some people. It is best to ask your doctor before driving or handling heavy machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

GLYCONEO 0.5/2.5 will be stored in the pharmacy or on the ward under the recommended storage conditions. It must be kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Keep it where young children cannot reach it.

When to discard your medicine

Any GLYCONEO 0.5/2.5 which has passed its expiry date, if the packaging is torn or shows signs of tampering. If the solution is not clear before use or is left in the container after

use, will be disposed of in a safe manner by your doctor, nurse, or pharmacist.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Less serious side effects fast, slow or irregular heartbeat high blood pressure flushing sweating or unable to sweat feeling sick or vomiting dry mouth or increased saliva or mucous production dry and/or itchy skin constipation, diarrhoea difficulty urinating or involuntary urination or defecation impotence reduced milk supply in breastfeeding women blurred vision or other problems with your eyesight headache nervousness, drowsiness or restlessness dizziness, faintness or weakness unable to sleep, sleep disorder over-excitement in children confusion, especially in elderly people fever feeling bloated or stomach cramps	Speak to your doctor if you have any of these side effects and they worry you.
 loss or alteration of taste muscle weakness, muscle cramps or twitching increased secretion of tears from the eyes slurred speech inability to smile, swallow, speak, cough, track objects with eyes inability to perform a deep breath chest discomfort facial weakness, facial numbness. 	
Rare side effects	
• injection site reactions like itchy skin, swelling, pain	

Serious side effects

Serious side effects	What to do
 rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing cold sweat, nausea, lightheadedness, discomfort in the chest or other areas of the upper body, e.g., pain or discomfort in one or both arms, the back, neck, jaw or stomach. 	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side affects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What GLYCONEO 0.5/2.5 contains

Active ingredient (main ingredient)	glycopyrronium bromide (glycopyrrolate) neostigmine methylsulfate.
Other ingredients (Inactive ingredients)	dibasic sodium phosphate dodecahydrate citric acid sodium hydroxide water for injections.

GLYCONEO 0.5/2.5 does not contain lactose, sucrose, tartrazine or any other azo dyes. Preservative and sulfite free.

Do not take this medicine if you are allergic to any of these ingredients.

What GLYCONEO 0.5/2.5 looks like

GLYCONEO 0.5/2.5 is solution for injection supplied in1mL Ampoule (Aust R 370931).

Who distributes GLYCONEO 0.5/2.5

KSJ Pharmatech C/O Inter Pharma Ply Ltd

Suite 103/39, East Esplanade, Manly, NSW, 2095

Ph: 02 9976 6876

www: interpharma.com.au

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