Glycopyrronium-AFT

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 Glycopyrronium-AFT?

Glycopyrronium-AFT contains the active ingredient glycopyrronium bromide. Glycopyrronium-AFT is used before surgery to decrease the volume of secretions from your mouth, lungs and stomach. It can also be used either before or during surgery to maintain your heart's normal beating rhythm. Glycopyrronium-AFT is also used to counter the effects of some other medicines, which can slow your heartbeat or produce excessive secretions when used during surgery.

.For more information, see Section 1. Why am I using Glycopyrronium-AFT? in the full CMI.

2. What should I know before I use Glycopyrronium-AFT?

Do not use if you have ever had an allergic reaction to glycopyrronium bromide or any of the ingredients listed at the end of the CMI.

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 Glycopyrronium-AFT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Glycopyrronium-AFT 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 Glycopyrronium-AFT?

Glycopyrronium-AFT injection will be given to you by a doctor or specially trained nurse.

More instructions can be found in Section 4. How do I use Glycopyrronium-AFT? in the full CMI.

5. What should I know while using Glycopyrronium-AFT?

Things you should do	Remind any doctor, dentist or pharmacist and any other health professionals you visit that you have been given Glycopyrronium-AFT	
Things you should not do	 Do not participate in physical exercise and take care in warm environments, as Glycopyrronium-AFT may reduce your ability to sweat which may result in overheating. 	
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Glycopyrronium-AFT affects you. Glycopyrronium-AFT may cause drowsiness or dizziness or blurred vision in some people and therefore may affect alertness. 	
Looking after your medicine	 Glycopyrronium-AFT will be stored in the hospital pharmacy or in the ward. It will be kept in original packaging below 25 °C. 	

For more information, see Section 5. What should I know while using Glycopyrronium-AFT? in the full CMI.

6. Are there any side effects?

Some common side effects include dry mouth, drowsiness, visual disturbance and fast, slow or irregular heartbeat. Serious side effects which require immediate medical attention include: cold sweat, nausea, light headedness, discomfort in chest or other areas of the upper body like pain or discomfort in one or both arms, the back, neck, jaw or stomach. Swelling mainly of the face, lips or tongue or other parts of the body, itching and rashes, could be signs of a severe allergic reaction.

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.

Glycopyrronium-AFT

Active ingredient(s): Glycopyrronium bromide (Glycopyrrolate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Glycopyrronium-AFT. 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 Glycopyrronium-AFT.

Where to find information in this leaflet:

- 1. Why am I using Glycopyrronium-AFT?
- 2. What should I know before I use Glycopyrronium-AFT?
- 3. What if I am taking other medicines?
- 4. How do I use Glycopyrronium-AFT?
- 5. What should I know while using Glycopyrronium-AFT?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Glycopyrronium-AFT?

Glycopyrronium-AFT contains the active ingredient glycopyrronium bromide. Glycopyrronium-AFT belongs to a group of medicines called anticholinergic drugs. It works in the nervous system by blocking an enzyme, which is responsible for producing saliva in your mouth and secretions in your stomach and lungs. This enzyme also slows down the heart rate. When this enzyme is blocked secretions dry up and the heart rate increases.

Glycopyrronium-AFT is used before surgery to decrease the volume of secretions from your mouth, lungs and stomach.

It can also be used either before or during surgery to maintain your heart's normal beating rhythm.

Glycopyrronium-AFT is also used to counter the effects of some other medicines, which can slow your heartbeat or produce excessive secretions when used during surgery.

2. What should i know before I use Glycopyrronium-AFT?

Warnings

Do not use Glycopyrronium-AFT if:

- you are allergic to glycopyrronium bromide, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.
- Always check the ingredients to make sure you can use this medicine.

You are breastfeeding or plan to breastfeed.
 Medicines like Glycopyrronium-AFT may reduce your milk supply. It is not known if Glycopyrronium-AFT is found in breast milk.

Check with your doctor if you:

- have any other medical conditions such as:
 - asthma
 - glaucoma, which is an increased pressure in your eves
 - diarrhoea
 - problems with your heart, kidney or thyroid
 - difficulty urinating, or enlarged prostate
 - stomach or bowel problems
 - hiatus hernia that causes heartburn and belching
 - high blood pressure
 - myasthenia gravis, a muscle weakness disorder
 - nerve or brain disorder, brain damage, or Down's Syndrome
- take any medicines for any other condition.
- are allergic to any other medicines, latex rubber or any other substances, such as foods, preservatives or dyes

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 6. 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.

Your doctor will discuss the risks and benefits of receiving Glycopyrronium-AFT during pregnancy

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 Glycopyrronium-AFT. These include:

- ritodrine hydrochloride
- medicines for Parkinson's disease
- phenothiazines, which are used to treat mental illness or severe nausea and vomiting
- antidepressants
- antihistamines
- narcotic pain killers such as pethidine

- medicines used to control heart rhythm
- digoxin used to treat heart failure
- thioxanthenes
- butyrophenones
- amantadine.

These medicines may be affected by Glycopyrronium-AFT or may effect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Glycopyrronium-AFT.

4. How do I use Glycopyrronium-AFT?

How much is given

A doctor or specially trained nurse gives Glycopyrronium-AFT Injection to you.

Your doctor will know how much Glycopyrronium-AFT you should be given. The dose of Glycopyrronium-AFT may be different for each person, and depends on your condition, age and body weight.

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.

How it is given

Glycopyrronium-AFT injection will be given to you by a doctor or specially trained nurse. The injection is usually given into a muscle or a vein.

If you use too much Glycopyrronium-AFT

This medicine will be given to you in hospital so it is unlikely you will receive too much.

If you think that you have been given too much Glycopyrronium-AFT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Glycopyrronium-AFT?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you have had Glycopyrronium-AFT Injection.

Tell your doctor if you feel Glycopyrronium-AFT Injection is not helping your condition.

Always discuss with your doctor any problems or difficulties during or after having Glycopyrronium-AFT Injection.

Be careful if you are elderly, unwell or taking other medicines. Some people may experience side effects such as drowsiness, or blurred vision, which may increase the risk of a fall.

Things you should not do

Do not participate in physical exercise and take care in warm environments, as Glycopyrronium-AFT may reduce your ability to sweat which may result in overheating.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Glycopyrronium-AFT affects you.

Glycopyrronium-AFT may cause drowsiness or dizziness or blurred vision in some people and therefore may affect alertness.

Make sure you know how you react to Glycopyrronium-AFT injection before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Drinking Alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Glycopyrronium-AFT will be stored in the hospital pharmacy or in the ward. It will be kept in original packaging below 25 °C, protected from light.

Keep it where young children cannot reach it.

When to discard your medicine

Any Glycopyrronium-AFT injection 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
Heart-r	elated Fast, slow or irregular heart beats	Speak to your doctor if you have any of these less serious side
Skin-re	lated Dry and/or itchy skin	effects and they worry you.
Gastroi • •	intestinal-rated Constipation Feeling bloated Feeling sick or vomiting	
Eye, ea • •	r, mouth-related Blurred vision or other problems with your eyesight Dry mouth Loss or alteration of taste.	
Mood-relatedOver-excitement in childrenNervousness		
•	Itchy skin Swelling Pain	
Genito	urinary-related	
•	Difficulty urinating Impotence	
Neurole	Neurological-related	
•	Headache Drowsiness Dizziness Confusion, especially in elderly people	

Body as a whole

- Flushing
- Unable to sweat
- Reduced milk supply in breastfeeding women
- Unable to sleep
- Fever

Serious side effects

Serious side effects	What to do
Allergy-related 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 Body as a whole Cold sweat Nausea, light headedness Discomfort in chest or other areas of the upper body like pain	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.
or discomfort in one or both arms, the back, neck, jaw or stomach	

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 effects 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 Glycopyrronium-AFT contains

Active ingredient	Glycopyrronium bromide
(main ingredient)	
Other ingredients	Sodium chloride
(inactive ingredients)	Hydrochloric acid
	Water for injection

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

What Glycopyrronium-AFT looks like

Glycopyrronium-AFT Injection comes in a glass 1 mL ampoule containing a clear, colourless solution. Available in packs of 5 and 10 single dose ampoules (Aust R 390250).

Who distributes Glycopyrronium-AFT

AFT Pharmaceuticals Pty Ltd. 113 Wicks Road, North Ryde, NSW 2113, Australia

Email: customer.service@aftpharm.com

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