

Glenmark Airz F

Glycopyrronium 12.5mcg and Formoterol Fumarate 12mcg Powder for Inhalation

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What Glenmark Airz F is used for

Glenmark Airz F is used for maintenance treatment of *Chronic Obstructive Pulmonary Disease* (COPD). COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. Glenmark Airz F is for long-term use and should be taken 2 times each day to improve symptoms of COPD for better breathing.

How Glenmark Airz F works

Anticholinergic medicines such as Glycopyrronium help the muscles around the airways in your lungs stay relaxed to prevent symptoms such as wheezing, coughing, chest tightness, and shortness of breath.

Formoterol fumarate dihydrate makes breathing easier by relaxing muscle spasms in the air passages of the lungs. It is also used to treat breathing problems in patients with COPD.

Before you use Glenmark Airz F

- When you must not use it

Do not use Glenmark Airz F

- if you are allergic (hypersensitive) to Glycopyrronium or Formoterol Fumarate or any of the other ingredients of this medicine.
- to treat sudden symptoms of COPD
- In children

Talk to your doctor if this applies to you.

- Before you start to use it

Before you take Glenmark Airz F, make sure the prescribing doctor knows

- Have kidney problems.
- Have eye problems such as glaucoma.
- Have prostate or bladder problems, or problems passing urine.
- Have any other medical conditions.
- suffer from any heart problems
- have high blood pressure
- have seizures
- have an overactive thyroid gland
- are diabetes

- have an aneurysm (area where an artery is swollen because the wall of the artery is weak)
- have a pheochromocytoma (a tumor of the adrenal gland that can affect your blood pressure)
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Are allergic to medicine or any of its ingredients, any other medicines, or food products.

- Use in Pregnancy and Lactation

Glenmark Airz F is not recommended for use during pregnancy unless there is no more established alternative. As with any medicine, use during pregnancy should only be considered if the expected benefit to the mother is greater than any risk to the foetus.

Women should be advised to contact their physician if they become pregnant while taking Glenmark Airz F. It is not known if Glenmark Airz F can harm your unborn baby.

It is not known whether Glenmark Airz F is excreted in human milk, but because many drugs are excreted in human milk, caution should be exercised if formoterol fumarate is administered to nursing women. Please discuss with doctor before use.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, or have recently taken any. This includes medicines obtained without a prescription / vitamins or herbal supplements.

Know the medicines you take. Keep a list of your medicines to discuss with your doctor or pharmacist.

The following medicines are particularly important:

- Medicines for heart conditions including irregular heart beats, angina and heart failure

- Medicines for high blood pressure
- Beta blockers (either as tablets or eye drops)
- Water tablets (diuretics)
- Medicines for depression, for example, monoamine oxidase inhibitors (MAOIs) or tricyclics
- Anti-histamines or cold remedies.
- Medicines called 'steroids'.
- Sympathomimetic agents, which are adrenaline-like medicines used to treat asthma and nasal congestion
- Phenothiazines, which are a group of medicines which control mental disorders such as schizophrenia, mania, psychotic conditions and

anxiety

- Xanthines, for example theophylline or aminophylline, which are a class of medicines

used to treat asthma and chronic obstructive airways diseases

- Macrolides (for example Erythromycin) used to treat bacterial infections

- Anaesthetics like Halogenated hydrocarbons (for example Halothane).

- Anticholinergic drugs (for example Ipratropium bromide) used to treat gastrointestinal disorders and genitourinary disorders

- Driving and using machines

In some patients, Glenmark Airz F has been reported to cause dizziness. If you feel dizzy, do not drive or operate machinery.

How to use Glenmark Airz F

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use, When to use it & How long to use it

The recommended dose is the inhalation of the content of one capsule twice daily using the inhaler.

Note: Use only as directed by a physician.

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not use Glenmark Airz F unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.

Do not swallow capsules. Only use capsules with the inhaler.

Use 1 capsule inhaled through the inhaler 2 times each day (1 capsule in the morning and 1 capsule in the evening).

To make sure the full dose has been taken, you should open the inhaler to check that there is no powder left in the capsule. As long as the capsule is empty, you have received 1 full dose.

- If you forget to use it

If you miss a dose of Glenmark Airz F, take it as soon as you remember. Take your next dose at your usual time.

Do not use 2 capsules at 1 time.

Do not use more than 2 capsules in a day

- If you use too much (overdose)

Talk to your doctor if you take too much Glenmark Airz F. Take the medicine pack with you.

- If you stop taking it

Only your doctor can decide when your treatment should be discontinued. Never stop the treatment yourself.

While you are using it

- Things you must do

If you have any questions on the use of this medicine, ask your doctor, pharmacist.

- Things you must not do

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

Read this Patient before you start using Glenmark Airz F and each time you get a refill. If you get any side effects, discuss with your doctor or pharmacist.

Side effects

Like all other medicines, this medicine may cause side effects although it may not affect everyone.

Glycopyrronium may cause serious side effects, including:

- **Sudden shortness of breath** immediately after use of Glycopyrronium. Sudden shortness of breath may be life-threatening. If you have sudden breathing problems immediately after inhaling your medicine, stop taking Glycopyrronium and go to the nearest hospital emergency room right away.
- **Serious allergic reactions.** Stop using Glycopyrronium and call your healthcare provider or get emergency medical care right away if you get any of the following symptoms of a serious allergic reaction: Rash, hives, swelling of the tongue, lips, and face, difficulty breathing or swallowing
- **New or worsened eye problems** including acute narrow-angle glaucoma. Acute narrow-angle glaucoma can cause permanent loss of vision if not treated. Symptoms of acute narrow-angle glaucoma may include: eye pain or discomfort, nausea or vomiting, blurred vision, seeing halos or bright colors around lights, red eyes. If you have these symptoms, stop taking Glycopyrronium and call your healthcare provider right away

before using another dose.

• **New or worsened urinary retention.** People who use Glycopyrronium may develop new or worse urinary retention. Urinary retention can be caused by a blockage in your bladder. Urinary retention can also happen in men who have a larger than normal prostate.

Symptoms of urinary retention may include: difficulty urinating, painful urination, urinating frequently, urination in a weak stream or drips. If you have these symptoms, stop taking Glycopyrronium and call your healthcare provider right away before taking another dose.

Common side effects of Glycopyrronium include upper respiratory tract infection, sore throat and runny nose.

Formoterol may cause serious side effects, including:

- Some side effects can be serious. Stop using formoterol and tell your doctor straight away if you notice: Bronchospasm with wheezing or coughing and difficulty in breathing. This may affect up to 1 in 100 people
- An allergic reaction such as if you feel faint (you might have low blood pressure), have a rash, or experience itching or facial swelling. This may affect up to 1 in 1,000 people
- If you feel you have muscle weakness, muscle spasms or an abnormal heart rhythm (these could mean you have a low blood potassium level). This may affect up to 1 in 1,000 people
- If you feel you have an irregular heart beat or a fast heart-beat. This may affect up to 1 in 1,000 people
- If you feel a crushing chest pain (symptoms of angina pectoris). This may affect up to 1 in 10,000 people.

The side effects listed below have also been reported.

Common (may affect up to 1 in 10 people)

Headache, tremor, palpitations.

Uncommon (may affect up to 1 in 100 people)

Agitation, anxiety, feeling nervous, difficulties with sleeping, dizziness, fast heartbeat, throat irritation, dry mouth, muscle cramps, muscle pain, worsening of asthma.

Rare (may affect up to 1 in 1,000 people)

Nausea.

Very rare side effects (may affect up to 1 in 10,000 people)

Distorted sense of taste, swelling of hands, ankles or feet, variations in blood pressure.

Excessive thirst, frequent urination and tiredness over an extended period of time (a possible indication of high blood sugar).

Not known (frequency cannot be estimated from the available data)

Headache and dizziness (symptoms of high blood pressure), cough and rash.

Some of these effects may wear off as you get used to the medicine.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can provide more information on the safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Glenmark Airz F

- Storage

Store below 30°C. Store the capsules in original package & do not remove until immediately before use.

- Disposal

Do not use this medicine after the expiry date which is stated on the carton. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Size #3 capsule with opaque light orange colored cap with "G" logo and clear transparent body, filled with white powder.

- Pack size(s)

A carton containing a device, a leaflet and Blister pack of 3 × 10's capsules.

- Ingredients

- Active ingredient(s)

Glycopyrronium, Formoterol Fumarate

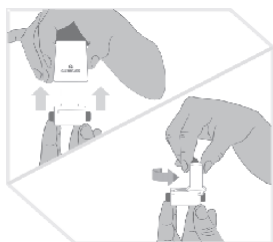
- Inactive ingredients

Lactose Monohydrate & hydroxypropyl methylcellulose capsules.

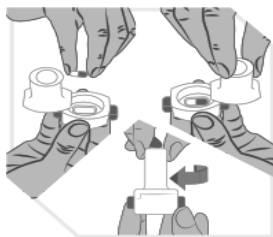
Instructions for Use
Glycopyrronium + Formoterol
fumarate Powder for Inhalation

How to use your inhaler:

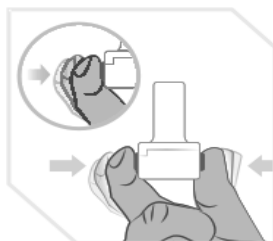
1. Remove the protection cover from Instahaler –P. Hold the base firmly and mouth piece in the direction given on the device.



2. Insertion: Insert the capsule into the chamber. Place the capsule properly into the slot as shown. Rotate the mouth piece back in position to close the device.



3. Puncture the capsule – Hold the lever between your thumb and index finger. Puncture the capsule firmly. In order to evenly puncture the capsule, make sure that you push both the buttons inwards, simultaneously.



4. Turn your head to the side and breathe out (exhale) as much air as you can – Your lungs should be as empty as possible right before you breathe in your medicine.

5. Put your mouth on the instahaler-P mouthpiece – Grip the mouthpiece between your teeth and close your lips firmly around the instahaler –P, so that no air or medicine can escape out. Tilt your head upwards.



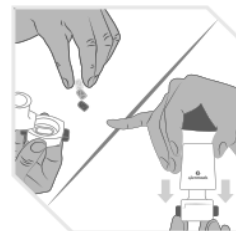
6. Using only your mouth, breathe in deep and fast. Continue breathing in, until your lungs are completely full of air. Instahaler-P is “breath-activated”. This means that breathing in fast and deep makes the right dose of medicine come out of the Instahaler-P. Then the medicine goes directly into your lungs.



7. Take your mouth off the Instahaler-P mouthpiece and hold your breath for 10 seconds or as long as possible. This will hold the medicine inside your airways and lungs and help you breathe easier. Slowly breathe out through your nose. Check that the capsule is empty and the total dose is consumed. If any dose remains in the capsule, repeat steps until you have taken the number of doses, as prescribed by your physician. Ensure that you give an interval of 1 min between two doses.



8. Remove the empty capsule and put the protective cover back. This helps to keep dirt and moisture (wetness) out of the Instahaler–P. Store in safe and dry place. Moisture or dirt may cause Instahaler-P to clog up or stop working correctly.



9. After taking the dose, rinse your mouth and brush your teeth.



Cleaning:

Clean your Instahaler-P with a brush or wipe with a clean, dry, lint-free cloth to remove any powder residue. While cleaning the capsule chamber, make sure you push the buttons inwards to ensure complete cleaning. Do not use water for cleaning.

- Product registration number:-

MAL23096007AZ

Manufacturer

Glenmark Pharmaceuticals Ltd
Village Kishanpura,
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Tehsil Baddi , Distt. Solan , (H.P)
– 173205, India

Product Registration Holder

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21.09.2023

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