SCHEDULING STATUS: [S2]

GLENBUTE (Pressurised Metered Dose Inhaler)

Salbutamol sulphate

Read all of this leaflet carefully because it contains important information for you:

GLENBUTE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **GLENBUTE** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **GLENBUTE** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What GLENBUTE is and what it is used for

GLENBUTE contains a medicine called salbutamol which belongs to a group of medicines called fast acting bronchodilators. Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out. They help to relieve chest tightness, wheezing and cough.

GLENBUTE is used to treat breathing problems in people with asthma and similar conditions. This includes relieving and preventing asthma brought on by exercise or other "triggers". Common triggers include house dust, pollen, cats, dogs and cigarette smoke.

2. What you need to know before you use GLENBUTE

Do not use **GLENBUTE**:

- If you are allergic to salbutamol sulphate or any of the other ingredients of this medicine (*listed in section 6*)
- If you unexpectedly go into early labour (premature labour)
- If you have a threatened abortion.

Warnings and precautions

Special care should be taken with **GLENBUTE**:

- If you suffer from a condition called hyperthyroidism where you have an excess of thyroid hormone in your body.
- If you suffer from a heart condition such as narrowed arteries, chest pain, fast heart rate, irregular heartbeats and high blood pressure.
- If you have received any other medicines which also act on the sympathetic nervous system such as salmeterol, epinephrine, dobutamine, dopamine and phenylephrine. Ask your doctor or pharmacist if you are not certain.
- If you are taking the class of medicines known as beta-blockers which are typically used for high blood pressure. Ask your doctor or pharmacist if you are not certain.
- If your asthma gets worse, as you may need another treatment. If you do not feel any relief with **GLENBUTE** for at least 3 hours, you should speak to your doctor as you will need additional treatment.
- If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking **GLENBUTE**.

Other medicines and GLENBUTE

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

- If you will be undergoing anaesthesia you should inform your doctor that you are using **GLENBUTE** as it may affect your heart.
- If you are taking any antidepressant medicines, or heart medicines you should inform your doctor or pharmacist before using **GLENBUTE** as you may be at an increased risk for irregular heartbeats.
- If you are taking antidepressants in the class of mono-amine oxidase inhibitors you should not be using **GLENBUTE**, and you should not use **GLENBUTE** for 14 days after you stop the antidepressant. Talk to your doctor or pharmacist if you are unsure of what type of antidepressant you are taking.
- You should not use **GLENBUTE** if you are already taking a heart medicine which falls in the class of non-selective beta-blockers such as propranolol and carvedilol. Talk to your doctor or pharmacist if you are unsure.

Pregnancy and breastfeeding

The safety during pregnancy and 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 using this medicine.

Driving and using machines

GLENBUTE may cause hand tremors, headaches, fatigue, dizziness and confusion. You should therefore be cautious when driving or operating heavy machinery unless you know the effect that **GLENBUTE** has on you.

It is not always possible to predict to what extent **GLENBUTE** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware

of the measure to which **GLENBUTE** affects them.

3. How to use GLENBUTE

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

Always use **GLENBUTE** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

FOR ORAL INHALATION ONLY.

The usual dose is one or two inhalations every 4 hours if required. The effect of **GLENBUTE** lasts for 4 hours, however if you feel that it does not work as long for you, you should inform your doctor.

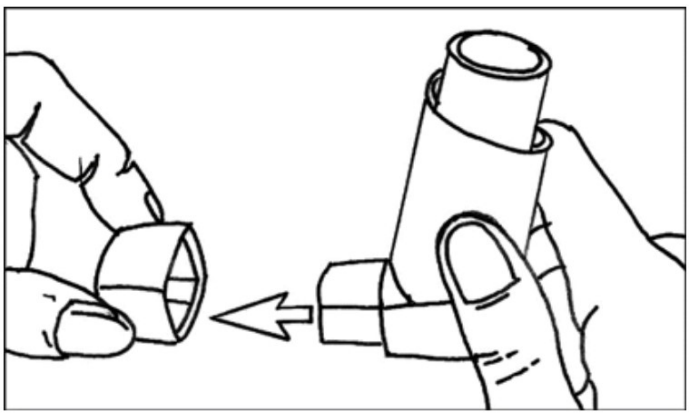
You may also use **GLENBUTE** before exercising to avoid having an asthma attack caused by exercising.

If you are unsure about how to use the device, you should ask your doctor or pharmacist to ensure that the right amount of medicine is getting delivered to your lungs.

Instructions to Use Inhaler

Testing your inhaler

1. When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.



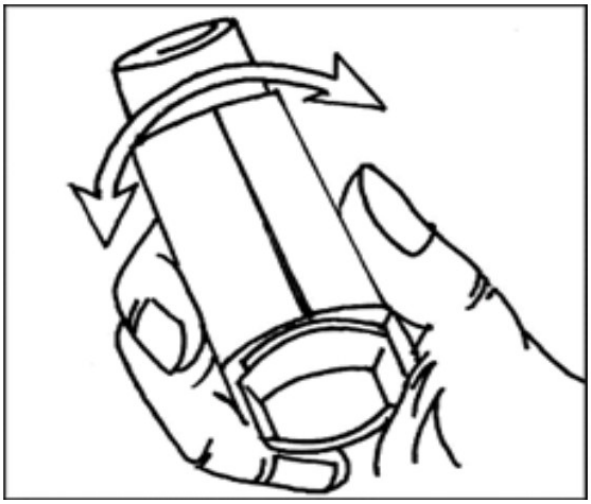
2. To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release two puffs into the air. If you have not used the inhaler for 5 days or more, shake it well and release two puffs of medicine into the air.

Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1. Stand or sit upright when using your inhaler.

2. Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.



3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.

4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.



5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



6. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.



7. Hold your breath; take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.



8. If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

9. After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Practice in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practice the technique together.

Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. Your doctor, nurse or pharmacist will be able to advise you.

Cleaning your inhaler

To stop your inhaler blocking, it is important to clean it at least once a week.

- Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
- Rinse the plastic casing thoroughly under warm running water.

- Dry the plastic casing thoroughly inside and out.
- Replace the metal canister into the plastic casing and put on mouthpiece cover.
- Do not put the metal canister in water.
- Actuate one spray in air after cleaning.

If you use more GLENBUTE than you should

If you use more than you should, talk to a doctor as soon as possible.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky
- hyperactivity
- hallucinations
- irritability

4. Possible side effects

GLENBUTE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

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

Talk to your doctor as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while you may feel your heartbeat is uneven or it gives an extra beat.
- your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.
- you experience chest pain due to heart problems such as angina.

If this happens to you, talk to your doctor as soon as possible. Do not stop using this medicine unless told to do so.

Tell your doctor if you have any of the following side effects which may also happen with this medicine:

Frequent side-effects:

- feeling shaky
- headache

Less frequent side-effects:

- mouth and throat irritation
- muscle cramps
- increased blood flow to your extremities (peripheral dilatation).
- changes in sleep patterns and changes in behaviour, such as restlessness and excitability

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 or 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 **GLENBUTE**.

5. How to store GLENBUTE

Store at or below 25 °C.

The canister should not be broken, punctured or burnt, even when apparently empty.

Replace the mouthpiece cover firmly and snap it into position.

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 GLENBUTE contains

- The active ingredient is salbutamol sulphate.
- The other ingredient is HFA 134a (Norflurane (1,1,1,2- Tetrafluoroethane)) which is used as the propellant.

What GLENBUTE looks like and contents of the pack

19 mL plain base non anodised aerosol canister crimped with 61 mcL metered valve and fitted with an actuator having white colour body and green colour dust cap suitable for oral inhalation.

Pack of one inhaler device (actuator with canister) is packed in a carton along with an information leaflet.

Holder of Certificate of Registration

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