
Patient Information Leaflet

SCHEDULING STATUS: [S4]

TIZAGLENN CO 12 µg/ 250 µg (Powder for inhalation)

Formoterol fumarate and fluticasone propionate

Read all of this leaflet carefully before you use TIZAGLENN CO:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **TIZAGLENN CO** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What TIZAGLENN CO is and what it is used for

TIZAGLENN CO (a powder for inhalation (in capsule)) contains two active ingredients:

- Fluticasone propionate which belongs to a group of medicines called steroids. Steroids help to reduce swelling and inflammation in the lungs.
- Formoterol fumarate which belongs to a group of medicines called long-acting beta2 agonists. Long-acting beta2 agonists are long-acting bronchodilators which help the airways in your lungs to stay open, making it easier for you to breathe.

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Together these two medicines help to improve your breathing and to prevent breathing problems if you suffer from asthma.

2. What you need to know before you take TIZAGLENN CO

Do not take TIZAGLENN CO:

If you are hypersensitive (allergic) or have had a previous allergic reaction to the active ingredients formoterol or fluticasone or to any of the other ingredients of **TIZAGLENN CO** (listed in *section 6*).

Do not swallow capsules as the intended effects on the lungs will not be obtained, capsules should only be used with the inhaler device.

Warnings and precautions

TIZAGLENN CO is not for the treatment of an acute attack of asthma. You should have appropriate inhalation medication available to treat worsening asthma.

You should also tell your doctor, pharmacist or nurse before using **TIZAGLENN CO** if you have:

- tuberculosis (TB) now or in the past. Symptoms include a persistent cough often with blood streaked phlegm, fever, tiredness, loss of appetite, loss of weight and night sweats;
- an infection of the lungs or chest;
- heart problems such as problems with the blood flow to your heart or narrowing of one of your heart valves (the aortic valve), heart failure which can cause shortness of breath or ankle swelling, a condition where the heart muscle is enlarged (hypertrophic obstructive cardiomyopathy), an irregular heart beat (cardiac arrhythmias) or if you have been told that your heart trace is abnormal (prolongation of the QTc interval);
- an abnormal bulging of a blood vessel wall (an aneurysm);
- diabetes;
- high blood pressure;

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- an overactive thyroid gland which can cause increased appetite, weight loss or sweating (thyrotoxicosis);
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm (hypokalaemia);
- poor adrenal gland function (if your adrenal gland is not working properly you may have symptoms such as headaches, weakness, tiredness, abdominal pain, loss of appetite, weight loss, dizziness, very low blood pressure, diarrhoea, feeling or being sick, or fits) or a tumour of the adrenal gland (phaeochromocytoma);
- liver problems.

If you notice that the medicines that you have been taking for your asthma are no longer working as effectively or if you need to take it more often or at higher doses to be effective, you should contact your doctor as soon as possible as your treatment may need to be changed.

You should not stop your treatment with **TIZAGLENN CO** abruptly.

You may experience an immediate increase in wheezing and shortness of breath after using **TIZAGLENN CO**. If this happens you will need to use your 'reliever' medicines and speak to your doctor immediately..

You may experience blurred vision or visual disturbances. If this happens you should speak to your doctor.

Other medicines and TIZAGLENN CO

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor if you are taking any medicine such as:

- medicines known as beta blockers (such as atenolol to treat high blood pressure, sotalol to

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treat an irregular heart beat, metoprolol to treat a fast heart beat or timolol eye drops to treat glaucoma);

- certain other medicines used to treat asthma or breathing conditions (such as theophylline or aminophylline);
- medicines containing adrenaline or related substances (including other beta agonists like salbutamol or beta antagonists including atenolol, metoprolol, propranolol, timolol). Additional long-acting beta2 agonists should not be used together with this inhaler.
- medicines to treat allergic reactions (antihistamines);
- medicines to treat high blood pressure or fluid build up by increasing the amount of urine produced (diuretics);
- medicines used to treat heart failure (such as digoxin);
- medicines to treat abnormal heart rhythms (such as quinidine, disopyramide, procainamide);
- medicines to treat symptoms of depression or mental disorders such as monoamine oxidase inhibitors (for example phenelzine and isocarboxazid), tricyclic antidepressants (for example amitriptyline and imipramine), or you have taken any of these types of medicine in the last two weeks;
- medicines used to treat psychiatric or mental disorders (phenothiazines or antipsychotics);
- other medicines containing steroids;
- antifungal medicines (such as ketaconazole or itraconazole);
- some medicines may increase the effects of **TIZAGLENN CO** and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, atazanavir, indinavir, nelfinavir, saquinavir or cobicistat);
- antibiotics (such as clarithromycin, telithromycin or furazolidone);
- medicine to treat Parkinson's disease (levodopa);
- medicine to treat an underactive thyroid gland (levothyroxine);
- medicine to treat Hodgkin's disease (procarbazine);

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- medicine to induce labour (oxytocin).

If you are going to have an operation under a general anaesthetic, please tell the doctor at the hospital that you are using **TIZAGLENN CO**.

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

Pregnancy, breastfeeding and fertility

You should not use **TIZAGLENN CO** if you are pregnant. If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor before you use **TIZAGLENN CO**. If you get pregnant during your treatment, you must immediately inform your doctor.

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 healthcare provider for advice before using **TIZAGLENN CO**.

Driving and using machines

TIZAGLENN CO is unlikely to produce an effect, as it has no or negligible influence on the ability to drive and use machines.

It is not always possible to predict to what extent **TIZAGLENN CO** 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 **TIZAGLENN CO** affects them.

TIZAGLENN CO contains lactose:

TIZAGLENN CO contains approximately 24,74 mg of lactose monohydrate per capsule.

The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

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3. How to take TIZAGLENN CO

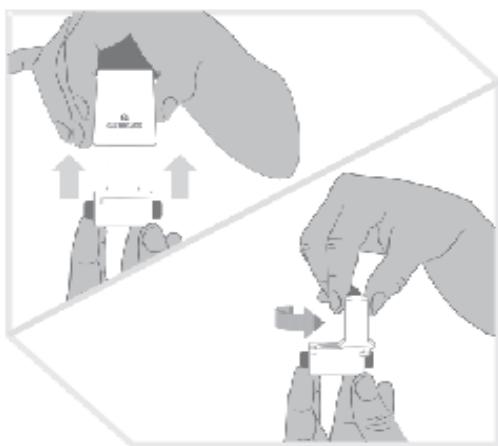
TIZAGLENN CO is for inhalation use only. You will need to use one **TIZAGLENN CO** capsule twice a day as directed by your doctor.

If your asthma or breathing gets worse tell your doctor straight away. You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. See your doctor as soon as possible as you may need additional treatment.

The inhaler is breath-triggered (or breath-actuated) which means that it will release these two active ingredients when you breath in through the mouthpiece.

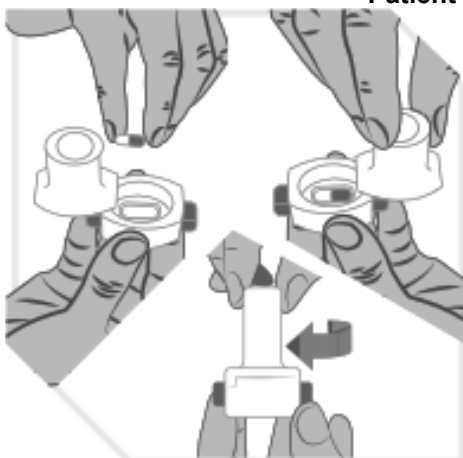
Instructions for use

1. Remove the protective cover from device. Hold the base firmly and turn the mouthpiece in the direction given on the device.

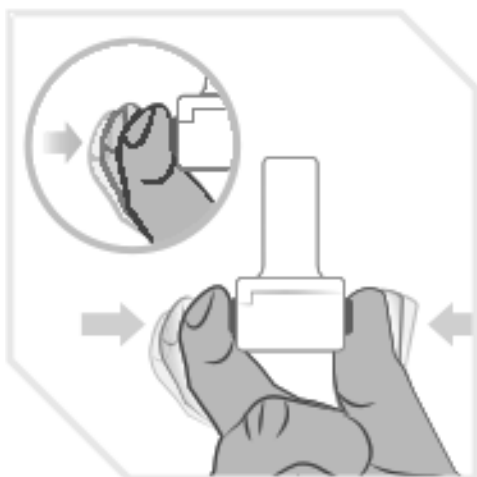


2. Insert the capsule into the slot in the chamber. Rotate the mouthpiece back in position to close the device.

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



4. Breathe out (exhale) as much air as you can – Your lungs should be as empty as possible right before you breathe in your medicine.



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5. Grip the mouthpiece between your teeth and close your lips firmly around the device 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.
7. Take your mouth off the mouthpiece and hold your breath for 10 seconds or as long as possible. 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 doctor. Ensure that you leave an interval of 1 minute between two doses.



8. Remove the empty capsule and put the protective cover back. Store in safe and dry place.

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



Cleaning:

Clean your inhaler 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.

Always rinse your mouth out, gargle with water or brush your teeth after you have taken your inhaler and spit out the residue. This may help prevent you developing a sore mouth and throat or a hoarse voice.

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

Always use **TIZAGLENN CO** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with **TIZAGLENN CO** will last. Do not stop early, because this can cause your symptoms to return.

If you have the impression that the effect of **TIZAGLENN CO** is too strong or too weak, tell your doctor or pharmacist.

If you use more TIZAGLENN CO than you should

If you inhale too many actuations of **TIZAGLENN CO** or accidental intake, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. You may suffer from severe chest pain (angina), high or low blood pressure, a headache, muscle cramps, difficulty in sleeping, nervousness, a dry mouth, a loss of appetite, seizures, fits or convulsions. You may feel shaky, light headed, faint, tired, sick or generally unwell. You may also notice changes in the rate of your heart beat and your blood may have low levels of potassium or an increase in the amount of sugar in your blood. You may also suffer from symptoms such as abdominal pain, being sick, weight loss, decreased level of consciousness (which could make you feel drowsy or confused) or a low blood sugar level.

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

If you forget to use TIZAGLENN CO

If you forgot to take a dose, take the dose as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop using TIZAGLENN CO

It is very important that you take this inhaler every day as directed by your doctor even if you feel well

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as it will help to control your asthma. If you want to stop using your inhaler talk to your doctor first. Your doctor will tell you how to do this, usually by decreasing the dose gradually so that you do not trigger an asthma attack.

4. Possible side effects

TIZAGLENN CO can have side effects.

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

- swelling of your hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- skin rash or itching
- anaphylactic shock (a severe, potentially life-threatening allergic reaction)

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- hypersensitivity reactions including bronchospasm (causing difficulty breathing and wheezing)
- irregular, fast heart beats or pain in your chest

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less Frequent side effects:

- Worsening of asthma.
- Headache.
- Shaking.
- An irregular heartbeat or palpitations.
- Dizziness.

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- Difficulty in sleeping.
- Alteration in voice/hoarse voice.
- Dry mouth, sore or irritated throat.
- Rash.
- An increase in the amount of sugar in your blood. If you are diabetic you may need to check your blood sugar more often and adjust your usual diabetic treatment. Your doctor may need to monitor you more closely.
- Thrush or other fungal infections in the mouth and throat.
- Inflammation of the sinuses (sinusitis).
- Fast heartbeat.
- Chest pain associated with heart disease.
- Muscle spasms.
- Coughing or shortness of breath.
- Diarrhoea.
- Indigestion.
- Changes in taste.
- A feeling of dizziness or 'spinning'.
- Abnormal dreams.
- Agitation.
- Itchy skin.
- High blood pressure.
- A feeling of unusual weakness.
- Swelling of hands, ankles or feet.

Side effects with unknown frequency:

- Depression, aggression (predominantly in children)
- Blurred vision

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The following side effects are associated with formoterol fumarate but they have not been reported during clinical trials with **TIZAGLENN CO**:

- Low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm.
- An abnormal heart trace potentially leading to an abnormal heart rhythm (QTc interval prolongation).
- High levels of lactic acid in the blood.
- Feeling sick.
- Muscle pain.

Inhaled steroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- changes in bone mineral density (thinning of the bones);
- cataracts (clouding of the lens in the eye);
- glaucoma (increased pressure in the eye);
- bruising or thinning of the skin;
- an increased chance of catching an infection;
- slowing of the rate of growth of children and adolescents;
- a round (moon shaped) face;
- an effect on the adrenal gland (a small gland next to the kidney) which means you may have symptoms such as weakness, tiredness, difficulty in coping with stress, abdominal pain, loss of appetite, weight loss, headache, dizziness, very low blood pressure, diarrhoea, feeling or being sick or fits.

Not all side effects reported for **TIZAGLENN CO** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **TIZAGLENN CO**, please consult

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your healthcare provider for advice.

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 **TIZAGLENN CO**.

5. How to store TIZAGLENN CO

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the container tightly closed in its original package.

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 TIZAGLENN CO contains

- The active ingredients are formoterol fumarate and fluticasone propionate
- The other ingredient is lactose monohydrate

What TIZAGLENN CO looks like and contents of the pack

Available as 30 capsules with one silica gel canister packed in a white, opaque HDPE round container and induction sealed. Such two HDPE containers are packed in a carton with a device and pack insert.

Dry Powder Inhaler device: Made up of material ABS (Acrylonitrile Butadiene Styrene). Consisting of cap & body fitted with piercing needles.

Holder of Certificate of Registration

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This leaflet was last revised in

27 November 2024

Registration number

57/10.2.1/0339