

Package Leaflet

Package leaflet: Information for the patient
Peiotal 25 microgram/50 microgram/dose pressurised inhalation, suspension
Peiotal 25 microgram/125 microgram/dose pressurised inhalation, suspension
Peiotal 25 microgram/250 microgram/dose pressurised inhalation, suspension
salmeterol/fluticasone propionate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Peiotal is and what it is used for

Peiotal contains two medicines: salmeterol and fluticasone propionate:

- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

The doctor has prescribed this medicine to help prevent breathing problems such as asthma.

You must use Peiotal every day as directed by your doctor. This will make sure that it works properly in controlling your asthma.

Peiotal helps to stop breathlessness and wheeziness coming on. However Peiotal should not be used to relieve a sudden attack of breathlessness or wheezing. If this happens you need to use a fast-acting ‘reliever’ (‘rescue’) inhaler, such as salbutamol. You should always have your fast-acting ‘rescue’ inhaler with you.

2. What you need to know before you use Peiotal

Do not take Peiotal:

- If you are allergic to salmeterol, fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Peiotal if you have:

- Heart disease, including an irregular or fast heart beat;
- Overactive thyroid gland;
- High blood pressure;
- Diabetes mellitus (Peiotal may increase your blood sugar);

- Low potassium in your blood;
- Tuberculosis (TB) now, or in the past, or other lung infections;

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Peiotal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines for asthma or any medicines obtained without a prescription. This is because Peiotal may not be suitable to be taken with some other medicines.

Tell your doctor if you are taking the following medicines, before starting to use Peiotal:

- β blockers (such as atenolol, propranolol and sotalol). β blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ketoconazole, itraconazole and erythromycin) including some medicines for HIV treatment (such as ritonavir, cobicistat-containing products). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase your risk of experiencing side effects with Peiotal, including irregular heartbeats, or may make side effects worse. Your doctor may wish to monitor you carefully if you are taking these medicines.
- Corticosteroids (by mouth or by injection). If you have had these medicines recently, this might increase the risk of this medicine affecting your adrenal gland.
- Diuretics, also known as 'water tablets' used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).
- Xanthine medicines. These are often used to treat asthma.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Peiotal is not likely to affect your ability to drive or use machines.

3. How to use Peiotal

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

- Use your Peiotal every day, until your doctor advises you to stop. Do not take more than the recommended dose. Check with your doctor or pharmacist if you are not sure.
- Do not stop taking Peiotal or reduce the dose of Peiotal without talking to your doctor first.
- Peiotal should be inhaled through the mouth into the lungs.
- Use your Peiotal always taking the count of the actuations.
The inhaler has been designed to deliver 120 actuations.
However it is not possible to tell when the inhaler is empty and when the 120 puffs have been released. There may still be a small amount of fluid left over in the container.
Please make sure that your inhaler is replaced after you have released 120 puffs so that you can be certain that you are getting the right amount of your medicine in each puff.

Adults and adolescents aged 12 years and over

- Peiotal 25/50 - 2 puffs twice a day
- Peiotal 25/125 - 2 puffs twice a day
- Peiotal 25/250 - 2 puffs twice a day

Children 4 to 12 years of age

- Peiotal 25/50 - 2 puffs twice a day
- Peiotal is not recommended for use in children below 4 years of age.

Your symptoms may become well controlled using Peiotal twice a day. If so, your doctor may decide to reduce your dose to once a day. The dose may change to:

- once at night - if you have **night-time** symptoms.
- once in the morning - if you have **daytime** symptoms.

It is very important to follow your doctor's instructions on how many puffs to take and how often to take your medicine.

If you are using Peiotal for asthma, your doctor will want to regularly check your symptoms. **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. If any of these happen, you should continue to take Peiotal but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

Instructions for use

- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the Peiotal properly or as prescribed may mean that it will not help your asthma as it should.
- The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.
- A new full inhaler has enough medicine for a minimum of 120 actuations of medication. After 120 puffs the inhaler may no longer have enough medicine to give a full dose of medication.

Testing your inhaler

1. When using your 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 the inhaler works, shake it well, point the mouthpiece away from you and press the canister to release a puff into the air. Repeat these steps, shaking the inhaler before releasing a second puff into the air. The total puffs released into the air, before using the inhaler, should be two.
3. After these first two test puffs, you can start using your inhaler.
4. If you have not used your inhaler for a week or more, or your inhaler gets very cold (below 0°C) release two puffs of medicine into the air.

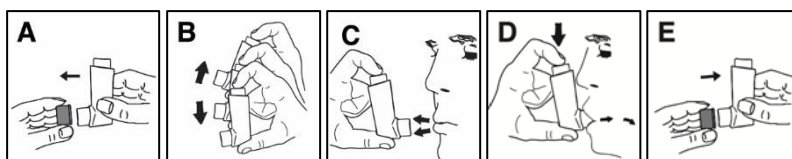
Warnings

Never detach the metal canister from the inhaler at any time.

Only if the inhaler gets very cold (below 0 °C), take the metal canister out of the plastic case and warm it in your hands for few minutes before use. Never use anything else to warm it up. After warming and before using, press the canister firmly to release two puffs 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 (Figure A).
3. Check inside and outside to make sure that the mouthpiece is clean and free of dust or other loose particles.
4. Shake the inhaler 4 or 5 times to ensure that the contents of the inhaler are evenly mixed (Figure B).
5. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable (Figure C).
6. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.
7. Breathe in through your mouth slowly and deeply. Just after starting to breathe in, press firmly down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply (Figure D).
8. 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.
9. Wait about half a minute between taking each puff of medicine and then repeat steps 4 to 8.
10. Afterwards, rinse your mouth with water and spit it out, and/or brush your teeth. This may help to stop you getting thrush and becoming hoarse.
11. After use always replace the mouthpiece cover straight away to keep out dust. (Figure E). When the mouthpiece cover is fitted correctly it will 'click' into position. Do not use too much force.

Do not rush steps 5, 6, 7 and 8. It is important that you breathe in as slowly as possible just before using your inhaler. You should use your inhaler whilst standing in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth, you should start again from step 4.

As with all inhalers, caregivers should ensure that children prescribed Peiotal use correct inhalation technique, as described above.

If you or your child find it difficult to use the inhaler, either your doctor or nurse or other healthcare provider may recommend using an AeroChamber Plus® spacer device with your inhaler. Your doctor, nurse, pharmacist or other healthcare provider should show you how to use the spacer device with your inhaler and how to care for your spacer device and will answer any questions you may have. It is important that if you are using a spacer device with your inhaler that you do not stop using it without talking to your doctor or nurse first. **Other spacer devices are not recommended for use with Peiotal and you should not switch from the AeroChamber Plus® device to another.** It is also important that you do not change or stop using the spacer without talking to your doctor, he will know how to modify the therapy. Always talk to your doctor before making any changes to your asthma treatment.

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.

Cleaning your inhaler

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

To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.

- Replace the mouthpiece cover. It will ‘click’ into place when fitted correctly.
- Do not use too much force.
- Do not put the metal canister in water.

If you use more Peiotal than you should

It is important to use the inhaler as instructed. If you accidentally take a larger dose than recommended, talk to your doctor or pharmacist. You may notice your heart beating faster than usual and that you feel shaky. You may also have dizziness, a headache, muscle weakness and aching joints.

If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of Peiotal may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Peiotal

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop using Peiotal

It is very important that you take your Peiotal every day as directed. Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Peiotal. This could make your breathing worse.

In addition, if you suddenly stop taking Peiotal or reduce your dose of Peiotal this may (very rarely) cause you to have problems with your adrenal gland (adrenal insufficiency) which sometimes causes side effects.

These side effects may include any of the following:

- Stomach pain
- Tiredness and loss of appetite, feeling sick
- Sickness and diarrhoea
- Weight loss
- Headache or drowsiness
- Low levels of sugar in your blood
- Low blood pressure and seizures (fits)

When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse and you may have any of the side effects listed above.

If you get any side effects, talk to your doctor or pharmacist. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids in tablet form (such as prednisolone).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of Peiotal to control your asthma.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Peiotal. You may be very wheezy and cough or be short of breath. You may also notice itching, a rash (hives) and swelling (usually of the face, lips, tongue or throat), or you may suddenly feel that your heart is beating very fast or you feel faint and light headed (which may lead to collapse or loss of consciousness). **If you get any of these effects or if they happen suddenly after using Peiotal, stop using Peiotal and tell your doctor straight away.** Allergic reactions to Peiotal are uncommon (they affect less than 1 person in 100).

Other side effects are listed below:

Very Common (may affects more than 1 in 10 people)

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

Common (may affects up to 1 in 10 people)

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue and hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately and/or brushing your teeth after taking each dose of your medicine may help. Your doctor may prescribe an anti-fungal medication to treat the thrush.
- Aching, swollen joints and muscle pain.
- Muscle cramps.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):

- Pneumonia and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum colour, fever, chills, increased cough, increased breathing problems.
- Bruising and fractures.
- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache).
- A reduction in the amount of potassium in the blood (you may get an uneven heartbeat, muscle weakness, cramp).

Uncommon (may affects up to 1 in 100 people)

- Increases in the amount of sugar (glucose) in your blood (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- Cataract (cloudy lens in the eye).
- Very fast heartbeat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heart beat (palpitations) - these are usually harmless and get less as treatment continues.
- Chest pain.
- Feeling worried (this effect mainly occurs in children).
- Disturbed sleep.
- Allergic skin rash.

Rare (may affects up to 1 in 1000 people)

- **Breathing difficulties or wheezing that get worse straight after taking Peiotal.** If this happens **stop using your Peiotal inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**
- Peiotal may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects include:
 - Slowing of growth in children and adolescents
 - Thinning of the bones
 - Glaucoma
 - Weight gain
 - Rounded (moon shaped) face (Cushing's Syndrome)

Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of Peiotal to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heart beat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Peiotal unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

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

- Depression or aggression. These effects are more likely to occur in children.
- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Peiotal

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25 °C.
- The canister contains a pressurized liquid. Do not expose to temperatures higher than 50 °C, protect from direct sunlight. Do not pierce, break or burn the canister even when apparently empty.
- Do not use this medicine if you notice visible signs of deterioration.
- As with most inhaled medicinal products in pressurized canisters, the therapeutic effect of this medicinal product may decrease when the canister is cold.

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.

6. Contents of the pack and other information

What Peiotal contains

The active substances are salmeterol and fluticasone propionate.

Peiotal 25 microgram/50 microgram/dose pressurised inhalation, suspension:

Each metered dose contains 25 micrograms of salmeterol (as salmeterol xinafoate) and 50 micrograms of fluticasone propionate.

Peiotal 25 microgram/125 microgram/dose pressurised inhalation, suspension:

Each metered dose contains 25 micrograms of salmeterol (as salmeterol xinafoate) and 125 micrograms of fluticasone propionate.

Peiotal 25 microgram/250 microgram/dose pressurised inhalation, suspension:

Each metered dose contains 25 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate.

The other ingredient is propellant: norflurane (HFA-134a).

This medicine contains fluorinated greenhouse gases.

Each inhaler of 120 actuation contains 11.2 g of norflurane (HFA-134a) corresponding to 0.016 tonne CO₂ equivalent (global warming potential GWP = 1 430).

What Peiotal looks like and contents of the pack

- Peiotal is supplied to you in a metered dose inhaler which delivers your medicine in a pressurised suspension for you to inhale through your mouth into your lungs.
- The pressurised canister contains a white homogenous suspension for inhalation.

Peiotal 25 microgram/50 microgram/dose pressurised inhalation, suspension:

- The canister is fitted into a plastic casing incorporating a mouthpiece and fitted with a lilac dust cap.

Peiotal 25 microgram/125 microgram/dose pressurised inhalation, suspension:

- The canister is fitted into a plastic casing incorporating a mouthpiece and fitted with a purple dust cap.

Peiotal 25 microgram/250 microgram/dose pressurised inhalation, suspension:

- The canister is fitted into a plastic casing incorporating a mouthpiece and fitted with a violet dust cap.

- Each pack contains 1 inhaler. Each inhaler contains 120 actuations.

Marketing Authorisation Holder

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Manufacturer

Genetic S.p.A.
Contrada Canfora 84084
Fisciano (SA)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal: Santime

Italy: SALMETEROLO E FLUTICASONE DOC Generics

Ireland: Peiotal

This leaflet was last revised in