

## **Package leaflet: Information for the patient**

**Duohal 25 micrograms /125 micrograms /dose pressurised inhalation, suspension**

**Duohal 25 micrograms /250 micrograms /dose pressurised inhalation, suspension**

Salmeterol/fluticasone propionate

**Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

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

### **1. What Duohal is and what it is used for**

Duohal 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 Duohal every day as directed by your doctor. This will make sure that it works properly in controlling your asthma.

Duohal helps to stop breathlessness and wheeziness coming on. However Duohal should not be used to relieve a sudden attack of breathlessness or wheezing. If that 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 Duohal**

#### **Do not take Duohal:**

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, pharmacist or nurse before using Duohal if you have:

- heart disease, including an irregular or fast heart beat
- overactive thyroid gland
- high blood pressure

- diabetes mellitus (Duohal 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 Duohal**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicine for asthma or any medicines obtained without a prescription. This is because Duohal 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 Duohal

- Beta-blockers (such as atenolol, propranolol and sotalol). Beta- blockers are mostly used for high blood pressure or other heart conditions
- Medicines to treat infections (such as ketoconazole, itraconazole and erythromycin). 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 Duohal including irregular heart beats, or may make side effects worse.
- 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.
- Medicines to treat viruses (including some medicines for HIV: ritonavir, cobicistat). Your doctor may wish to monitor you carefully if you are taking these medicines.

### **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**

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

## **3. How to use Duohal**

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 Duohal 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 Duohal or reduce the dose of Duohal without talking to your doctor first
- Duohal should be inhaled through the mouth into the lungs.

### **Adults and adolescents aged 12 years and over**

- Duohal 25 micrograms /125 micrograms /dose - 2 puffs twice a day
- Duohal 25 micrograms /250 micrograms /dose - 2 puffs twice a day

### **Use in children and adolescents**

Duohal is not recommended for use in children below 12 years of age.

The dose should be titrated to the lowest dose at which effective control of symptoms is maintained.

Where the control of symptoms is maintained with the lowest strength of Duohal (25/125 micrograms), the next step could include a switch to a different inhaled salmeterol fluticasone product available in a lower strength (25/50 micrograms).

Your symptoms may become well controlled using Duohal 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 inhalations to take and how often to take your medicine.

If you are using Duohal 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 Duohal 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 Duohal 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.
- There is an indicator in front of the inhaler which tells you how many doses are left. As you use the inhaler the dose indicator will typically rotate during every five to seven puffs towards next decreasing number. The dose indicator will show the approximate no of puffs remaining in the inhaler
- Take care not to drop the Inhaler as this may cause the indicator to count down.

### 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 four puffs into the air. The dose indicator will show the number '120' indicating the number of puffs in the inhaler. If you have not used your inhaler for a week or more, shake 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 inhaler.

1. Stand or sit upright when using your inhaler.
2. Remove the mouthpiece cover. Check inside and outside to make sure that the mouthpiece is clean and free of loose objects (figure A).



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



4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable (figure C).



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



6. 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).
7. Hold your breathe, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breathe for a few seconds, or as long as is comfortable (figure E).



8. Wait about half a minute between taking each puff of medicine and then repeat steps 3 to 7.
9. 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.
10. After use always replace the mouthpiece cover straight away to keep out dust. When the mouthpiece cover is fitted correctly it will 'click' into position. If it does not 'click' into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.

Do not rush steps 4, 5, 6 and 7. 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 3.

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

If you find it difficult to use the inhaler, a spacer device may be used such as the Volumatic or AeroChamber Plus or other spacer devices (depending on National Guidance). Before starting to use a spacer device for the first time or if you need to change your make of spacer device, talk to your doctor, nurse or pharmacist.

You should get a replacement when the indicator shows the number '40' and the color on the dose indicator will change from green to red. Stop using the Inhaler when the indicator shows '0' as any puffs left in the device may not be enough to give you a full dose. Never try to alter the numbers on the indicator or detach the indicator from the actuator. The indicator cannot be reset and is permanently attached to the actuator.

### **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. If it does not 'click' into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.

Do not put the metal canister in water.

### **If you use more Duohal 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 Duohal may reduce the amount of steroid hormones produced by the adrenal gland.

### **If you forget to use Duohal**

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 Duohal**

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

In addition, if you suddenly stop taking Duohal or reduce your dose of Duohal 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 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 Duohal to control your asthma.

**Allergic reactions:** you may notice your breathing suddenly gets worse immediately after using Duohal. 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 these effects or if they happen suddenly after using Duohal, stop using Duohal and tell your doctor straight away. Allergic reactions to Duohal are uncommon (may affect up to 1 in 100 people).

Other side effects are listed below:

**Very common (may affect 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 affect 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 antifungal 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 (infection of the lung).

Tell your doctor if you have any of the following while taking Duohal they could be symptoms of a lung infection:

- fever or chills,
  - increased mucus production, change in mucus colour
  - increased cough or increased breathing difficulties.
- Throat irritation. Rinsing your mouth out with water and spitting it out immediately after taking each puff may help
- 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 affect 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.
- Cloudy lens in the eye (cataract)
- 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 affect up to 1 in 1000 people)**

- Breathing difficulties or wheezing that get worse straight after taking Duohal. If this happens stop using your Duohal. Use your fast-acting 'reliever' inhaler to help your breathing and tell your doctor straight away.
- Duohal 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
  - damage to eye's optic nerve (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 Duohal to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heartbeat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Duohal unless they tell 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 like 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 the side effects directly via the national reporting system listed in Appendix V\*. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Duohal**

- Keep this medicine out of the sight and reach of children.
- Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.
- Do not expose to temperatures higher than 50°C. Do not store Duohal in a cold place, as your medicine may not work as well.
- 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.
- The metal canister contains a pressurised liquid. Do not pierce the canister.
- 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 Duohal contains**

- Each metered dose of Duohal provides:  
25 micrograms of salmeterol (as salmeterol xinafoate) and 125 or 250 micrograms of fluticasone propionate (delivered from the valve). This is equivalent to 21 micrograms of salmeterol and 110 or 220 micrograms of fluticasone propionate delivered from the actuator (delivered dose).
- This medicine contains fluorinated greenhouse gases.  
Each inhaler contains 12.5g of HFC-134a (Norflurane) corresponding to 0.018 tonne CO<sub>2</sub> equivalent (global warming potential GWP = 1430).

**What Duohal looks like and contents of the pack**

- Aluminium canister with a suitable metering valve and a polypropylene actuator with dust cap having dose indicator.
- Each container is filled to deliver 120 doses.

Pack sizes:

1, 2 (bundled package 2x1) or 3 (bundled package 3x1) canisters containing 120 doses.  
10 (bundled package 10x1) canisters containing 120 doses -hospital/pharmacy use only

Not all pack sizes may be marketed.

## Marketing Authorisation Holder and Manufacturer

### Marketing Authorisation Holder

[To be completed nationally]

### Manufacturer

S&D Pharma CZ, spol. s r.o.,  
Theodor 28, 273 08  
Pchery (Pharmos a.s. facility),  
Česká Republika.

Arrow Generiques  
26 Avenue Tony Garnier  
69007 LYON  
France

Cipla Europe NV  
De Keyserlei, 60C, Bus-1301,  
2018, Antwerp,  
Belgium

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

|                 |                                                                                                                                                                                                                                                                            |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sweden</b>   | Duohal                                                                                                                                                                                                                                                                     |
| <b>Bulgaria</b> | Салметерол и флутиказон Сипла 25 микрограма/ 125 микрограма на впръскване, суспензия под налягане за инхалация<br><br>Салметерол и флутиказон Сипла 25 микрограма/ 250 микрограма на впръскване, суспензия под налягане за инхалация                                       |
| <b>France</b>   | PROPIONATE DE FLUTICASONE/SALMETEROL TEVA 125 microgrammes/25 microgrammes/ dose, suspension pour inhalation en flacon pressurisé<br><br>PROPIONATE DE FLUTICASONE/SALMETEROL TEVA 250 microgrammes/25 microgrammes/ dose, suspension pour inhalation en flacon pressurisé |

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