

#### Package leaflet: Information for the user

## Fludalt Duo 50 /100 microgram inhalation powder, hard capsule

## Fludalt Duo 50 /250 microgram inhalation powder, hard capsule

## Fludalt Duo 50 /500 microgram inhalation powder, hard capsule

### Salmeterol (as Salmeterol Xinafoate)/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, or 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Fludalt Duo is and what it is used for

Fludalt Duo 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
- Chronic Obstructive Pulmonary Disease (COPD). Fludalt Duo ,at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

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

**Fludalt Duo helps to stop breathlessness and wheeziness coming on. However Fludalt Duo should not be used to relieve 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 Fludalt Duo

##### Do not use Fludalt Duo

If you are allergic to salmeterol, fluticasone propionate or to the other ingredient lactose monohydrate.

##### Warnings and precautions

Talk to your doctor before using Fludalt Duo if you have:

- Heart disease, including an irregular or fast heartbeat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Fludalt Duo may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now or in the past, or other lung infections

If you have ever had any of these conditions, tell your doctor before you use Fludalt Duo.

##### Other medicines and Fludalt Duo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines for asthma or any medicines obtained without a prescription. This is because Fludalt Duo 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 Fludalt Duo:

- Beta-blockers (such as atenolol, propranolol, sotalol). Beta-blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ritonavir, 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 Fludalt Duo including irregular heartbeats, 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.

##### 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

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

##### Fludalt Duo contains lactose

Fludalt Duo contains up to 12.5 milligrams of lactose in each dose. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

#### 3. How to use Fludalt Duo

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 Fludalt Duo 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 Fludalt Duo or reduce the dose of Fludalt Duo without talking to your doctor first.

Fludalt Duo should be inhaled through the mouth into the lungs.

##### For asthma

##### Children 4 to 12 years of age

- Fludalt Duo 50/100 mcg - One inhalation twice a day
- Fludalt Duo is not recommended for use in children below 4 years of age.

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

- Fludalt Duo 50/100 mcg- One inhalation twice a day
- Fludalt Duo 50/250 mcg- One inhalation twice a day
- Fludalt Duo 50/500 mcg- One inhalation twice a day

##### For adults with Chronic Obstructive Pulmonary Disease (COPD)

- Fludalt Duo 50/500 - One inhalation twice a day

Your symptoms may become well controlled using Fludalt Duo 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 Fludalt Duo 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 Fludalt Duo but do not increase the dosage 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 (plastic device). They should check how you use it from time to time. Not using Fludalt Duo properly or as prescribed may mean that it will not help your asthma or COPD as it should.

##### Using your device

1. Pull off the cap



2. Hold the base of the inhaler firmly and turn the mouthpiece in the direction of the arrow to open.



3. Take one of today’s capsules. Place it in the capsule-shaped compartment in the base of the inhaler. It is important that you remove the capsule from the pack only immediately before you use it.



4. Twist the mouthpiece to the closed position until it clicks.



5. Keeping the inhaler upright, firmly squeeze the two buttons once only. This will pierce the capsule. Release the buttons. Although the capsule is now pierced, the powder will not be released until you inhale it.



6. Breathe out fully.



7. Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips around the mouthpiece and breathe in as quickly and as deeply as you can. As you breathe in, you will inhale the medicine into your lungs.

You should hear the capsule spinning in the inhaler. If you do not hear this whirring noise, the capsule may be stuck in the compartment. If this occurs, open the inhaler and loosen the capsule by prising it out of the compartment. Do not try to loosen the capsule by repeatedly pressing the buttons.

8. If you have heard the whirring noise, hold your breath for as long as you comfortably can while taking the inhaler out of your mouth. Then breathe normally. Open the inhaler to see if any powder is still in the capsule. If there is still powder in the capsule repeat steps 6 to 8.

9. After use, tip out the empty capsule and close the mouthpiece.

10. Replace the cap.

11. If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a dry cloth or a clean soft brush.

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

##### If you forget to use Fludalt Duo

If you forget to use your inhaler, just take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

##### If you stop using Fludalt Duo

It is very important that you take your Fludalt Duo every day as directed. Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Fludalt Duo. This could make your breathing problem worse. In addition, if you suddenly stop taking Fludalt Duo or reduce your dose of Fludalt Duo 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 diarrhea
- 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 Fludalt Duo to control your asthma or COPD.

**Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Fludalt Duo.** 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 your heart 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 Fludalt Duo, stop using Fludalt Duo and tell your doctor straight away.** Allergic reactions to Fludalt Duo are uncommon (they affect less than 1 person in 100).

Other side effects are listed below:

##### Very Common (affects more than 1 person in 10)

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

##### Common (affects less than 1 person in 10)

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat, sore tongue, hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately and/or brushing your teeth after taking each puff 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 and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum color, fever, chills, increased cough, and 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 and cramp).

##### Uncommon (affects less than 1 person in 100)

- Increases in the amount of sugar (glucose) in your blood (hyperglycemia). 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 (affects less than 1 person in 1000)

- **Breathing difficulties or wheezing that get worse straight after taking Fludalt Duo. If this happens stop using your Fludalt Duo inhaler.**

Use your fast-acting ‘reliever’ inhaler to help your breathing and tell your doctor straight away.

- Fludalt Duo 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 Fludalt Duo 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 Fludalt Duo unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

##### Frequency not known, but may also occur:

Depression or aggression (these effects are more likely to occur in children).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### 5. How to store Fludalt Duo

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the label of the bottle and carton after Exp. The expiry date refers to the last day of that month.

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 Fludalt Duo contains

- The active substance(s) are 100, 250 or 500 micrograms fluticasone propionate and 50 micrograms salmeterol (as salmeterol xinafoate).
- The other ingredient is lactose monohydrate.

##### What Fludalt Duo looks like and contents of the pack

Fludalt Duo 50/100 microgram, 50/250 microgram and 50/500 microgram inhalation powder is conditioned in capsules and then these are packed in bottles. Then the bottles are packed in an aluminium bag with 1 plastic device (1 inhaler). Each bottle contains 60 capsules.

The aluminium bag is then packed in a cardboard box.

##### Marketing Authorisation Holder and Manufacturer

##### Product License holder, secondary packager & Batch releaser:

**Pharmaline s.a.l.** - Lebanon

P.O. Box **90201 Jdeidet-el-Mten**, Lebanon

Under license of **Exeltis Healthcare S.L., 28050 Madrid**, Spain

##### Manufacturer and primary packager:

Laboratorios Liconsa, S.A., Spain

Avenida Miralcampo 7, Polígono Industrial Miralcampo

19200 Azuqueca de Henares, Guadalajara - SPAIN

##### Other information

- This is a medicament**
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.