

## PATIENT INFORMATION LEAFLET

### AIRTIDE 500/50 mcg Capsules for Inhalation

**It is taken by inhalation. (Pulling with lungs with breath)**

- **Active substances:** Each capsules for inhalation each breathing contains 500 mcg fluticasone propionate and 72.50 mcg salmeterol xinafoate equivalent to 50 mcg salmeterol.
- **Excipients:** Lactose monohydrate (cow milk sourced.)

**Read all of this PATIENT INFORMATION 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.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *Please state that you are taking this drug if you visit a doctor or hospital during the administration of this drug.*
- *Please follow the instructions here precisely. Do not use higher or lower dose other than the recommended.*

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

1. ***What AIRTIDE is and what is it used for***
2. ***What you need to know before you take AIRTIDE***
3. ***How to use AIRTIDE?***
4. ***Possible side effects.***
5. ***How to store AIRTIDE?***

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

\* AIRTIDE contains flucatose and salmeterol as active substances.

\* 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.

\* Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

Fluticasone belongs to a group of drugs called corticosteroids and relieves the problems of breathing by reducing swelling and tenderness on the walls of the airways in the lungs, as it is a relieving inflammation (inflammation).

The lactose monohydrate is cow milk sourced.

AIRTIDE is found in packages containing 60 capsules for inhalation that contains salmeterol xinafoate equivalent to 50 mcg salmeterol and 500 mcg fluticasone propionate and contains 1 inhalation device.

AIRTIDE is used in the following situations:

- For the purpose of correcting and controlling asthma symptoms. It is given in the step-by-step treatment of the asthma disease from the 3rd stage.
- Mild and severe Chronic obstructive pulmonary disease (COPD), to reduce the number of flare ups of symptoms.

Airtide helps to stop shortness of breath and wheezing that is about to start. It will not work if the shortness of breath or wheezing has already started. If this happens, you will need to use a fast-acting "rescue" medicine such as salbutamol. Carry your fast-acting "rescue" medicine with you at all times.

You should see your doctor if you are short of breath or wheeze more often than usual, or if you are using your fast-acting rescue medicine more often than usual.

## **2. What you need to know before you take AIRTIDE**

### **DO NOT USE AIRTIDE in the following situations:**

If;

- you are allergic (hypersensitive) to salmeterol, fluticasone propionate or lactose ingredients of this medicine.

### **Use AIRTIDE cautiously in the following situations:**

- Salmeterol, one of the active ingredients, should not be used as a stand-alone treatment in patients with asthma.
- Rarely, serious and sometimes fatal asthma-related respiratory problems may occur due to long-acting beta-agonist preparations.
- AIRTIDE is not recommended for the initial treatment of asthma.
- Long-acting beta agonists should be used for the shortest period of time that provides control of asthma symptom(s) and their use should be discontinued, if possible, when asthma control is achieved. Afterwards, patients should be maintained with a control treatment.
- A combination of both an inhaled corticosteroid and a long-acting beta agonist to ensure compliance with both drugs in pediatric (child) and adolescent (adolescent) patients using a long-acting beta agonist in addition to an inhaled corticosteroid. It is recommended to use the preparation.
- Treatment with long-acting beta-agonists should not be initiated if patients are in exacerbations or have severe or acutely (short-term ongoing) worsening asthma.
- Do not use AIRTIDE to relieve sudden onset of symptoms, always keep medicines you use for such cases.
- If you have improved the use of a short-acting bronchodilator (bronchodilator) for the indication, tell your doctor, which indicates that asthma control is getting worse.
- If your asthma worsens suddenly and progressively, inform your doctor.
- Do not interrupt your medication without consulting your doctor. Treatment of AIRTIDE should be stopped gradually under the supervision of a doctor.
- There is an increased likelihood of developing pneumonia (pneumonia) in patients with COPD using AIRTIDE.
- If you have active and silent pulmonary tuberculosis, inform your doctor, you may want to make changes to your treatment.
- Tell your doctor if you have thyrotoxicosis (thyroid gland excess hormone secretion), you may want to change your treatment.

- If AIRTIDE administered at doses higher than the therapeutic doses, it may lead to elevated blood pressure and heart rate, so if you have any cardiovascular disease, tell your doctor that you may want to make changes to your treatment.
- When taken at higher treatment doses, AIRTIDE may cause a decrease in the levels of local potassium, so if your potassium level is low or if you have a tendency to do so, tell your doctor, and you may want to change your treatment.
- Cushing's syndrome due to its corticosteroids, AIRTIDE especially in high doses when used for a long time, especially in high doses, Cushing's syndrome (back fat-like fat accumulation, rounding of the face, excessive hair growth and especially bones in the waist and pelvis bones), Cushing-like symptoms, adrenal suppression (suppression of hormone secretion from the adrenal gland) and pubertal growth retardation, decreased bone mineral density, cataracts and glaucoma (eye strain).
- It may lead to growth retardation in children and adolescents. Therefore, the size of children who have been taking AIRTIDE for a long time should be followed up regularly.
- If there is a sudden increase in wheezing after taking the medicine, inform your doctor immediately. The doctor may want to make changes to your treatment.
- Some patients may be more susceptible to inhaled corticosteroids, so your doctor will closely monitor you when you are being treated for oral corticosteroid therapy or inhaled corticosteroid therapy.
- After starting the treatment of inhaled fluticasone propionate, you will have a warning card next to you indicating that you may need additional treatment during stress periods.
- AIRTIDE may increase the level of blood sugar, so inform your doctor if you have diabetes and may want to make changes in your treatment.
- If you are using ritonavir (a drug used against viruses), tell your doctor, you may want to change your treatment.
- Consult your doctor if you have blurred vision or other visual disorders.

Please consult your doctor if these warnings apply to you, even at any time in the past.

#### **Using AIRTIDE with food and drink:**

There is no interaction with food and drinks due to the use of AIRTIDE.

#### **Pregnancy**

*Consult your doctor or pharmacist for advice before taking this medicine.*

If you are pregnant, think you may be pregnant or are planning to have a baby, please tell your doctor.

*If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

#### **Breastfeeding**

*Consult your doctor or pharmacist for advice before taking this medicine.*

Use it only if your doctor decides it is necessary during the breastfeeding period because experience with the use of salmeterol and fluticasone during breastfeeding is inadequate.

### **Driving and using machines**

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

### **Important information about some excipients of AIRTIDE**

AIRTIDE contains lactose. There is no need for any warning because the application route of AIRTIDE is inhalation.

### **Taking with other medicines**

If you are taking or have recently taken any other medicines, please inform your doctor or pharmacist about them. These medications also include asthma medications or over-the-counter medications. The reason for this is the possibility that AIRTIDE may not be appropriate to take with other drugs.

Before using AIRTIDE, please inform your doctor if you are using any of the following medicines:

- Beta-blockers (such as atenolol, propranolol and sotalol). Beta-blockers are mostly high It is used for blood pressure or other heart conditions.
- Medicines used against infections (such as ketoconazole, itraconazole and erythromycin), including some medicines used in the treatment of HIV (such as ritonavir, cobicistan-containing drugs). Some of these medicines can cause an increase in the amount of fluticasone propionate or salmeterol in your body. This may increase your risk of experiencing or make any side effects worse. If you are using these drugs, your doctor may want to monitor you closely.
- Corticosteroids (anti-inflammatory medicines, taken by mouth or by injection). If you have recently used these medicines, this may increase the risk of this medicine affecting your adrenal gland.
- Diuretics, also known as diuretics, used in the treatment of high blood pressure (drugs containing diuretics that can lower the potassium level in the blood, such as furosemide, hydrochlorothiazide)
- Other bronchodilators (such as salbutamol) used as rescue medication in the treatment of asthma and COPD.
- Xanthine medicine (they are used in the treatment of asthma.)

*If you are now taking or have taken recently any prescription or non-prescription medicines, please inform your doctor or pharmacist about these medicines.*

### **3. How to use AIRTIDE?**

#### **Instructions for appropriate use and dose/administration frequency:**

Use AIRTIDE every day until your doctor tells you to stop. Do not use higher doses than recommended by your doctor. If you are unsure, consult your doctor or pharmacist.

Do not stop using AIRTIDE and do not reduce the dose you use without consulting your doctor.

AIRTIDE is taken into the lungs by inhalation through the mouth.

Even if you have used the appliance correctly, you may not feel or taste the powder on your tongue.

#### ***For asthma:***

Adults and adolescents aged 12 years and over:

One inhalation twice a day (pulling with lungs with breath) (50 microgram salmeterol ve 500 microgram fluticasone)

***For Chronic Obstructive Pulmonary Disease (COPD):***

One inhalation twice a day (pulling with lungs with breath) (50 microgram salmeterol ve 500 microgram fluticasone)

**Instructions for use and method:**

AIRTIDE is only administered by inhalation. Inhalation of the powdered drug into the lungs through the mouth (inhalation: taking medicine from the mouth when breathing).

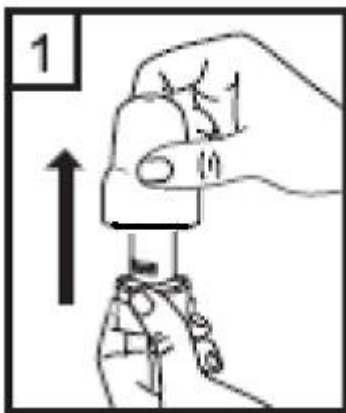
If AIRTIDE is given for a child, the application should be made under the supervision of an adult who understands how to use AIRTIDE.

It is necessary to use AIRTIDE regularly in order to get full benefit. Even if you feel better, do not interrupt your treatment.

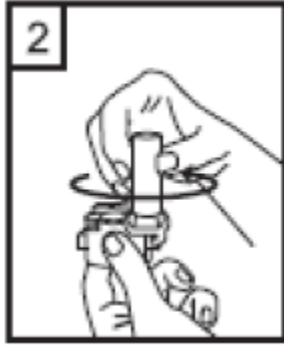
Do not change the medicine dose without telling your doctor.

**Instructions for use of AIRTIDE**

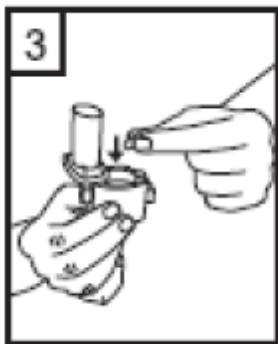
1. Pull out the lid.



2. Hold the lower part of the appliance with one hand and open the mouthpiece with the other hand by turning it in the direction of the arrow.



3. Place a capsule in the opening in the device. Remove the capsule immediately before using it.

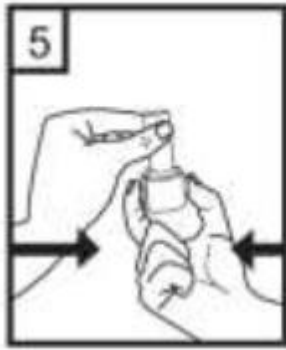


4. Close the mouthpiece by turning it.



5. Keep the appliance upright, press and release the buttons on the side only once exactly. The capsule will be pierced from both ends.

*During your breathing, you may come to your mouth with small pieces of gelatin capsules. The gelatinous components are harmless and will be digested after being swallowed. The risk of the formation of small pieces of gelatin is removed from the packaging of the capsule, can not be removed immediately, and is reduced by pressing the buttons only once.*



6. Give your breath out.



7. Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips tightly around the mouthpiece and breathe as fast and deep as you can.



8. Remove the appliance from your mouth and hold your breath for as long as possible without discomfort. Then breathe normally. Turn the device on again and check that there is no dust inside the capsule. If there is dust in the capsule, repeat steps 6, 7 and 8.
9. After use, throw empty capsules and close the mouthpiece.

**DO NOT FORGET!**

Keep your device dry.

Keep it closed when not in use.

Never breathe into the appliance.

Push it when you are only ready to take the pill.

Do not take more than the mentioned dose.

**Various age groups:**

**Use in children:**

Children aged 4 -12 years:

1 inhalation (50 microgram salmeterol and 100 microgram fluticasone propionate) 2 times a day.

**Use in the elderly:**

Dose adjustment is not necessary in old age.

**Special use cases:**

**Renal/Liver failure:** Dose changes are not necessary in patients with renal failure or hepatic failure.

*If you believe that the effect of AIRTIDE is very strong or weak, consult your physician or pharmacist.*

**If you take more AIRTIDE than you should:**

It is important that you use AIRTIDE in accordance with the instructions. If you accidentally take a larger dose than recommended, consult your doctor or pharmacist. You may feel your heart beating faster than normal and you may be wobbliness. You may also feel dizzy, headache, muscle weakness and joint pain.

If you have used high doses for a long time, consult your doctor or pharmacist for advice. This is because AIRTIDE taken in high doses may reduce the amount of steroid hormones produced in the adrenal glands.

*If you use more AIRTIDE than you should, talk to your doctor or pharmacist.*

**If you forget to use AIRTIDE:**

If you forget to use AIRTIDE, just take your next dose at the usual time.

*Do not take a double dose to make up for a forgotten dose.*

**Effects that may occur when treatment with AIRTIDE is terminated**

It is important to use AIRTIDE every day as directed by your doctor. Keep using it until your doctor tells you to stop. Do not stop using AIRTIDE suddenly or reduce your dose. This can make your breathing worse.

Also, if you suddenly stop using AIRTIDE or reduce your dose, this may (very rarely) cause problems with your adrenal glands (adrenal insufficiency) and related side effects.



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

Interruption of treatment in COPD patients may lead to symptomatic decompensation (failure of organ function), treatment should be discontinued under the supervision of a physician.

Although very rare, adrenal insufficiency may get worse if you have an infection or are under extreme stress (for example, after a serious accident or surgery) and you may experience any of the side effects listed above. To prevent these symptoms from occurring, your doctor may prescribe you extra corticosteroids (such as prednisolone).

If you have any further questions on the use of the medicine, please consult your doctor or pharmacist.

#### **4. Possible side effects**

As with all medicines, there may be side effects in people sensitive to substances in the content of AIRTIDE. To reduce the chance of side effects your doctor will prescribe the lowest dose of this combination of drugs to control your asthma.

If any of the following happens, stop taking AIRTIDE and tell your doctor IMMEDIATELY or contact the emergency department of the nearest hospital:

**Allergic reactions** You may notice that your breathing suddenly worsens after taking AIRTIDE. You may experience excessive wheezing, shortness of breath and cough. You may also notice itching, rashes and swelling on your body (usually on the face, lips or throat) or you may suddenly feel your heart beating very fast or you may feel faint or dizzy (which may lead to collapse or loss of consciousness). If you experience these effects or if they occur immediately after taking AIRTIDE, stop taking AIRTIDE and tell your doctor immediately. Allergic reactions to AIRTIDE are uncommon (affecting less than 1 in 100 people).

These are all very serious side effects.

If you have one of these, you have a serious allergy to AIRTIDE. You may need urgent medical attention or hospitalization.

#### **Other side effects**

Side effects are classified as shown in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients.

Unknown: Cannot be estimated from the available data.

**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 chronic obstructive pulmonary disease (COPD).

**Common (may affect less than 1 in 10 people):**

- Pneumonia (infection in the lungs) in patients with COPD

Tell your doctor if you experience any of the following symptoms while using AIRTIDE. These symptoms may be signs of lung infection:

- fever or chills
- increased mucus production, change in mucus color
- increased cough or increased difficulty breathing
- Thrush in the mouth and throat (sore, creamy-yellow, raised patches). 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 medicine to treat the thrush
- Pain, swelling and muscle aches in the joints.
- Muscle cramp

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: they could be symptoms of a lung infection: fever or chills; increased mucus production, changes in mucus colour; increased cough or increased breathing difficulties.
- Bruising and bone fractures.
- Inflammation of sinuses (sinusitis, 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 (affects less than 1 person in 100):**

- An increase in the amount of sugar (glucose) in your blood (hyperglycemia). If you have diabetes, your blood sugar may need to be monitored more often and possibly your usual diabetes treatment may need to be adjusted.
- Cataracts (clouding of the eye, blurred vision)

- Very fast heartbeat (tachycardia)
- Tremors and rapid or irregular heartbeat (palpitations, atrial fibrillation) - these are usually harmless and decrease as treatment continues.
- Chest pain (angina pectoris)
- Anxious mood (this is often seen in children)
- Sleep disturbance
- Allergic skin rash

**Very rare (affects less than 1 person in 10.000) :**

- ✓ Allergic reactions: After using AIRTIDE, you may notice that your breath suddenly worsens. You may experience extreme wheezing and depression. In addition, itching and swelling in your body (usually on the face, lips, or throat region) can occur. If you experience these effects or if they occur immediately after use of AIRTIDE, discontinue use of AIRTIDE **and IMMEDIATELY contact your doctor or the emergency department of your nearest hospital.**
- ✓ AIRTIDE 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
  - Cataract and 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 AIRTIDE of drugs to control your asthma.

- ✓ Uneven or irregular heart beat or an extra heart beat (arrhythmias). Tell your doctor, but do not stop taking AIRTIDE unless the doctor tells you to stop.
- ✓ Behavioral changes such as anxious mood, sleep disturbances, and unusually active or restlessness (these effects are usually seen in children).
- ✓ Fungal infection of the esophagus (esophagus) (can cause difficulty swallowing)

**Unknown:**

- Depression or irritability (aggression). These effects can usually be seen in children.
- Blurred vision

Reporting of side effects

If you get any side effects, stated or not stated in the Patient Information Leaflet, talk to your doctor or pharmacist. Also, please report the side effects you have to Turkish Pharmacovigilance Center (TÜFAM) by either clicking to “Reporting Drug Side Effect” icon on [www.titck.gov.tr](http://www.titck.gov.tr) or calling side effect reporting line via 0 800 314 00 08. By reporting the side effects you can help provide more information on the safety of this medicine.

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| TÜFAM | Turkish Pharmacovigilance Center<br><a href="http://www.titck.gov.tr">www.titck.gov.tr</a> |
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*If you have any side effect which is not specified in the Patient Information Leaflet, inform your doctor or pharmacist about your condition.*

## **5. How to store AIRTIDE?**

Keep out of reach and sight of children and in its original container.

Keep AIRTIDE at room temperature below 25 °C.

### **Comply with the expiry date.**

*Do not take AIRTIDE after the expiry date indicated on the package.*

“Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.”

### **Marketing Authorisation Holder:**

Humanis Saglik A.S.  
Mahmutbey Mahallesi, Tasocagi Yolu  
Caddesi, Solen Residance Apt.No:19/1/11  
Bagcilar/Istanbul/TURKEY

### **Manufacturer:**

Arımed İlaç San. ve Tic A.Ş.  
Cumhuriyet Mah. Vize Caddesi No:102 Cakilli, Vize/Kirklareli

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