

AIRPLUS INHALATION POWDER

Salmeterol/fluticasone propionate (50/100mcg, 50/250mcg, 50/500mcg)

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What *Airplus* is used for

Airplus is used in treatment of asthma and chronic obstructive pulmonary disease (COPD).

How *Airplus* works

Airplus contains salmeterol and fluticasone propionate. Salmeterol works by relaxing the airway tubes. Fluticasone propionate reduces inflammation within the lungs to reduce symptoms and asthma attacks.

Before you use *Airplus*

- When you must not use it

Do not use *Airplus* if:

- You are allergic to salmeterol, fluticasone propionate or any of the ingredients in this product.
- Some medicines may increase the effects of *Airplus* and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

Pregnancy and lactation

Do not take *Airplus* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Airplus* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor before using *Airplus* if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure

- Diabetes mellitus (*Airplus* may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now, or in the past, or other lung infections

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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

- 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 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 *Airplus*, 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

How to use *Airplus*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

For asthma

Adults and adolescents aged 12 years and over

- *Airplus* 50/100 - One inhalation twice a day
- *Airplus* 50/250 - One inhalation twice a day
- *Airplus* 50/500 - One inhalation twice a day

Children 4 to 12 years of age

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

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- *Airplus* 50/500 - One inhalation twice a day

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Airplus* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much dose may cause your heart beating faster than usual and that you feel shaky. You may also have dizziness, a headache, muscle weakness and aching joints.

While you are using it**- Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Airplus*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Airplus* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines
Airplus is not likely to affect your ability to drive or use machines.

Side effects

Like all medicines, *Airplus* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common side effects:

- Headache
- Colds

Common side effects:

- infection of the mouth, throat and lung
- inflammation of airway tube
- low potassium level
- throat irritation
- hoarseness
- inflammation of sinuses
- Bruising and fractures
- Aching, swollen joints and muscle pain.
- Muscle cramps.

Possible Side Effects:

Pneumonia (infection of the lung) in COPD patients (common side effect)

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

- Fever or chills;
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties.

Uncommon side effects:

- Increases in the amount of sugar in your blood.
- Cataract (cloudy lens in the eye).
- Very fast heart beat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heart beat (palpitations)
- Chest pain
- Feeling worried
- Disturbed sleep.
- Allergic skin rash.

Rare side effects:

- Breathing difficulties or wheezing that get worse straight after taking *Airplus*.
- Slowing of growth in children and adolescents
- Thinning of the bones
- Glaucoma
- Weight gain
- Rounded (moon shaped) face (Cushing's Syndrome)
- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *Airplus***- Storage**

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

AIRPLUS 50/100mcg inhalation powder

The powder contained within a blister held within a plastic inhaler of white body and light pink coloured mouthpiece cover.

AIRPLUS 50/250mcg inhalation powder

The powder contained within a blister held within a plastic inhaler of white body and pink coloured mouthpiece cover.

AIRPLUS 50/500mcg inhalation powder

The powder contained within a blister held within a plastic inhaler of white body and mauve coloured mouthpiece cover.

- Ingredients

- Active ingredients
Salmeterol
Fluticasone propionate
- Inactive ingredients
Lactose monohydrate

- MAL numbers:

AIRPLUS 50/100mcg inhalation powder: MAL21036026AZ

AIRPLUS 50/250mcg inhalation powder: MAL21036027AZ

AIRPLUS 50/500mcg inhalation powder: MAL21036028AZ

Manufacturer

Neutec Inhaler Ilac Sanayi ve Ticaret A.S.

Turkey, Sakarya, Arifiye, 1. Organize Sanayi Bolgesi,
2 Nolu Yol No: 3

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22,
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47301 Petaling Jaya, Selangor,
Malaysia

Date of revision

26/08/2024

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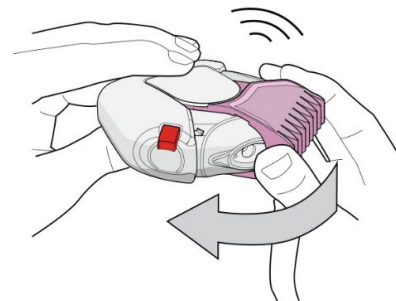
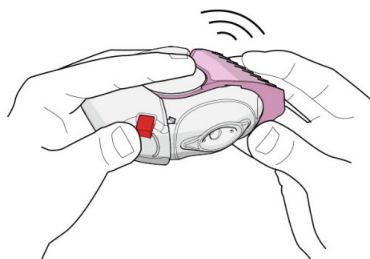
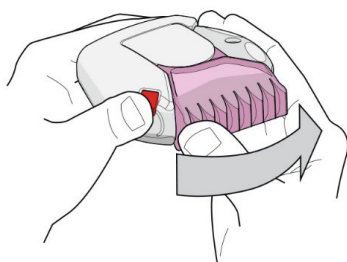
Instructions for use

- 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 Airplus Discair properly or as prescribed may mean that it will not help your asthma or COPD as it should.
- The inhalation device holds blisters containing the medication as a powder.
- There is a counter on top of the Accuhaler which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty.

Using your inhaler

1. Opening

To open the inhalation device and make it ready for inhalation, press the red button to remove the outer cover. Hold the inhalation device so that the mouthpiece is facing you. The inhalation device is now ready for use. At each opening of the outer lid, one dose is ready for inhalation. This is seen in the dose indicator. Do not play with the outer lid to avoid losing the medication.



2. Inhaling

You should read this section carefully before you take the medicine.

- Keep the inhalation device away from your mouth. Breathe out as much as you can.

Remember - never breathe out into the inhalation device.

- Rest your lips to the mouthpiece. Breathe-in long and deeply through the mouth – do not breathe from your nose.



- Remove the inhaler from your mouth.
- Hold your breath for 10 seconds or as long as you can comfortably hold it.
- Breathe out slowly through the nose.

3. Closing

- To close the inhaler, you only need to slide the outer lid to its original position.
- The inhalation device is ready for reuse.

If you are advised to take two inhalations, you should repeat steps 1 through 3.

REMEMBER!

Keep the inhalation device dry.
Keep it closed when not in use.
Never breathe out into the inhalation device.
Open the outer cover when you are ready to take the medication.
Do not take more than the mentioned dose.