

PACKAGE LEAFLET: INFORMATION FOR THE USER

FIXCORT 4.5/160 mcg Capsair Inhalation Powder

Do not swallow. Inhaled orally.

- **Active substances:** Each capsule containing powder for inhalation contains 4.5 mcg formoterol fumarate dihydrate and 160 mcg budesonide.
- **Excipient:** Lactose

Read all of this PACKAGE 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 only you. Do not pass it on to others.*
- *During the use of this medicine, inform your doctor that you are using this medicine when you go to the doctor or hospital.*
- *Adhere strictly instructions in this leaflet. Do not use **high** or **low** doses other than the recommended dose.*

What is in this leaflet:

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

1. What FIXCORT is and what it is used for?

FIXCORT is an inhaler. It contains: budesonide and formoterol fumarate dihydrate.

- Budesonide is included in a group of medicines called “corticosteroids”. It works by reducing and preventing swelling and inflammation in your lungs.
- Fixcort 4.5/160 mcg Capsair Inhalation Powder is presented for use with 60 and 120 capsules, in blister packages, and 1 inhalation device containing powder for inhalation.
- Formoterol fumarate dihydrate belongs to the group of drugs called “long-acting beta-agonists” or “bronchodilators”. It works by relaxing the muscles in your respiratory tract. This allows you to breathe easier.
- Your doctor has prescribed this medicine for you to treat your asthma or chronic obstructive pulmonary disease (COPD).

Asthma

FIXCORT is used to correct and control asthma symptoms. It is given from the 3rd step in the stepwise treatment of asthma.

FIXCORT can be prescribed for asthma in two different ways:

a) **Some people are prescribed two asthma inhalers: FIXCORT and a separate ‘reliever inhaler’.**

- They use FIXCORT every day. This helps to prevent asthma symptoms.
- They use their ‘reliever inhaler’ when they get asthma symptoms, to make it easier to breathe again.

b) **Some people are prescribed FIXCORT as their only asthma inhaler.**

- They use FIXCORT every day. This helps to prevent asthma symptoms.
- They also use FIXCORT when they need extra doses for relief of asthma symptoms, to make it easier to breathe again. They do not need a separate inhaler for this.

Chronic Obstructive Pulmonary Disease (COPD)

It reduces the symptoms and frequency of attacks in moderate and severe COPD cases. COPD is a long-term disease of the airways and lungs, mostly caused by smoking.

2. What you need to know before you take FIXCORT

DO NOT take FIXCORT:

If;

1. You are allergic (hypersensitive) to budesonide, formoterol, or the other ingredient, which is lactose (which contains small amounts of milk proteins).
2. Primary treatment of status asthmatics or acute episodes of asthma or COPD requiring intensive measures.

TAKE SPECIAL CARE with FIXCORT in the conditions listed below:

If any of the following apply to you, consult your doctor or pharmacist before you start using FIXCORT:

- You are diabetic.
- You have a lung infection.
- You have high blood pressure or you have ever had a heart problem (including an uneven heart beat, a very fast pulse, narrowing of the arteries or heart failure).
- You have problems with your thyroid or adrenal glands.
- You have low levels of potassium in your blood.
- You have severe liver problems.

Please consult your doctor if these warnings apply to you, even at any time in the past. It may take 2 weeks to see the full effective.

Pregnancy

Pregnancy category C. Consult your doctor or pharmacist before using this medicine.

If you are pregnant, or planning to get pregnant, talk to your doctor before using FIXCORT - do not use FIXCORT unless your doctor tells you to.

If you get pregnant while using FIXCORT, do not stop using FIXCORT but talk to your doctor immediately.

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

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

If you are breast-feeding, talk to your doctor before using FIXCORT

Driving and using machines

FIXCORT has no or negligible effect on your ability to drive or to use machines.

Important information about some of the excipients of FIXCORT

FIXCORT does not contain any excipients that require special warning.

Using together with other drugs

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Beta-blocker drugs (such as atenolol or propranolol) used to treat high blood pressure, including eye drops (such as timolol) used to treat increased intraocular pressure (glaucoma)
- Medicines used for fast and irregular heartbeats (such as quinidine)
- Medicines mostly used in the treatment of heart failure (such as digoxin)
- Diuretics (such as furosemide) used in the treatment of high blood pressure
- Oral steroid drugs (such as prednisolone)
- Xanthine drugs used in the treatment of asthma (such as theophylline or aminophylline)
- Other airway expanders (such as salbutamol),
- Tricyclic antidepressants and monoamine oxidase inhibitors used in the treatment of depression and anxiety (such as amitriptyline),
- Phenothiazine derivative drugs (such as chlorpromazine and prochlorperazine) used in the treatment of serious mental illnesses
- Some drugs used in the treatment of HIV (AIDS) (such as the protease inhibitor ritonavir)
- Drugs used in the treatment of fungi (such as itraconazole, voriconazole, posaconazole and ketoconazole)
- Medicines used in Parkinson's disease (such as levo-dopa)
- Medicines used in the treatment of diseases and dysfunctions of the thyroid gland (such as levo-thyroxine)
- Antibiotics (such as clarithromycin and telithromycin)
- Furazolidone, procarbazine, monoamino oxidase inhibitors, alcohol, oxytocin,
- Terfenadine, disopyramide
- Beta₂-agonist (drugs that stimulate Beta₂ receptors)
- Anesthetic drugs in the structure of halogenated hydrocarbons (containing the active substances isoflurane, desflurane, chloroform, trichloroethylene, halothane, enflurane and sevoflurane)

If any of the above apply to you or you are unsure, consult your doctor or pharmacist before using **FIXCORT**.

Also, tell your doctor or pharmacist if you are going to receive general anesthesia for surgery or dental treatment..

If you are currently using any prescription or non-prescription medication, or if you have used it recently, please inform your doctor or pharmacist about them.

3. How to use FIXCORT

- **Instruction for proper use and dose/administration frequency:**
 - Always use FIXCORT exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- It is important to use FIXCORT every day, even if you have no asthma symptoms at the time.
- Your doctor will want to regularly check your asthma symptoms.

If you have a steroid tablet for your asthma or COPD, your doctor may reduce amount of tablets you take when you start using FIXCORT. If you have been taking an oral steroid tablet for a long time, your doctor may order some blood tests from time to time. While the oral steroid tablets are being tapered, you may feel generally unwell, and you may even experience improvement in your chest symptoms. You may experience symptoms such as runny or stuffy nose, joint weakness, muscle pain, rash or eczema. If any of these symptoms bother you or if you experience headache, tiredness, nausea, vomiting, contact your doctor immediately. If you develop symptoms of allergies or arthritis, you may need to take another medicine. You should talk to your doctor about continuing to use FIXCORT.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using FIXCORT , you should continue to use FIXCORT but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor **IMMEDIATELY** if:

- Your breathing is getting worse or you often wake up at night with asthma.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your asthma is not being properly controlled and you may need different or additional treatment immediately

Asthma

FIXCORT can be prescribed for asthma in two different ways. The amount of FIXCORT to use and when to use it depends on how it has been prescribed for you.

- a. If you have been prescribed FIXCORT and a separate reliever inhaler, read the section called “a) Using FIXCORT and a separate reliever inhaler”.
- b. If you have been prescribed FIXCORT as your only inhaler, read the section called “b) Using FIXCORT as your only asthma inhaler”.

a) Using FIXCORT and a separate reliever inhaler

Use your FIXCORT every day. This helps to prevent asthma symptoms from happening.

Adults (18 years and above)

- The usual dose is 1 or 2 inhalations, twice a day.
- The maximum recommended dosage in adult and adolescent patients 12 years and older is budesonide/formoterol 160/4.5, two inhalations twice daily.
- More frequent administration or a higher number of inhalations (more than 2 inhalations twice daily) of the prescribed strength of medicine is not recommended as some patients are more likely to experience adverse effects with higher doses of formoterol.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Your doctor (or asthma nurse) will help you to manage your asthma. They will adjust the dose of this medicine to the lowest dose that controls your asthma. However, do not adjust the dose without talking to your doctor (or asthma nurse) first.

Use your separate ‘reliever inhaler’ to treat asthma symptoms when they happen. Always keep your ‘reliever inhaler’ with you to use when you need it. Do not use FIXCORT to treat asthma symptoms - use your reliever inhaler.

b) Using FIXCORT as your only asthma inhaler

Only use FIXCORT in this way if your doctor has told you to and if you are aged 18 or above. Use FIXCORT every day. This helps to prevent asthma symptoms from happening.

You can take:

- 1 inhalation in the morning and 1 inhalation in the evening
or
- 2 inhalations in the morning
or
- 2 inhalations in the evening.

Your doctor may increase this to 2 inhalations twice a day.

Also use FIXCORT as a ‘reliever inhaler’ to treat asthma symptoms when they happen.

- If you get asthma symptoms, take 1 inhalation and wait a few minutes.
- If you do not feel better, take another inhalation.
- The maximum recommended dosage in adult and adolescent patients 12 years and older is budesonide/formoterol 160/4.5, two inhalations twice daily.

Always keep your FIXCORT with you, so you can use it when you need it.

- The maximum recommended dosage in adult and adolescent patients 12 years and older is budesonide/formoterol 160/4.5, two inhalations twice daily.

If you are doing exercise and you get asthma symptoms, use FIXCORT as described here. However, do not use FIXCORT just before exercise to stop asthma symptoms from happening.

Chronic Obstructive Pulmonary Disease (COPD)

- To be used only in adults (18 years and over)
- The recommended dose is 2 inhalations twice a day.

• Administration route and method:

Use FIXCORT by mouth as inhalation.

The medicine reaches your lungs when you breathe in through the inhaler. Therefore, it is important to breathe deeply and forcefully through the mouthpiece of the device.

The use of the inhaler will be shown to you by the doctor or another healthcare professional.

Do not swallow capsules. Capsules should only be used with the inhaler (device) in the box. This device is specially designed for use with Fixcort 4.5/160 mcg Capsair Inhalation Powder.

- Powder in capsules will only be used by inhalation (by breathing).
- Take capsules out of the foil pack just before use. Make sure your fingers are dry so that capsules do not get wet.
- Do not use capsules with any device other than the device in the box.
- Using FIXCORT at same time every day will help you remember when to use your medicine.
- It is important that you use FIXCORT regularly, according to your doctor's instructions.
- If you have questions about how long to use FIXCORT, ask your doctor or pharmacist.

Detailed information on use is available in the instructions for use. For the correct use of the inhaler, carefully follow the rules given below.

Questions and Answers Related to the Application

1. How can I prevent the capsules from breaking into small particles?

During device use, the capsules may break and may escape into your mouth or throat while you are breathing. You can prevent this by applying the following:

- Keep the capsules in the original packaging (blister packs) before using.
- Store the capsules at room temperature below 25 ° C.
- Protect the capsule from moisture.

2. Are the capsule particles harmful?

No. The capsule is made of edible gelatin which is harmless to human. Gelatin particles escaping from your mouth or throat could be swallowed.

3. How can I remove the capsule that is stuck in the capsule reservoir?

Open the device, turn it upside down and gently tap the bottom.

4. How can I be sure that I really take the dose or not?

- You will detect the vibrates of capsule when you breathe.
- You will feel ‘sugar taste’ in your mouth caused by lactose. You can feel the powder on the back your throat. This is normal.
- The capsule will be empty when the dose is taken.

5. How can I clean the powder remaining inside the device?

- Use a dry cloth or a soft brush.
- You should not forget that you should never wash the device.

Different age groups:

Use in children:

Adolescents (12 to 17 years)

- The usual dose is 1 or 2 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

A lower strength of FIXCORT is available for children aged from 6 to 11 years.

Use in elderly:

Use in elderly is same as adults.

Special cases:**Renal failure:**

Formal pharmacokinetic studies have not been conducted in patients with renal impairment.

Liver failure:

Systemic bioavailability may increase in patients with hepatic impairment. Since both budesonide and formoterol fumarate are predominantly cleared by hepatic metabolism, impairment of liver function may lead to accumulation of budesonide and formoterol fumarate in plasma. Therefore, patients with hepatic disease should be closely monitored.

It is recommended that the dose is gradually reduced when the treatment is discontinued. Treatment should not be stopped abruptly

Worsening or acutely deteriorating asthma is a life-threatening condition, it requires urgent medical control

You should have their rescue inhaler available at all times, either FIXCORT (for patients using FIXCORT as maintenance and reliever therapy) or a separate rapid-acting bronchodilator (for patients using FIXCORT as maintenance therapy only)

You should take the FIXCORT maintenance dose as prescribed by your doctor, even when you do not have symptoms.

Once asthma symptoms are controlled, your doctor may reduce your FIXCORT dose gradually.

Your doctor will monitor you closely during the first 3 months of treatment. Serious asthma-related side effects and exacerbations may occur during treatment with FIXCORT. You should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of FIXCORT.

The risk of pneumonia may increase in elderly patients who are combined with inhaled steroids. Clinical evidence for the advantage of high-dose use in COPD is insufficient.

If you have the impression that the effect of FIXCORT is either too strong or too weak, discuss this with your doctor or pharmacist.

If you use more FIXCORT than you should

If you have used more FIXCORT than you should, talk to your doctor or pharmacist immediately.

The most common symptoms that may occur if you use more FIXCORT than you should are trembling, headache or a rapid heartbeat.

If you forget to use FIXCORT

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

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

4. Possible side effects

Like all medicines, side effects may develop in patients which are sensitive to any ingredient of FIXCORT.

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

If either of the following happen to you, stop using FIXCORT and talk to your doctor IMMEDIATELY or go to the emergency department at your nearest hospital:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty swallowing) or hives together with difficulty breathing (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. This happens very rarely, affecting less than 1 in 10,000 people.

These are very serious side effects. If you have any of these effects, you may need urgent medical attention.

Other possible side effects:

Side effects are listed in the following categories:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people, more than 1 in 100 people.

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Unknown: Cannot be estimated from the available data

Common (affects less than 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use FIXCORT.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your FIXCORT.
- Mild sore throat, coughing and a hoarse voice.
- Headache.

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

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

- Fever or chills
- Increase in mucus production, change in mucus color
- Increased cough or increased difficulty breathing

Uncommon (affects less than 1 in 100 people)

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heart beat.
- Bruising of the skin.
- Muscle cramps.

Rare (affects less than 1 in 1,000 people)

- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using FIXCORT stop using and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heart beat.

Very rare (affects less than 1 in 10,000 people)

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.
- An abnormal electrical signal in the heart (QTc interval prolongation)
- Cushing syndrome (an adrenal gland disease, that causes weight gain, round ‘moon face’, high blood pressure and excess hair development, due to high levels of cortisol in the blood)
- Cataract (clouding of the lens in the eye)
- Glaucoma (increased pressure in the eye)

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- Changes in bone mineral density (thinning of the bones)

- Cataract (clouding of the lens in the eye)
- Glaucoma (increased pressure in the eye)
- Slowing of the rate of growth of children and adolescents
- An effect on the adrenal gland.

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store FIXCORT

Keep FIXCORT and its package out of the reach and sight of children.

Store at room temperature below 25°C.

Store with the mouthpiece down.

Use it properly accordance to the expiry date

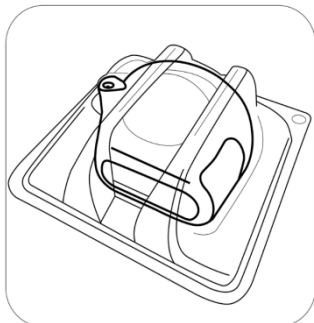
Do not use FIXCORT after the expiry date on the packaging.

Do not use FIXCORT if you notice defects in the product and / or packaging.

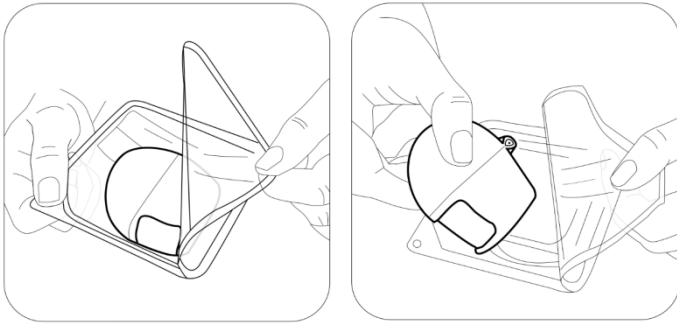
Inhaler instructions for use:

Inhaler is for you to inhale (inhale) the medicine in the FIXCORT inhaler capsule that your doctor has prescribed for your respiratory problems.

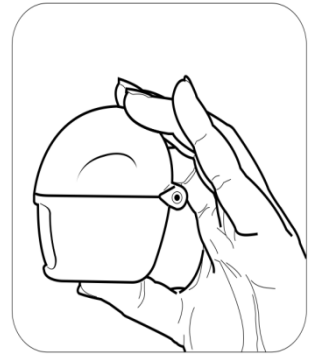
Inhaler, which is presented to the market in a cardboard box, is placed in a protective packaging for safety purposes.



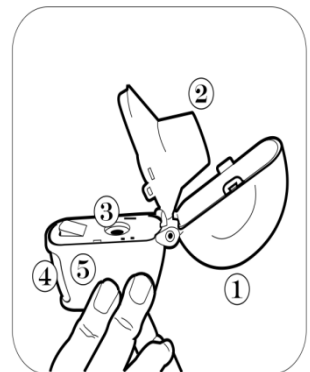
Please take out your device from the package before using as shown at figure.



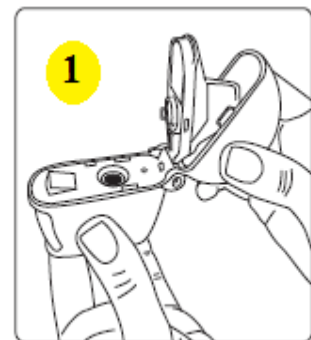
When using FIXCORT , be sure to follow your doctor's instructions carefully. The inhaler is an inhaler specially designed for the inhalation of the FIXCORT inhaler capsule. It should not be used to take any other medication.



1. Powder cap
2. Mouthpiece
3. Central reservoir
4. Drill button
5. Bottom reservoir



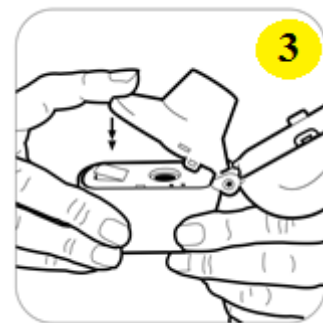
1. Open the powder cap completely by pulling it upward and then open the mouthpiece by pulling it upward.



2. Take a FIXCORT inhaler capsule from the blister pack (it should be removed just before use.) and place it in the central chamber as shown in the figure (2). It does not matter which direction the capsule is placed in the chamber.



3. Close the mouthpiece tightly until it “clicks”. Leave the powder cap open.



4. Keep the inhaler device upright and push the drilling button only a single motion and leave. Thus holes will be opened in the capsule and will allow the drug to be released when you breathe.



5. Breathe out fully.

Important: Please do not breathe into the mouthpiece at any time.



6. 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.

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 5 and 6.



7. Open the mouthpiece again. Turn the device and discard the used capsule. If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a dry cloth or a clean soft brush. Close the mouthpiece and powder cap and leave your device.



NOTE: DO NOT use water to clean the inhaler.

The capsules should not be exposed to extreme temperatures.

Fixcort 4.5/160 mcg Capsair Inhalation Powder contain a small amount of a powder; therefore, capsules are only partially filled.

Marketing Authorization Holder: Vitalis Ilac San. Tic. A.S.
Esenler/ISTANBUL/TURKEY

Manufacturer: Neutec Inhaler Ilac San. ve Tic. A.S.
Arifiye/ SAKARYA/TURKEY