

TASARIM KODU LBFTCR45160KT01	A B △	A : 190 mm B : 490 mm KAĞIT : 1.Hamur MARKASI : Edixion GRAMAJI : 45 gr/m²	Black	HAZIRLAYAN: Murat AKAR Grafik Tasarım
ÜRÜN ADI Fixcort 4,5/160 mcg Capsair				
ÜRÜN CİNSİ Kullanma Talimatı				

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)

• 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, monoamine oxidase inhibitors, alcohol, oxytocin,

• Terfenadine, disopyramide

• Beta,-agonist (drugs that stimulate Beta, 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.

ONAYLAR (İsim, Görev, Tarih, İmza)	
KONTROL EDEN	YÜRÜRLÜK ONAYI

