



PACKAGE LEAFLET

COSEBLAR 85 mcg / 43 mcg Hard Capsules with Inhalation Powder

It is used by inhalation (breathing through the mouth).

Active substances : Each hard capsule contains 143 mcg of indacaterol maleate equivalent to 110 mcg of indacaterol, and 63 mcg of glycopyrronium bromide equivalent to 50 mcg of glycopyrronium.

Excipients : Lactose monohydrate (Inhalac 230) (from bovine milk), lactose monohydrate (Inhalac 400) (from bovine milk), HPMC Capsules (No:3): hypromellose, tartrazine- FD&C Yellow 5.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. See the end of section 4 for how to report side effects.

Read 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.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *During the use of this medicine, tell your doctor that you are taking this medicine when you go to the doctor or hospital.*
- *Follow these instructions exactly. Do not use a **higher** or a **lower** dose than recommended.*

What is in this leaflet:

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

1. WHAT COSEBLAR IS AND WHAT IT IS USED FOR

This medicinal product contains two active substances called indacaterol and glycopyrronium. They belong to a group of medicines called bronchodilators.

COSEBLAR is packaged in blister packs. Blisters of 30 or 90 hard capsules are supplied with a monodose dry powder inhaler in a plastic separator, in a cardboard box.

This medicine is used in order to facilitate the respiration in patients with breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD). In COPD patients, the muscles surrounding the respiratory tract becomes constricted, causing difficulty breathing. This medicine blocks this constricting effect on those muscles surrounding the respiratory tract, thus, facilitates it for air to move in and out of the lungs.

If you use this product once daily, it will help reduce your COPD symptoms in your daily life.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE COSEBLAR

DO NOT USE COSEBLAR in the following cases:

- If you are allergic to glycopyrronium bromide or indacaterol maleate or any of the other ingredients of this product (listed in section 'Excipients' above).



USE COSEBLAR CAREFULLY in the following cases:

Tell your doctor, pharmacist or nurse before taking COSEBLAR if:

- You have asthma - this medicine should not be used as a treatment for asthma
- You have heart problems
- You have experienced a stroke or seizures
- You have thyroid gland problems (thyrotoxicosis)
- You have diabetes
- You are using medicines containing the active substances similar to those of COSEBLAR (from the same class) for your lung disease (see section "Other medicines and COSEBLAR")
- You have kidney problems
- You have severe liver problems
- You have an eye problem called narrow-angle glaucoma
- You have difficulty urinating

Even if such warnings were present for any period in the past, please consult your doctor.

Asthma-related breathing problems associated with long-acting beta-agonist preparations (formoterol, salmeterol, etc.) can rarely occur, which can be serious and sometimes fatal.

COSEBLAR is not recommended for the initial treatment of asthma.

Long-acting beta agonists (formoterol, salmeterol, etc.) should be used for the shortest duration that allows a control in asthma symptoms and your doctor will discontinue the use, if possible, once the control is achieved. Your doctor will then ensure continuity with a control treatment.

If you are a pediatric or adolescent patient on a treatment with a long-acting beta agonist (formoterol, salmeterol, etc.) in addition to an inhaled corticosteroid (ciclesonide, fluticasone, budesonide, etc.), your doctor will advise you to use a combination preparation containing both inhaled corticosteroid (ciclesonide, fluticasone, budesonide, etc.) and long-acting beta agonist (formoterol, salmeterol, etc.) to ensure compliance with both medications.

Treatment with long-acting beta-agonists (formoterol, salmeterol, etc.) should not be initiated if you are in an exacerbation or have significantly or acutely worsening asthma symptoms.

Using COSEBLAR with food and drinks

You can use COSEBLAR at any time before or after a meal.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

There are no data on the use of this medicine in pregnant women. Indacaterol, one of the active substances of COSEBLAR, can prevent labor because of its effect on the uterus.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. You should not use COSEBLAR unless your doctor tells you to.

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

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

It is not known whether the active substances in COSEBLAR are excreted in breast milk.

If you are breast-feeding your baby, tell your doctor or pharmacist before using this medicine.

You should not use COSEBLAR without consulting your doctor.

Driving and using machines

This medicine is unlikely to affect your ability to drive and use machines. However, it may cause drowsiness, including dizziness (see section 4). If you experience dizziness while taking this medicine, do not drive or operate machinery.

Important information about some excipients found in the content of COSEBLAR

COSEBLAR does not contain any excipients that require warning.

Other medicines and COSEBLAR

Tell your doctor or pharmacist if you are taking, have recently taken or may take any other medicines. Tell your doctor or pharmacist, especially if you use:

- Any medicine similar to COSEBLAR (containing similar active substances)
- Medicines called beta-blockers, which can be used to treat high blood pressure or other heart problems (e.g. propranolol) or to treat an eye condition called glaucoma (e.g. timolol)
- Medicines that reduce the amount of potassium in your blood. These include the following:
 - Steroids (e.g. prednisolone)
 - Diuretics (water pills) used for high blood pressure (e.g. hydrochlorothiazide)
 - Medicines for breathing problems (e.g. theophylline)

3. HOW TO USE COSEBLAR

Instructions for proper use and dose/frequency of administration

Always take this medicine exactly as directed by your doctor or pharmacist.

If you are not sure, ask your doctor or pharmacist.

The usual daily dose is taken by oral inhalation of the contents of 1 capsule only.

Since the effect of this medicine lasts for 24 hours, inhalation should be done only once a day.

Do not take more medicines than your doctor has told you.

Use COSEBLAR at the same time each day. This will also help you remember your medicine.

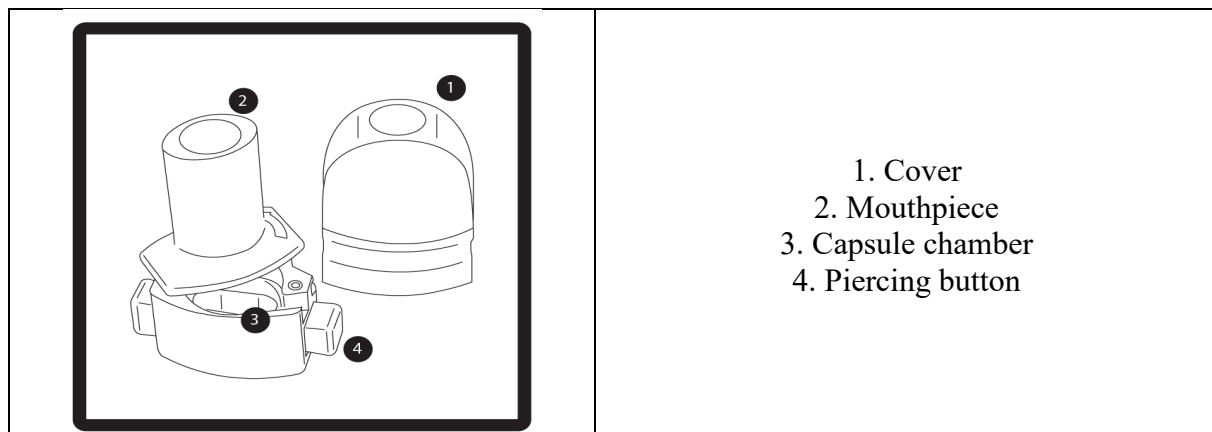
Route and method of administration

COSEBLAR is used by oral inhalation only. Each COSEBLAR package includes:

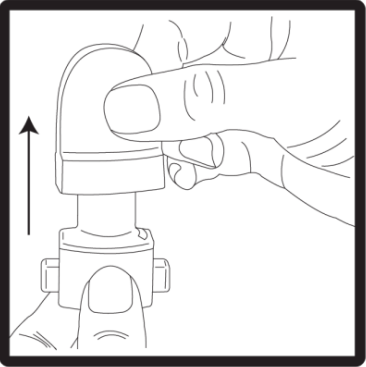

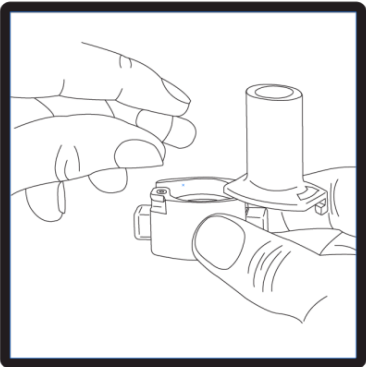

- A monodose dry powder inhaler
- One or more blisters containing COSEBLAR capsules to be used in the inhaler

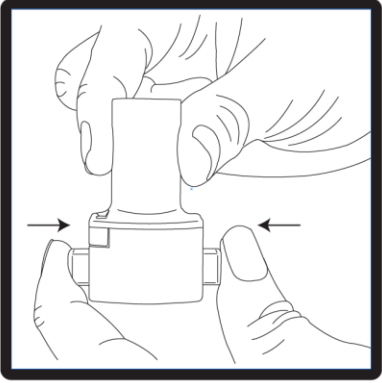
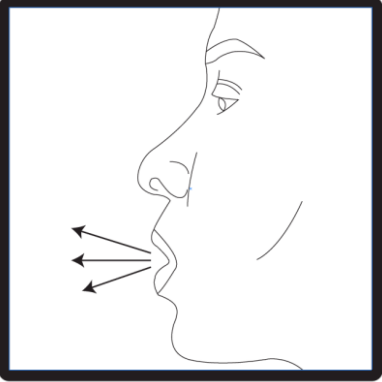

Only use the inhaler device given in the COSEBLAR box. Do not use COSEBLAR capsules with another inhaler or do not use the COSEBLAR inhaler to take another medicine's capsules.

- Discard the inhaler after every 30 days of use. Ask your pharmacist how to dispose of medicines and inhalers that are no longer needed.
- **Do not swallow the capsules.** Only the powder inside the capsules is for inhalation.



Instructions for use

	<p>1. Pull the cover off.</p>
	<p>2. While holding the bottom of the device firmly, open the mouthpiece by turning it in the direction of the arrow.</p>
	<p>3. Remove the capsule out of its package right before use. Place a capsule into the capsule shaped chamber at the bottom of the device.</p>
	<p>4. Turn the mouthpiece to close it.</p>

	<p>5. Hold the device upright (with the mouthpiece up) and press the tabs on the side ONLY ONCE simultaneously. After the capsule is pierced, release the side tabs. Please note: The capsule can be broken into pieces during this process and there is a possibility that small capsule pieces escape into mouth and throat during inhalation. Capsule fragments are harmless. Removing the capsule from its package just before use and pushing the tabs at sides only once for piercing the capsule minimize the risk of capsule being broken into pieces (see Step 3).</p>
	<p>6. Blow your breath away strongly.</p>
	<p>7. Place the mouthpiece in your mouth and tilt your head back slightly. Close your lips tightly around the mouthpiece and inhale as quickly and deeply as possible. You will hear a "buzz" sound because of the capsule rotating in its chamber during powder dispersion. If you did not hear that sound, the capsule could have been stuck in its chamber. If that is the case, open your device, and dislocate the capsule in its chamber and loosen it. DO NOT PUSH the buttons more than once in order to loosen the capsule.</p>
<p>8. Hold your breath: While removing the inhaler from your mouth, hold your breath for 5 to 10 seconds or for as long as possible. Then exhale. Open the inhaler to check that no powder remains in the capsule. If powder remains in the capsule, turn off the inhaler and repeat the steps 6, 7 and 8. Most patients can empty the capsule in one or two inhalations. Some people rarely cough for a short time after inhaling the medicine. Do not worry if you cough. As long as the capsule is empty, you will receive the full dose of your medicine.</p>	
<p>9. Discard the empty capsule after using it and close the mouthpiece.</p>	



REMEMBER:

- **Do not swallow COSEBLAR capsules.**
- **Only use the inhaler provided in the COSEBLAR box.**
- COSEBLAR capsules should be stored in their blisters and only removed just before use.
- Never insert a COSEBLAR capsule directly into the mouthpiece of the COSEBLAR inhaler.
- Do not press the side buttons more than once.
- Do not blow into the mouthpiece of the COSEBLAR inhaler.
- Release the side buttons before inhalation. They should not be pressed during inhalation.
- Never wash the COSEBLAR inhaler with water. Keep it dry. See "Cleaning the inhaler".
- Do not disassemble the COSEBLAR inhaler.
- Use the new COSEBLAR inhaler that comes in each new COSEBLAR box.
- Do not store the capsules inside the COSEBLAR inhaler.
- Always store the COSEBLAR inhaler and COSEBLAR capsules in a dry place.

Additional information

Occasionally, very small pieces of the capsule can get past the screen and enter your mouth. If this happens, you may be able to feel these pieces on your tongue. It is not harmful if these pieces are swallowed or inhaled. The chances of the capsule shattering will be increased if the capsule is pierced more than once (see Step 5).

Cleaning the inhaler

Never wash the inhaler with water. If you want to clean it, wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry.

Different age groups

Use in children

Do not give this medicine to children or adolescents under 18 years of age. Because this medicine has not been studied in this age group.

Use in the elderly

If you are 75 years of age or older, you can use this medicine at the same dose as other adults.

Special conditions for use

Kidney / Liver failure

For kidney/liver patients, **consult a doctor, pharmacist or nurse before using COSEBLAR.**

If you use more COSEBLAR than you should

If you have used more COSEBLAR than you should, talk to a doctor or pharmacist.

If you take too much from this medicine or if someone else accidentally uses your capsules, you should promptly either tell your doctor or go to the nearest emergency room and show the COSEBLAR package. Medical intervention may be required. You may experience your heart beating faster than normal, headache, drowsiness, nausea, vomiting, visual disturbances, constipation, difficulty urinating.

If you forget to take COSEBLAR

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

If you forget to receive your dose, inhale a dose as soon as possible on the same day. However, do not inhale two doses on the same day. Then receive the next dose as usual.



Possible effects when treatment with COSEBLAR is discontinued

Continue using COSEBLAR for as long as your doctor tells you to.

COPD is a long-term disease and you should take COSEBLAR **every day**, not just when you have breathing problems or other symptoms of COPD.

If you have any questions about how long you should continue your treatment with this medicine, talk to your doctor or pharmacist.

If you have any other questions about COSEBLAR, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, COSEBLAR may cause side effects in people sensitive to its ingredients.

If any of the following occurs, stop using COSEBLAR and IMMEDIATELY inform your doctor or go to the emergency service of the nearest hospital:

- Eye pain or discomfort, temporary blurring of vision, seeing halos or colored images in the eye with redness - these can be symptoms of an acute attack of narrow-angle glaucoma
- Difficulty breathing or swallowing; swelling of your tongue, lips and face; skin rash, itching and hives (signs of an allergic reaction)
- Tightness in your chest, coughing, wheezing or shortness of breath immediately after taking this medicine - these may be symptoms of a condition called paradoxical bronchospasm
- In case your COPD symptoms such as shortness of breath, wheezing or coughing do not get better or get worse

COSEBLAR is used in your ongoing treatment for COPD. It should not be used for sudden attacks of breathing difficulty and wheezing.

These are all very serious side effects. If you have any of them, it means that you have serious allergy to COSEBLAR. You may need urgent medical attention or hospitalization.

Side effects are listed as shown in the following categories:

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

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

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

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

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

Not known : frequency cannot be estimated from the available data.

Some side effects can be serious:

Common

- Difficulty breathing or swallowing; swelling of the tongue, lips and face; urticaria, skin rash - these can be signs of an allergic reaction
- Feeling tired or extremely thirsty, increased appetite without weight gain and urinating more than usual - these can be signs of high levels of sugar in the blood (hyperglycemia)

Uncommon

- Crushing chest pain accompanied by increased sweating - this can be a sign of a serious heart problem (ischemic heart disease – a heart disease in which blood flow to any tissue or organ in the body is reduced or cut off)
- Swelling, especially of the tongue, lips and throat (possible signs of angioedema)
- Difficulty breathing with coughing and wheezing
- Eye pain or discomfort, temporary blurring of vision, seeing halos or colored images in the eye with redness - these can be signs of glaucoma
- Irregular heartbeats

If you experience any of these serious side effects, **contact your doctor immediately.**



Other side effects may include the following:

Very common

- Stuffy nose, sneezing, coughing, headaches with or without fever - these can be symptoms of an upper respiratory tract infection

Common

- Runny nose with sore throat - may be a sign of nasopharyngitis
- Painful and frequent urination - can be a sign of a urinary tract infection called cystitis
- A feeling of pressure or pain in the cheeks and forehead – this may be a sign of inflammation of the sinuses, called sinusitis
- Runny or stuffy nose
- Dizziness
- Headache
- Cough
- Sore throat
- Discomfort in the stomach, indigestion
- Dental caries
- Difficulty and pain when urinating - may be a sign of bladder obstruction or a buildup of urine in the bladder
- Fever
- Chest pain

Uncommon

- Difficulty falling asleep
- Heartbeat acceleration
- Palpitations - a symptom of abnormal heartbeat
- Change in voice (thickening)
- Nosebleeds
- Diarrhea and abdominal pain
- Dry mouth
- Itching or rash
- Pain in muscles, ligaments, tendons, joints and bones
- Muscle spasms
- Muscle pain, soreness or tenderness
- Pain in the arms or legs
- Swelling of the hands, ankles and feet
- Fatigue

Rare

- Tingling or numbness

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

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.



5. HOW TO STORE COSEBLAR

Keep COSEBLAR out of the reach and sight of children and in its original package.

Store at room temperature below 25°C.

In order to protect the capsules from moisture, keep them in blister packs and remove only immediately before use.

Do not use COSEBLAR after the expiry date stated on the cardboard box.

Use according to its expiry date.

Do not use COSEBLAR after the expiry date on the package.

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.

Marketing Authorization Holder:

DEVA Holding A.Ş.

Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturer:

DEVA Holding A.Ş.

Kapaklı – TEKİRDAĞ / TÜRKİYE

This package leaflet was approved on 13/12/2021.