



INSTRUCTIONS FOR USE OF THE ENERZAIR BREEZHALER
Please read the full set of **Instructions for Use** before using Enerzair Breezhaler.



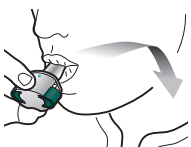
Insert

1




Pierce and release

2



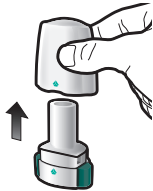
Inhale deeply

3

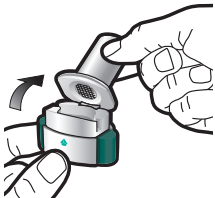


Check capsule is empty

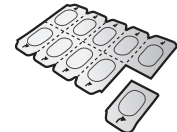
Check




Step 1a:
Pull off cap



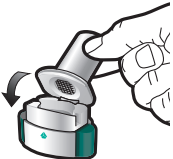
Step 1b:
Open inhaler



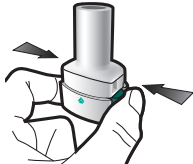
Step 1c:
Remove capsule
Separate a part of the blister that contains one capsule from the entire tray.
Peel off the foil from the tray strip to take out the capsule.
Do not push the capsule out through the foil.
Do not swallow the capsule.



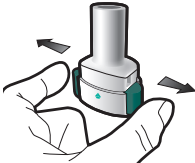
Step 1d:
Insert capsule
Never place a capsule directly into the mouthpiece.




Step 1e:
Close inhaler




Step 2a:
Pierce capsule once
Hold the inhaler upright.
Pierce capsule by firmly pressing on both side buttons at the same time. You should hear a noise as the capsule is pierced.
Only pierce the capsule once.




Step 2b:
Release side buttons



Step 3a:
Breathe out fully
Do not blow into the inhaler.




Step 3b:
Inhale medicine deeply
Hold the inhaler as shown in the picture.
Place the mouthpiece in your mouth and close your lips firmly around it.
Do not press the side buttons.
Breathe in quickly, as deeply as you can.
During inhalation you will hear a whirring sound.
You may taste the medicine as you inhale.




Step 3c:
Hold breath
Hold your breath for up to 5 seconds.


Step 3d:
Rinse mouth
After inhaling the dose, rinse your mouth with water and spit out.




Check capsule is empty
Open the inhaler to see if any powder is left in the capsule.
If there is powder left in the capsule:
• close the inhaler
• repeat steps 3a to 3d.



Empty



Powder remaining



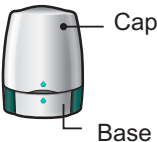
Remove empty capsule
Put the empty capsule in your household waste.
Close the inhaler and replace the cap.

Important Information

- Enerzair Breezhaler capsules must always be stored in the blister card and only removed immediately before use.
- Do not push the capsule through the foil to remove it from the blister.
- Do not swallow the capsule.
- Do not use the Enerzair Breezhaler capsules with any other inhaler.
- Do not use the Enerzair Breezhaler inhaler to take any other capsule medicine.
- Never place the capsule into your mouth or into the mouthpiece of the inhaler.
- Do not press the side buttons more than once.
- Do not blow into the inhaler mouthpiece.
- Do not press the side buttons while inhaling through the mouthpiece.
- Do not handle capsules with wet hands.
- Never wash your inhaler with water.

Each Enerzair Breezhaler Inhaler pack contains:

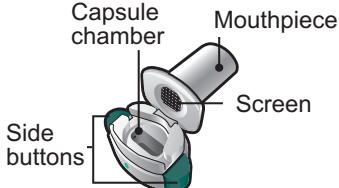
- One Enerzair Breezhaler inhaler
- 30 Enerzair Breezhaler capsules to be used in the inhaler



Inhaler

Cap

Base



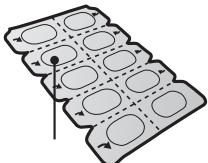
Inhaler base

Capsule chamber

Mouthpiece

Screen

Side buttons



Blister

Blister

Frequently Asked Questions

Why didn't the inhaler make a noise when I inhaled the medicine?
The capsule may be stuck in the capsule chamber. If this happens, carefully loosen the capsule by tapping on the base of the inhaler. Inhale the medicine again by repeating steps 3a to 3d.

What should I do if there is powder left inside the capsule?
You have not received enough medicine. Close the inhaler and repeat steps 3a to 3d.

I coughed after inhaling the medicine. Does this matter?
This may happen. As long as the capsule is empty, you have received enough of the medicine.

I felt small pieces of the capsule on my tongue – does this matter?
This can happen. It is not harmful. The chances of the capsule breaking into small pieces increase if the capsule is pierced more than once.

Cleaning the inhaler
Wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry. Never wash the inhaler with water.

Disposing of the inhaler after use
Dispose of the inhaler after you have used all the capsules.
Ask the pharmacist how to dispose of medicines and inhalers that are no longer required.

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Enerzair® Breezhaler®

114 mcg/46 mcg/136 mcg

Inhalation powder hard capsules

Each capsule contains:
Indacaterol acetate 173 mcg (corresponds to indacaterol 150 mcg)
Glycopyrronium bromide 63 mcg (corresponds to glycopyrronium 50 mcg)
Mometasone furoate 160 mcg

Each dose released from the inhaler is equivalent to:
Indacaterol 114 mcg, glycopyrronium 46 mcg and mometasone furoate 136 mcg

Inactive ingredients: see section 6 “Further information”.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Enerzair Breezhaler is indicated as a maintenance treatment for asthma in adults whose disease is not controlled by combination treatment with beta-agonist bronchodilators and inhaled steroids, who experienced at least one asthma attack in the past year.

Enerzair Breezhaler is not intended for the treatment of chronic obstructive pulmonary disease (COPD).

Therapeutic group:

Medicines for obstructive airway diseases, adrenergics in combination with anti-cholinergics. The medicine contains three active substances called indacaterol, glycopyrronium and mometasone furoate.

Indacaterol and glycopyrronium belong to a group of medicines called bronchodilators. They relax the muscles of the small airways in the lungs which helps to open the airways and makes it easier for air to get in and out of the lungs. When they are taken regularly, it helps the small airways remain open.

Mometasone furoate belongs to a group of medicines called corticosteroids (steroids). Steroids reduce inflammation. They reduce swelling and irritation in the small airways in the lungs and thereby gradually relieve breathing problems. Steroids also help to prevent asthma attacks.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine, listed in section 6 “Further information”.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or breathing difficulties
- swelling of the face, lips, tongue or other part of the body
- skin rash, itch or hives

Do not give this medicine to a child or adolescent under 18 years of age.

The medicine is not intended for children and adolescents under 18 years of age since the effectiveness and safety of use of this medicine have not been proven for these ages.

Special warnings regarding use of this medicine

Before beginning treatment with Enerzair Breezhaler, tell the doctor if:

Tell your doctor if you have an allergy to medicines, food, preservatives or dye.

Tell your doctor if you are suffering, or have suffered in the past, from any of the following medical conditions:

- heart problems, including an irregular or fast heart rate
- thyroid gland problems
- diabetes or high blood sugar level
- epilepsy seizures
- low blood potassium level
- severe liver problems
- severe kidney problems
- eye problem called narrow-angle glaucoma
- difficulty passing urine
- tuberculosis
- chronic infections

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding. If you become pregnant during the course of treatment with this medicine, tell your doctor immediately. Also see “Pregnancy, breastfeeding and fertility” section later in this leaflet.

Children and adolescents

Do not give this medicine to a child or adolescent under 18 years of age.

The safety and effectiveness in children under 18 years of age have not been established.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- medicines to treat depression (e.g., tricyclic antidepressants, monoamine oxidase inhibitors)
- medicines similar to Enerzair Breezhaler (medicines containing similar active ingredients). These medicines may increase the risk of side effects
- medicines that decrease the level of potassium in your blood such as:
 - diuretics, used to treat high blood pressure (e.g., hydrochlorothiazide)
 - medicines for breathing problems (methylxanthines, e.g., theophylline)
 - steroids (e.g., prednisolone)
- medicines to treat high blood pressure or other heart problems (e.g., propranolol) or to treat an eye problem called glaucoma (e.g., timolol)
- medicines to treat fungal infections (e.g., ketoconazole or itraconazole)
- medicines to treat AIDS (e.g., ritonavir, nelfinavir or cobisistat)

Pregnancy, breastfeeding and fertility

Tell the doctor if you are pregnant or are planning to become pregnant, or are breastfeeding. The doctor will discuss with you the risk and benefit of treatment.

Do not use Enerzair Breezhaler during the course of pregnancy if the expected benefit does not justify the risk to the unborn baby.

It is not known whether the active ingredients pass into breast milk. If you are breastfeeding, your doctor will help you decide if you can use Enerzair Breezhaler.

Driving and operating machinery

Exercise caution when driving or operating machinery until you know how Enerzair Breezhaler affects you.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

If you are about to start using a new medicine, remind the doctor and pharmacist that you are using Enerzair Breezhaler.

Tell each of your attending doctors, dentists and pharmacists that you use this medicine. If you are about to undergo surgery, tell the surgeon or the anesthesiologist that you are using this medicine.

Be sure to come to all appointments with your doctor so the doctor will be able to monitor your condition.

Do not use Enerzair Breezhaler to treat other complaints you have, unless you were told to do so by the doctor.

How much medicine to use?

Treatment initiation and determination of the dosage will be done by a doctor specializing in treatment of asthma.

The recommended dosage is usually inhalation of the content of one capsule every day. You only need to inhale once a day because the effect of the medicine lasts for 24 hours.

Do not exceed the recommended dosage.

How to use the inhaler?

Carefully read the full instructions for use at the end of the package leaflet before using the medicine.

- Enerzair Breezhaler is intended for inhalation.
- The package contains an inhaler (Breezhaler) and capsules (in blister strips) that contain the medicine in the form of a powder for inhalation. The inhaler enables you to inhale (breathe into the lungs) the medicine in the capsule.
- Only use the capsules with the inhaler provided in the pack. The capsules should be left in the blister until you need to use them.
- Peel the foil from the blister to open it - do not push the capsule through the foil.
- **Do not swallow the capsules.**
- **Rinse your mouth with water after each use.**
- Do not open and disperse the content of the capsule. The powder in the capsules is intended for inhalation via the inhaler only.
- **Make sure you understand how to use the Breezhaler inhaler properly. Read the instructions at the end of this leaflet** for additional information on how to use the inhaler. **If you are not sure, ask the doctor or pharmacist.**

When to use the medicine?

Inhale Enerzair Breezhaler at the same time each day. This will help minimize symptoms throughout the day and night. It will also help you to remember to use the medicine.

Treatment duration

Adhere to the treatment regimen recommended by the doctor.

Keep using Enerzair Breezhaler for as long as your doctor tells you to continue treatment.

Inhale the contents of the capsule every day and continue using the medicine even when you don't have asthma symptoms.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor, even if you feel better, since the symptoms may worsen.

This medicine helps control your disease, but does not cure it. The asthma symptoms may come back if you stop using this medicine.

If you have questions about the duration of treatment with Enerzair Breezhaler, consult the doctor or pharmacist.

If you forget to take the medicine

If you forgot to take this medicine at the scheduled time, inhale a dose as soon as possible on that same day. After that, inhale the next dose as usual on the next day. Do not inhale two doses on the same day. It may increase the risk of undesirable side effects. **If you are uncertain as to what to do, ask the doctor or pharmacist.**

If you have a hard time remembering to take the medicine, consult the pharmacist for help.

If you accidentally take a higher dosage

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Enerzair Breezhaler may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop using Enerzair Breezhaler and refer to the doctor if you experience any of the following effects:

- chest pain, cough, wheezing or shortness of breath immediately after inhaling Enerzair Breezhaler (symptoms of paradoxical bronchospasm)
- difficulty breathing or swallowing, swelling of the tongue, lips or face, skin rash, itch and urticaria (symptoms of an allergic reaction)
- eye pain or discomfort, temporary blurred vision, lit up (halos) or colorful shapes with red eyes – these may be signs of narrow-angle glaucoma

Common side effects - effects that occur in 1-10 in 100 users:

- oral thrush (sign of a candidiasis)
- a frequent urge to urinate or burning sensation when urinating (signs of a urinary tract infection)
- rapid heart rate
- headache
- sore throat
- cough
- voice alteration (hoarseness)
- diarrhea, abdominal cramps, nausea and vomiting (gastroenteritis)
- dry mouth
- rash
- muscle spasm
- muscle, bone or joint pain
- fever

Uncommon side effects - effects that occur in 1-10 in 1000 users:

- high blood sugar level
- itchy skin
- difficulty and pain when passing urine (signs of dysuria)

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature that exceeds 30°C. Store in the original package to protect from light and moisture.
- Do not remove the capsules from the blister until immediately before use.
- Follow the Breezhaler cleaning and handling instructions.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Capsule content:

Lactose monohydrate, Magnesium stearate.

The capsule shell ingredients:

Hypromellose, Purified water, Carrageenan, Potassium chloride.

Dyes:

Iron oxide yellow, Indigotine

Ingredients of the black ink imprinted on the capsule:

Purified water, Iron oxide black, Isopropyl alcohol, Propylene glycol, Hypromellose.

What the medicine looks like and the contents of the pack:

The pack contains an inhaler with capsules in blister strips.

The capsules have a transparent green cap and a natural transparent body. They contain a white powder with the product code “IGM150-50-160” printed in black above two black lines on the body of the capsule and the company logo (Ⓛ), is printed in black on the cap.

Pack size: 30 capsules + one inhaler

Registration Holder and Importer and address: Novartis Israel Ltd., P.O.B. 7126, Tel Aviv.

Revised in July 2022 according to MOH guidelines.

Registration number of the medicine in the National Registry of Medicines at the Ministry of Health: 168 70 36695