

Package leaflet: Information for the patient

Indacaterol/Glycopyrronium Polpharma 85 micrograms/43 micrograms inhalation powder, hard capsules

indacaterolum/glycopyrronium

Read all of 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
 2. What you need to know before you use [Invented name]
 3. How to use [Invented name]
 4. Possible side effects
 5. How to store [Invented name]
 6. Contents of the pack and other information
- Instructions for use of [Invented name] inhaler

1. What [Invented name] is and what it is used for

What [Invented name] is

This medicine contains two active substances called indacaterol and glycopyrronium. These belong to a group of medicines called bronchodilators.

What [Invented name] is used for

This medicine is used to make breathing easier for adult patients who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD).

In COPD the muscles around the airways tighten. This makes breathing difficult. This medicine blocks the tightening of these muscles in the lungs, making it easier for air to get in and out of the lungs.

If you use this medicine once a day, it will help to reduce the effects of COPD on your everyday life.

2. What you need to know before you use [Invented name]

Do not use [Invented name]

- if you are allergic to indacaterol or glycopyrronium or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using [Invented name] if any of the following applies to you:

- you have asthma - this medicine should not be used as a treatment for asthma,
- you have heart problems,
- you have seizure or fits,
- you have thyroid gland problems (thyrotoxicosis),

- you have diabetes,
- you are using any medicines for your lung disease which contain active substances similar (same class) to those in [Invented name] (see section “Other medicines and [Invented name]”),
- you have kidney problems,
- you have severe liver problems,
- you have an eye problem called narrow-angle glaucoma,
- you have difficulty passing urine.

If any of the above applies to you (or you are not sure), **talk to your doctor, pharmacist or nurse before using this medicine.**

During treatment with [Invented name]

- **Stop using this medicine and seek medical help immediately** if you experience any of the following:
 - eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes – these may be signs of an acute attack of narrow-angle glaucoma,
 - difficulty breathing or swallowing, swelling of the tongue, lips or face, skin rash, itching and hives (signs of an allergic reaction),
 - tightness of the chest, coughing, wheezing or breathlessness immediately after using this medicine – these may be signs of a condition called paradoxical bronchospasm,
- **Tell your doctor immediately** if your COPD symptoms such as breathlessness, wheezing or cough do not improve or get worse.

[Invented name] is used as an ongoing treatment for your COPD. Do not use this medicine to treat a sudden attack of breathlessness or wheezing.

Children and adolescents

Do not give this medicine to children or adolescents below the age of 18 years. This is because it has not been studied in this age group.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, please tell your doctor or pharmacist if you are using:

- any medicines that may be similar to [Invented name] (contain similar active substances),
- medicines called beta blockers that may be used for high blood pressure or other heart problems (such as propranolol), or for an eye problem called glaucoma (such as timolol),
- medicines that lower the amount of potassium in your blood. These include:
 - steroids (such as prednisolone),
 - diuretics (water tablets) used for high blood pressure (such as hydrochlorothiazide),
- medicines for breathing problems (such as theophylline).

Pregnancy and breast-feeding

There are no data on the use of this medicine in pregnant women and it is not known whether the active substances of this medicine pass into human milk. Indacaterol, one of the active substances in [Invented name], may prevent labour due to its effect on the uterus.

If you are pregnant or breast-feeding, 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 [Invented name] unless your doctor tells you to do so.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive and use machines. However, this medicine may cause dizziness (see section 4). If you feel dizzy while taking this medicine, do not drive or use machines.

[Invented name] contains lactose

This medicine contains lactose (which may contain milk proteins). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

Ask your doctor or pharmacist for advice before using any medicine.

3. How to use [Invented name]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much [Invented name] to use

The usual dose is to inhale the content of one capsule each day.

You only need to inhale once a day because the effect of this medicine lasts for 24 hours.

Do not use more than your doctor tells you to use.

Elderly people

You can use this medicine if you are aged 75 years and over at the same dose as for other adults.

When to inhale [Invented name]

Use this medicine at the same time each day. This will also help you to remember to use it.

You can inhale [Invented name] any time before or after food or drink.

How to inhale [Invented name]

- [Invented name] is for inhalation use.
- In this pack, you will find an inhaler and capsules (in blisters) that contain the medicine as inhalation powder. Only use the capsules with the inhaler provided in this pack ([Invented name] inhaler). The capsules should remain in the blister until you need to use them.
- Peel the backing away from the blister to open it - do not push the capsule through the foil.
- When you start a new pack, use the new [Invented name] inhaler that is supplied in the pack.
- Dispose of the inhaler in each pack after all capsules in that pack have been used.
- Do not swallow the capsules.
- Please read the instructions at the end of this leaflet for more information on how to use the inhaler.

If you use more [Invented name] than you should

If you have inhaled too much of this medicine or if someone else accidentally uses your capsules, you must immediately either tell your doctor or go to the nearest emergency unit. Show the pack of [Invented name]. Medical attention may be needed. You may notice that your heart is beating faster than usual, or you may have a headache, feel drowsy, feel nauseous or have to vomit, or you may notice visual disturbances, feel constipated or have difficulty when passing urine.

If you forget to use [Invented name]

If you forget to inhale a dose at the usual time, inhale one as soon as possible that day. Then, inhale the next dose as usual the next day. Do not inhale more than one dose on the same day.

How long to continue your treatment with [Invented name]

- Keep using [Invented name] for as long as your doctor tells you.
- COPD is a long-term disease and you should use [Invented name] **every day** and not only when you have breathing problems or other symptoms of COPD.

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Some side effects may be serious:

Common (may affect up to 1 in 10 people)

- difficulty breathing or swallowing, swelling of tongue, lips or face, urticaria, skin rash – these may be signs of an allergic reaction,
- feeling tired or very thirsty, having an increased appetite without gaining weight and passing more urine than usual – these may be signs of high level of sugar in the blood (hyperglycaemia).

Uncommon (may affect up to 1 in 100 people)

- crushing chest pain with increased sweating – this may be a serious heart problem (ischaemic heart disease),
- swelling mainly of the tongue, lips, face or throat (possible signs of angioedema),
- difficulty breathing with wheezing or coughing,
- eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes – these may be signs of glaucoma,
- irregular heartbeat.

If you get any of these serious side effects, **seek medical help immediately.**

Other side effects may include:

Very common (may affect more than 1 in 10 people)

- blocked nose, sneezing, cough, headache with or without fever - these may be signs of an upper respiratory tract infection.

Common

- combination of sore throat and runny nose - these may be signs of nasopharyngitis,
- painful and frequent urination – these may be signs of a urinary tract infection called cystitis,
- feeling of pressure or pain in the cheeks and forehead – these may be signs of inflammation of the sinuses called sinusitis,
- runny or stuffy nose,
- dizziness,
- headache,
- cough,
- sore throat,
- upset stomach, indigestion,
- dental caries,
- difficulty and pain when passing urine – these may be signs of a bladder obstruction or urinary retention,
- fever,
- chest pain.

Uncommon

- difficulty sleeping,
- fast heartbeat,
- palpitations – signs of abnormal heart beat,
- voice alteration (hoarseness),
- nose bleeds,
- diarrhoea or stomach ache,

- dry mouth,
- itching or rash,
- pain that affects the muscles, ligaments, tendons, joints and bones,
- muscle spasm,
- muscle pain, aches or tenderness,
- pain in arms or legs,
- swollen hands, ankles and feet,
- tiredness.

Rare (may affect up to 1 in 1,000 people)

- tingling or numbness.

Reporting of side effects

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

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store the capsules in the original blister in order to protect from moisture. The capsules must only be removed immediately before use.

The inhaler in each pack should be disposed of after all capsules in that pack have been used.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

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.

6. Contents of the pack and other information

What [Invented name] contains

- The active substances are indacaterol maleate and glycopyrronium bromide.
- Each capsule contains 143 micrograms of indacaterol maleate equivalent to 110 micrograms of indacaterol (*Indacaterolum*) and 63 micrograms of glycopyrronium bromide equivalent to 50 micrograms of glycopyrronium (*Glycopyrronium*).
Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 110 micrograms of indacaterol maleate equivalent to 85 micrograms of indacaterol and 54 micrograms of glycopyrronium bromide equivalent to 43 micrograms of glycopyrronium.
- The other ingredients of the inhalation powder are lactose monohydrate and magnesium stearate;
cap of the capsule: indigo carmine, yellow iron oxide (E172), carrageenan, potassium chloride, hypromellose, water purified; *body of the capsule*: carrageenan, potassium chloride, hypromellose, water purified.

What [Invented name] looks like and contents of the pack

[Invented name] 85 micrograms/43 micrograms inhalation powder are hard capsules with green cap and clear, transparent body made of HPMC (hypromellose), capsule size 3, containing white or almost white powder.

In this pack, you will find a device called an inhaler together with capsules in blister.

The following pack sizes are available: 30x1, 60x1 or 90x1 hard capsules, together with one inhaler.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

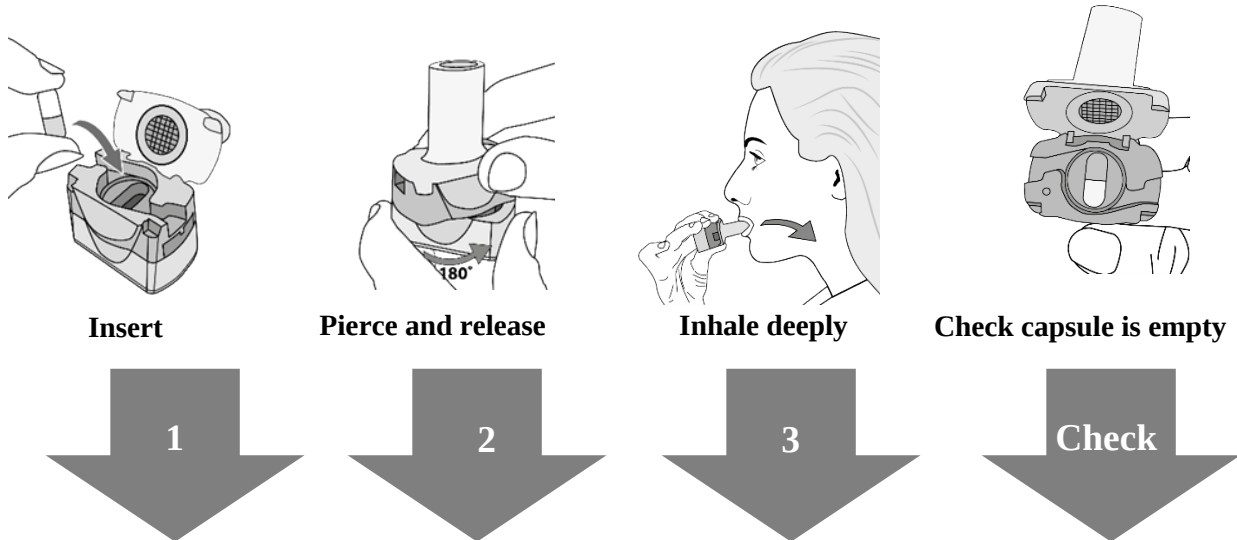
<{Name of the Member State}> <{Name of the medicine}>

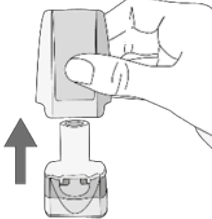
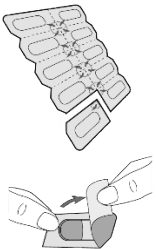
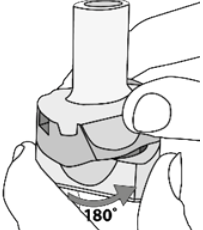
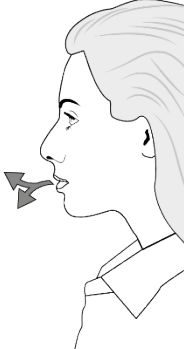
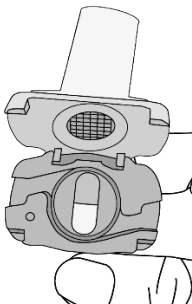
<{Name of the Member State}> <{Name of the medicine}>

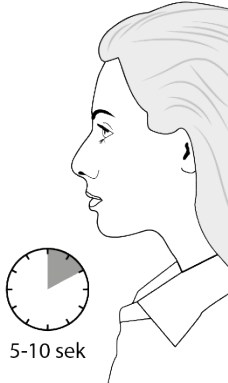
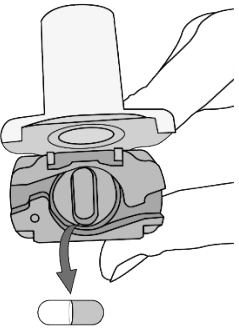
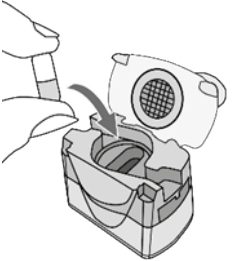
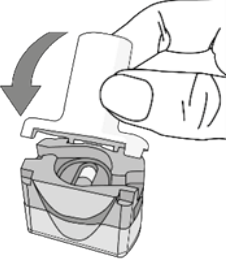
This leaflet was last revised in 18 June 2025.

Instructions for use of [Invented name]

Please read the full **Instructions for Use** before using the [Invented name].



 Step 1a: Pull off cap  Step 1b: Open inhaler  Step 1c: Remove capsule Separate one of the blisters from the blister card. Peel to	 Step 2a: Pierce capsule once Hold the inhaler upright. Pierce capsule by turning the base of inhaler by 180°. You should hear a noise as the capsule is pierced. <u>Only pierce the capsule once.</u>	 Step 3a: Breathe out fully Before starting inhalation, exhale calmly, slowly and as deeply as possible outside the inhaler. <u>Do not blow into the inhaler.</u>  Step 3b: Inhale medicine deeply Hold the inhaler as shown in the picture. Place the mouthpiece in your mouth and	 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 3c. Powder remaining Empty  Return to step 3
---	---	--	--

open the blister and remove the capsule. <u>Do not push the capsule through the foil.</u> <u>Do not swallow the capsule.</u>		close your lips firmly around it. Breathe in quickly and as deeply as you can. During inhalation you will hear a whirring noise. You may taste the medicine as you inhale.  5-10 sek Step 3c: Hold breath Immediately after inhalation, hold your breath for at least 5-10 seconds, then exhale slowly outside the inhaler.	 Remove empty capsule Put the empty capsule in your household waste. Close the inhaler and replace the cap.
 Step 1d: Insert capsule <u>Never place a capsule directly into the mouthpiece.</u>  Step 1e: Close inhaler			Important Information • [Invented name] 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 [Invented name] capsules with any other inhaler. • Do not use the [Invented name] inhaler to take any other capsule medicine. • Never place the capsule into your mouth or the mouthpiece of the inhaler. • Do not turn the base of inhaler more than once. • Do not blow into the mouthpiece.

			• Do not turn the base of inhaler while inhaling through the mouthpiece. • The device contains sharp needles. To avoid injuries, never put your fingers into the capsule chamber while turning the base of the inhaler. • Do not handle capsules with wet hands. • Never wash your inhaler with water.	
Your [Invented name] contains: • One [Invented name] inhaler • One or more blister card with capsules to be used in the inhaler Inhaler Inhaler base + mouthpiece Blister card			Frequently Asked Questions Why didn't the inhaler make a noise when I inhaled? The capsule may be stuck in the capsule chamber. If this happens, carefully loosen the capsule by tapping the base of the inhaler. Inhale the medicine again by repeating steps 3a to 3c. What should I do if there is powder left inside the capsule? You have not received enough of your medicine. Close the inhaler and repeat steps 3a to 3c. I coughed after inhaling – does this matter? This may happen. As long as the capsule is empty you have received enough of your 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	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 your inhaler with water. Disposing of the inhaler after use Each inhaler should be disposed of after all capsules have been used. Ask your pharmacist how to dispose of medicines and inhalers that are no longer required.

	pieces will be increased if the capsule is pierced more than once.	
--	--	--