Package leaflet: Information for the user

Indacaterol/Glycopyrronium Clonmel 85 microgram/43 microgram inhalation powder, hard capsules
indacaterol/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 Indacaterol/Glycopyrronium Clonmel is and what it is used for
2. What you need to know before you use Indacaterol/Glycopyrronium Clonmel
3. How to use Indacaterol/Glycopyrronium Clonmel
4. Possible side effects
5. How to store Indacaterol/Glycopyrronium Clonmel
6. Contents of the pack and other information

Instructions for use of
Indacaterol/Glycopyrronium Clonmel inhaler

1. What Indacaterol/Glycopyrronium Clonmel is

and what it is used for What

Indacaterol/Glycopyrronium Clonmel is
This medicine contains two active substances called indacaterol and glycopyrronium. These belong to a group of medicines called bronchodilators.

What Indacaterol/Glycopyrronium Clonmel 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

Indacaterol/Glycopyrronium Clonmel Do not use

Indacaterol/Glycopyrronium Clonmel
- 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 Indacaterol/Glycopyrronium Clonmel 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 Indacaterol/Glycopyrronium Clonmel (see section "Other medicines and Indacaterol/Glycopyrronium Clonmel").
- 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 Indacaterol/Glycopyrronium Clonmel
- **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.

Indacaterol/Glycopyrronium Clonmel 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 Indacaterol/Glycopyrronium Clonmel
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, please tell your doctor or pharmacist if you are using:
- any medicines that may be similar to Indacaterol/Glycopyrronium Clonmel (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 Indacaterol/Glycopyrronium Clonmel, 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 Indacaterol/Glycopyrronium Clonmel 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.

Indacaterol/Glycopyrronium Clonmel contains lactose
This medicine contains lactose (as monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

3. How to use Indacaterol/Glycopyrronium Clonmel

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 Indacaterol/Glycopyrronium Clonmel 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 (age 75 years and over)
You can use this medicine if you are aged 75 years and over at the same dose as for other adults.

When to inhale Indacaterol/Glycopyrronium Clonmel
Use this medicine at the same time each day. This will also help you to remember to use it.
You can inhale Indacaterol/Glycopyrronium Clonmel any time before or after food or drink.

How to inhale Indacaterol/Glycopyrronium Clonmel
- Indacaterol/Glycopyrronium Clonmel is for inhalation use.
- In this pack, you will find an inhaler and capsules (in perforated unit-dose blisters) that contain the medicine as inhalation powder. Only use the capsules with the inhaler provided in this pack. The capsules should remain in the perforated unit-dose blister until you need to use them.
- Peel the backing away from the perforated unit-dose blister to open it - do not push the capsule through the foil.
- When you start a new pack, use the new Indacaterol/Glycopyrronium Clonmel 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 Indacaterol/Glycopyrronium Clonmel 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 Indacaterol/Glycopyrronium Clonmel. 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 Indacaterol/Glycopyrronium Clonmel
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 Indacaterol/Glycopyrronium Clonmel
- Keep using Indacaterol/Glycopyrronium Clonmel for as long as your doctor tells you.
- COPD is a long-term disease and you should use Indacaterol/Glycopyrronium Clonmel **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 heart beat.
- 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 1000 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Indacaterol/Glycopyrronium Clonmel

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 perforated unit-dose blister after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

Store the capsules in the original perforated unit-dose blister in order to protect from moisture and do not remove until 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 Indacaterol/Glycopyrronium Clonmel

contains

The active substances are indacaterol and glycopyrronium . Each capsule contains 143 microgram of indacaterol maleate equivalent to 110 microgram of indacaterol and 63 microgram of glycopyrronium bromide equivalent to 50 microgram of glycopyrronium. Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 110 microgram of indacaterol maleate equivalent to 85 microgram of indacaterol and 54 microgram of glycopyrronium bromide equivalent to 43 microgram of glycopyrronium.

- The other ingredients of the inhalation powder are lactose monohydrate and magnesium stearate (see section 2 under "Indacaterol/Glycopyrronium Clonmel contains lactose").
- The ingredients of the capsule shell are hypromellose.

What Indacaterol/Glycopyrronium Clonmel looks like and contents of the pack

Indacaterol/Glycopyrronium Clonmel 85 microgram/43 microgram inhalation powder, hard capsules is an inhalation white powder, pre-metered into size 3 HPMC uncoloured, transparent capsule for administration via a dry powder inhaler.

In this pack, you will find a device called an inhaler together with capsules in perforated unit-dose

blister strips. Each perforated unit-dose blister contains 10x1 hard capsules.
Each pack contains 10x1, 30x1 or 90x1 capsules, together with 1 inhaler
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
Genetic S.p.A., Pharmaceutical Manufacturing Site, Contrada Canfora, 84084 Fisciano (SA), Italy
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Belgium:	Indacaterol/Glycopyrronium EG 85 microgram/43 microgram inhalatiepoeder in harde capsules Indacaterol/Glycopyrronium EG 85 microgrammes/43 microgrammes poudre pour inhalation en gélules Indacaterol/Glycopyrronium EG 85 Mikrogramm/43 Mikrogramm Hartkapseln mit Pulver zur Inhalation
Bulgaria:	Indacaterol /Glycopyrronium STADA 85 микрограма/43 микрограма прах за инхалация, твърди капсули
Croatia:	Indakaterol/glikopironij STADA 85 mikrograma/43 mikrograma, prašak inhalata, tvrde kapsule
Denmark:	Indacaterol /Glycopyrronium STADA
Finland:	Indacaterol /Glycopyrronium STADA 85 mikrogrammaa/43 mikrogrammaa, inhalaatiojauhe, kovat kapselit
France:	Indacaterol/Glycopyrronium EG RS01 85 microgrammes/43 microgrammes, poudre pour inhalation en gélule
Germany:	Indacaterol/Glycopyrronium STADA 85 Mikrogramm/ 43 Mikrogramm Hartkapseln mit Pulver zur Inhalation
Greece:	Indacaterol+Glycopyrronium/STADA
Ireland:	Indacaterol/Glycopyrronium Clonmel 85 microgram/43 microgram inhalation powder, hard capsules
Italy:	Indacaterolo e Glicopirronio EG
Netherlands:	Indacaterol/Glycopyrronium STADA 85 microgram/43 microgram, inhalatiepoeder in harde capsules
Norway:	Indacaterol /Glycopyrronium STADA
Poland:	Idemo
Portugal:	Brometo de glicopirrónio + Indacaterol STADA
Romania:	Indacaterol/Glicopironiu Stada 85 micrograme/ 43 micrograme pulbere de inhalat, capsule
Sweden:	Indacaterol /Glycopyrronium STADA

This leaflet was last revised in month May 2026

Instructions for handling and use

Please read the full **Instructions for Use** before using the Indacaterol/Glycopyrronium Clonmel.



Insert

1



Step 1a:
Pull off cap



Step 1b:
Open inhaler



Pierce and release

2



Step 2a:
Pierce capsule once
Hold the inhaler upright. Pierce capsule by firmly pressing 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



Inhale deeply

3



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 and as deeply as you can.



Check capsule is empty

Check

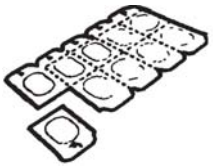


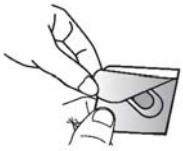
Check capsule is empty
Open the inhaler to see if any powder is left in the capsule.

If there is powder left in the capsule:
- Close the inhaler.
- Repeat steps 3a to 3c.

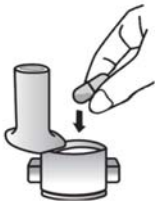


Powder remaining **Empty**





Step 1c:
Remove capsule
Separate one of the perforated unit-dose blisters from the blister card.
Peel open the perforated unit-dose blister and remove the capsule.
Do not push the capsule through the foil.
Do not swallow the capsule.



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



Step 1e:
Close inhaler

During inhalation you will hear a whirring noise.
You may taste the medicine as you inhale.



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



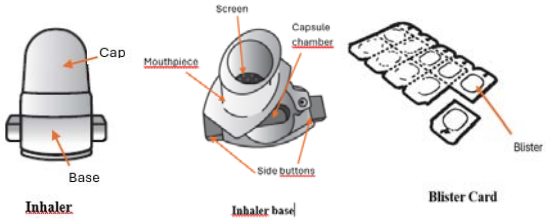
Remove empty capsule
Put the empty capsule in your household waste.
Close the inhaler and replace the cap.

Important Information

- Indacaterol/Glycopyrronium Clonmel capsules must always be stored in the perforated unit-dose blister card and only removed immediately before use.
- Do not push the capsule through the foil to remove it from the perforated unit-dose blister.
- Do not swallow the capsule.
- Do not use the Indacaterol/Glycopyrronium Clonmel capsules with any other inhaler.
- Do not use the Indacaterol/Glycopyrronium Clonmel inhaler to take any other capsule medicine.
- Never place the capsule into your mouth or the mouthpiece of the inhaler.
- Do not press the side buttons more than once.
- Do not blow into the mouthpiece.
- Do not press the side buttons while inhaling

Your Indacaterol/Glycopyrronium Clonmel Inhaler pack contains:

- One Indacaterol/Glycopyrronium Clonmel inhaler
- One or more perforated unit-dose blister cards, each containing 10x1 Indacaterol/Glycopyrronium Clonmel capsules to be used in the inhaler



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

Cleaning the inhaler
Wipe the mouthpiece weekly 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 l onger required.