LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Indacaterol/Glycopyrronium Polpharma (indacaterol maleate, glycopyrronium bromide)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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Inhalation powder, hard capsule, 85 mikrogram/43 mikrogram

This is a summary of the public assessment report (PAR) for Indacaterol/Glycopyrronium Polpharma. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Indacaterol/Glycopyrronium Polpharma and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Ultibro Breezhaler.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

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).

How does Indacaterol/Glycopyrronium Polpharma work?

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

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.

How is Indacaterol/Glycopyrronium Polpharma used?

The pharmaceutical form is inhalation powder, hard capsules for inhalation.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Indacaterol/Glycopyrronium Polpharma have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Ultibro Breezhaler, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Indacaterol/Glycopyrronium Polpharma?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Indacaterol/Glycopyrronium Polpharma approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Ultibro Breezhaler, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Indacaterol/Glycopyrronium Polpharma?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Indacaterol/Glycopyrronium Polpharma

The full PAR for Indacaterol/Glycopyrronium Polpharma can be found on the following website: MRI - Home. For more information about treatment with Indacaterol/Glycopyrronium Polpharma, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-08.