

Summary Public Assessment Report

Glycopyrronium Cantabria (glycopyrronium bromide)

SE/H/2170/01/DC

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Glycopyrronium Cantabria
glycopyrronium bromide, glycopyrronium

Cream, 2.2 mg/actuation

This is a summary of the public assessment report (PAR) for Glycopyrronium Cantabria. It explains how Glycopyrronium Cantabria was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Glycopyrronium Cantabria.

For practical information about using Glycopyrronium Cantabria, patients should read the package leaflet or contact their doctor or pharmacist.

What is Glycopyrronium Cantabria and what is it used for?

Glycopyrronium Cantabria contains the active substance glycopyrronium. Glycopyrronium Cantabria is used for topical treatment of severe primary axillary hyperhidrosis in adults and adolescents 12 years of age and older.

How does Glycopyrronium Cantabria work?

The active substance glycopyrronium belongs to a group of sweat reducing medicines called antihidrotics.

Primary axillary hyperhidrosis causes excessive sweating in both armpits without any apparent reason like sports, hard physical work, hot weather, certain diseases or medicines. A feature of primary axillary hyperhidrosis is also that it occurs usually during the day but not during sleep.

External use of Glycopyrronium Cantabria in the armpits leads to reduced sweat production in the sweat glands.

How is Glycopyrronium Cantabria used?

The pharmaceutical form of Glycopyrronium Cantabria is cream for topical use in the underarm area only and not for use in other body areas.

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 Glycopyrronium Cantabria have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Glycopyrronium Cantabria is effective in topical treatment of severe primary axillary hyperhidrosis in adults.

What are the possible side effects from Glycopyrronium Cantabria?

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 Glycopyrronium Cantabria approved?

The Swedish Medical Products Agency decided that Glycopyrronium Cantabria's 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 Glycopyrronium Cantabria?

A risk management plan has been developed to ensure that Glycopyrronium Cantabria 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 for Glycopyrronium Cantabria, 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 Glycopyrronium Cantabria

The full PAR for Glycopyrronium Cantabria can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Glycopyrronium Cantabria

This summary was last updated in 2026-03.