

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alvesco 160 micrograms pressurised inhalation, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 actuation (delivered dose from the mouthpiece) contains 160 micrograms of ciclesonide.

Excipient(s) with known effect:

1 actuation contains 4.7 mg of ethanol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, solution

Product imported from *Czech Republic and Bulgaria*:

Clear and colourless.

4 CLINICAL PARTICULARS

As per PA22986/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22986/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Norflurane (HFA-134a)

Ethanol, anyhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

The container contains a pressurised liquid. Do not expose to temperatures higher than 50°C.

The container should not be punctured, broken or burnt even when apparently empty.

6.5 Nature and contents of container

The inhaler comprises a pressurised container made from aluminium and is sealed with a metering valve, mouthpiece and cap.

60 metered actuations

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Patients should be carefully instructed in the proper use of their inhaler (see Patient Information Leaflet).

As with most inhaled medicinal products in pressurised containers, the therapeutic effect of this medicinal product may decrease when the container is cold. However, Alvesco delivers a consistent dose from -10°C to 40°C .

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/175/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st January 2022

10 DATE OF REVISION OF THE TEXT

May 2023