



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Seebri Breezhaler

### Procedural steps taken and scientific information after the authorisation\*

\*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
Variation type IB /	C.I HUMAN AND VETERINARY MEDICINAL	06/08/2025		SmPC and PL	

<sup>1</sup> Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



EMA/VR/0000280390	<p>PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc.</p> <p>Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Accepted</p> <p>C.I.z. - to update section 6.1 of the SmPC and section 6 of the Package Leaflet to add to the list of excipients the complete components of capsule shell and printing ink, under a separate heading "Capsule Shell".</p>				
Variation type IA / EMA/VR/0000272066	<p>A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted</p> <p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted</p>	21/05/2025	N/A		