Nintedanib Accord

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 [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I.11 Introduction of, or change(s) to, the	29/08/2025	N/A		

[1] 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.
[2] 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.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000286140	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) – To update the RMP to align with the RMP of the reference product Ofev, with the following changes: Part I: Information added to the section "Important information about its composition", and including the paediatric indication; Part II (Module SVIII): Inclusion of "weight decreased in the paediatric population" as an important identified risk, along with updates to the important potential risks; Part III and VII (Annex 4): Targeted follow-up questionnaires added for: 'Effect on bone development and growth in the paediatric population' and 'Effect on tooth development disorders in the paediatric population'; Part VI: Updated the summary of the RMP in line with the updated sections; Part VII: Updates made to Annex 7 to update the EMA website address for the RMP of the reference product.				
Variation type IB / EMA/VR/0000268330	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a	20/06/2025	09/07/2025	SmPC and PL	To extend the indication for use in children and adolescents aged 6 to 17 years in the treatment of progressive fibrosing interstitial lung diseases (ILDs), the respective sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 of the SmPC are updated. The PL is

	Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a – To extend the indication for use in children and adolescents aged 6 to 17 years in the treatment of progressive fibrosing interstitial lung diseases (ILDs), the respective sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 of the SmPC are updated. The PL is updated accordingly. The change follows assessment of the same change for the reference product, Ofev. Additionally, the MAH took the opportunity to add a statement to section 4.2 of the SmPC, emphasizing that 25mg capsules are not marketed by the MAH, and therefore, another product should be used for certain subsets of the authorized patient population. Furthermore, the MAH has updated sections 4.8 and 5.1 of the SmPC, as well as sections 2, 5, and 6 of the PL, with editorial changes to align with the PI of the reference product.				updated accordingly. The change follows assessment of the same change for the reference product, Ofev. Additionally, the MAH took the opportunity to add a statement to section 4.2 of the SmPC, emphasizing that 25mg capsules are not marketed by the MAH, and therefore, another product should be used for certain subsets of the authorized patient population.