



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SIRTURO

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
Article 61(3) /	Outcome:	02/06/2026		PL	

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/N/0000349520	- Notification acc. Article 61(3) - Accepted Update of the Package Leaflet with revised contact details of the local representatives as well as to include the text 'This medicine does not require any special temperature storage conditions' in section '5. How to store SIRTURO ' to align it with the approved text in SmPC.				
Variation type II / EMA/VR/0000249065	Outcome: C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted Extension of indication to include treatment of paediatric patients (2 years to less than 5 years of age and weighing at least 7 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampicin and isoniazid, for SIRTURO, based on the Week 24 primary analysis from Cohort 3 (≥ 2 to < 5 years of age) of Study TMC207-C211; this is an open-label, multicentre, single-arm study to evaluate pharmacokinetics, safety/tolerability, antimycobacterial activity and dose selection of bedaquiline in children (birth to < 18 years) with multidrug-resistant-TB (MDR-TB). Long-term follow-up to Week 120 in participants of Cohort 1 (≥ 12 to < 18 years	24/07/2025	22/08/2025	SmPC and PL	Please refer to Scientific Discussion "SIRTURO-EMAVR0000249065"

	of age) and Cohort 2 (≥5 to <12 years of age) have also been submitted. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.1 of the RMP has also been approved. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and introduce minor changes to the PI.				
PSUR / EMA/PSUR/0000317651	EURD: PSUSA/00010074/202509 Active substance: bedaquiline Outcome: Maintenance	10/04/2026			Maintenance