Artesunate Amivas

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.1 Change(s) in the summary of product	24/03/2026		SmPC and PL	To update Section 6.5 of the SmPC by adding the

[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/0000325106	characteristics, labelling or package leaflet intended to implement the outcome of a Union referral procedure - C.1.z Other variation - Accepted				word "chlorobutyl" to the description of the rubber stopper. In addition, the MAH has added a Quick Response (QR) code to the Package Leaflet.
Variation type IB / EMA/VR/0000310090	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	21/11/2025			
Variation type IA / EMA/VR/0000307005	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted B.I.a.2 Changes in the manufacturing	20/10/2025			

	process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type IB / EMA/VR/0000292306	B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	01/10/2025			
Variation type IB / EMA/VR/0000293304	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	11/09/2025			
Variation type IB / EMA/VR/0000291545	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted	28/08/2025			

Variation type II / EMA/VR/0000256857	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Other changes - Accepted B.II.e.1.a Qualitative and quantitative composition - B.II.e.1.a.3 Sterile medicinal products and biological/ immunological medicinal products - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	26/06/2025			
Variation type IB / EMA/VR/0000268080	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	20/05/2025		SmPC	
Variation type IB / EMA/VR/0000255637	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real	13/03/2025			

	time data - Accepted				
Variation type IA / EMA/VR/0000249287	This was an application for a group of variations. B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted	12/02/2025			
PSUR / EMA/PSUR/0000296558					Maintenance