Methylthioninium chloride Proveblue

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 II /	C.I HUMAN AND VETERINARY MEDICINAL	02/10/2025		SmPC	This variation concerns the final study report of 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/0000265559	PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study PVP-2016005; this is an Open-label, Parallel group, Population-matched, Single-Dose Study to Investigate the Influence of Hepatic Impairment on the Pharmacokinetics and safety of ProvayBlue (methylene blue). The RMP version 3.4 has also been submitted.				PVP-2016005 to investigate the influence of hepatic impairment on the pharmacokinetics of methylthioninium chloride. No recommendation regarding dose adjustment for hepatically impaired populations can be given based on available study data. The totality of evidence provided does not support a clear and consistent effect of hepatic impairment on the pharmacokinetics of methylthioninium chloride and the metabolite azure B.
Variation type IB / EMA/VR/0000291776	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 time data - Accepted	01/09/2025	N/A		
Variation type IB / EMA/VR/0000284330	B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	23/07/2025	N/A		