Sitagliptin SUN

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 /	B.II.e.1.a Qualitative and quantitative	22/10/2025		SmPC and PL	To change the qualitative and quantitative

[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/0000290396	composition - B.II.e.1.a.1. Solid pharmaceutical forms - Accepted				composition of the immediate packaging of the finished product
Article 61(3) / EMA/N/0000244632	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised details of local representatives, and to delete United Kingdom (Northern Ireland) from the list of local representatives to comply with the Windsor Framework for labelling and packaging of medicines (QRD template 10.4).	24/02/2025		PL	