



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Atosiban 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, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



Variation type II / EMA/VR/0000167976	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.d The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes - Accepted	25/04/2024	N/A		
Article 61(3) / EMA/N/0000170579	- - Accepted  Update of the package leaflet with revised contact details of local representatives.	21/03/2024		PL	