

## Tulissin

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued / amended on	Product Information affected <sup>2</sup>	Summary <sup>3</sup>
IB/0001/G	This was an application for a group of variations.  B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	19/10/2020		SPC	The Agency accepted the group of variations including the change to extend the shelf-life of the finished product as packaged for sale from 30 months to 3 years.

<sup>1</sup> Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

<sup>3</sup> Since October 2019 summary information is no longer published for variations that do not impact upon the product information

