Public Assessment Report

Update

Diclofenac Renantos 10 mg/g gel

DICLOFENAC SODIUM

CZ/H/0792/001/DC

This module reflects the procedural steps and scientific information after the finalisation of the initial procedure.

Procedure number*	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
IB/001/G	Change the medicinal products' names in CMS Belgium, Germany, Italy and Luxembourg.	Yes	28.05.2020	16.06.2020	Approved
IA/002	Introduction of the PSMF.	No	06.05.2020	12.05.2020	Approved
IB/003/G	Introduction of a different immediate packaging due to a change in screw cap used for proposed pack sizes: 30 g a 50 g of drug product. Addition of a new pack sizes: 30 g and 50 g of gel.	Yes	29.05.2020	16.06.2020	Approved

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)