





*products for human use* ( )  
²

(Summary of Product Characteristics: SmPC)  
SmPC

SmPC  
SmPC

## (EPAR)

EPAR

EPAR

SmPC PL variation application ( )  
referral ( )  
EU EMA

ADR (PSUR)  
SmPC PL

ADR

EU

ADR Urgent Union Procedure (EU) EMA

EMA (EPAR PL)

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