



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 March 2022
EMA/PRAC/155930/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pilocarpine / timolol

Procedure no.: PSUSA/00002408/202107

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Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
EQUITON 5mg/ml + 10mg/ml COLLIRIO, SOLUZIONE	not available	026064016	BRUSCHETTINI S.R.L	IT
FOTIL 20 mg/ 5mg/ ml eye drops, solution ФОТИЛ 20 mg/ 5mg/ ml капки за очи, разтвор	not available	9900221	SANTEN OY	BG
Fotil 20 mg/ml + 5 mg/ml oční kapky, roztok	not available	64/316/98-C	SANTEN OY	CZ
FOTIL 5 mg/20 mg/ml akių lašai (tirpalas)	not available	LT/1/96/1924/001	SANTEN OY	LT
Fotil 5 mg/ml + 20 mg/ml acu pilieni, šķīdums	not available	97-0400	SANTEN OY	LV
Fotil 5 mg/ml + 20 mg/ml Augentropfen	DE/H/6061/001/MR	43830.00.00	SANTEN OY	DE
Fotil 5 mg/ml + 20 mg/ml ögondroppar, lösning	not available	11655	SANTEN OY	SE
Fotil 5 mg/ml + 20 mg/ml oldatos szemcsepp	not available	OGYI-T-6742/01	SANTEN OY	HU

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Fotil 5 mg/ml + 20 mg/ml, øyedråper, oppløsning	not available	7849	SANTEN OY	NO
FOTIL FORTE 40 mg/ 5 mg/ ml eye drops, solution ФОТИЛ ФОРТЕ 40 mg/ 5mg/ ml капли за очи, разтвор	not available	9900222	SANTEN OY	BG
Fotil Forte 40 mg/ml + 5 mg/ml oční kapky, roztok	not available	64/318/98-C	SANTEN OY	CZ
Fotil forte 5 mg/mg + 40 mg/ml, øyedråper, oppløsning	not available	8146	SANTEN OY	NO
Fotil forte 5 mg/mg + 40 mg/ml, øyedråper, oppløsning i endosebeholdere	not available	03-2104	SANTEN OY	NO
Fotil forte 5 mg/ml + 40 mg/ml augndropar, lausn í stakskammtaíláti	not available	940090	SANTEN OY	IS
Fotil forte 5 mg/ml + 40 mg/ml ögondroppar, lösning	not available	11763	SANTEN OY	SE
Fotil forte 5 mg/ml + 40 mg/ml ögondroppar, lösning i endosbehållare	not available	11964	SANTEN OY	SE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Fotil forte 5 mg/ml + 40 mg/ml oldatos szemcsepp	not available	OGYI-T-6744/01	SANTEN OY	HU
Fotil Forte, øjendråber, opløsning	not available	15251	SANTEN OY	DK
Fotil Forte, øjendråber, opløsning enkelt dosisbeholder	not available	15725	SANTEN OY	DK
Fotil sine 5 mg/ml + 20 mg/ml Augentropfen im Einzeldosisbehältnis	DE/H/6061/002	43831.00.00	SANTEN OY	DE
Fotil, øjendråber, opløsning	DE/H/6061/001	14737	SANTEN OY	DK
FOTIL® forte -silmätipat, liuos	not available	10940	SANTEN OY	FI
FOTIL® forte -silmätipat, liuos, kerta-annospakkaus	not available	11465	SANTEN OY	FI
FOTIL® forte-ögondroppar, lösning	not available	10940	SANTEN OY	FI
FOTIL® forte-ögondroppar, lösning i endosbehållare	not available	11465	SANTEN OY	FI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
FOTIL® -silmätipat, liuos	not available	10939	SANTEN OY	FI
FOTIL®-ögondroppar, lösning	not available	10939	SANTEN OY	FI