



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 March 2017
EMA/173192/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal

Active substance: pilocarpine / timolol

Procedure no.: PSUSA/00002408/201607



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 20 mg/ 5mg/ ml eye drops, solution ФОТИЛ 20 mg/ 5mg/ ml капки за очи, разтвор		9900221	SANTEN OY	BG
FOTIL FORTE 40 mg/ 5 mg/ ml eye drops, solution ФОТИЛ ФОРТЕ 40 mg/ 5mg/ ml капки за очи, разтвор		9900222	SANTEN OY	BG
FOTIL Oční kapky, roztok		64/316/98-C	SANTEN OY	CZ
FOTIL FORTE Oční kapky, roztok		64/318/98-C	SANTEN OY	CZ
TP® -Ophtal®		33376.00.00	DR. WINZER PHARMA GMBH	DE
Fotil sine 5 mg/ml + 20 mg/ml Augentropfen im Einzeldosisbehältnis	DK/H/0128/002	43831.00.00	SANTEN OY	DE
Fotil 5 mg/ml + 20 mg/ml Augentropfen	DK/H/0128/001	43830.00.00	SANTEN OY	DE
Fotil Forte, øjendråber, opløsning		15251	SANTEN OY	DK

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Fotil Forte, øjendråber, opløsning, enkeltdosisbeholder		15725	SANTEN OY	DK
FOTIL	DK/H/0128/001	14737	SANTEN OY	DK
Fotil, øjendråber, opløsning, enkeltdosisbeholder	DK/H/0128/002	15724	SANTEN OY	DK
FOTIL® -silmätipat, liuos		10939	SANTEN OY	FI
FOTIL® -silmätipat, liuos kerta-annospipetissä		11464	SANTEN OY	FI
FOTIL® forte -silmätipat, liuos		10940	SANTEN OY	FI
FOTIL® -ögondroppar, lösning		10939	SANTEN OY	FI
FOTIL® -ögondroppar, lösning i endosbehållare		11464	SANTEN OY	FI
FOTIL® forte-ögondroppar, lösning		10940	SANTEN OY	FI

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FOTIL® forte -silmätipat, liuos kerta-annospipetissä		11465	SANTEN OY	FI
FOTIL® forte-ögondroppar, lösning i endosbehållare		11465	SANTEN OY	FI
Fotil 5 mg/ml + 20 mg/ml oldatos szemcsepp		OGYI-T-6742/01	SANTEN OY	HU
Fotil forte 5 mg/ml + 40 mg/ml oldatos szemcsepp		OGYI-T-6744/01	SANTEN OY	HU
Fotil augndroppar, lausn		940087	SANTEN OY	IS
Fotil forte augndroppar, lausn		940089	SANTEN OY	IS
Fotil forte augndroppar, lausn í stakskammtaílláti		940090	SANTEN OY	IS
Fotil augndroppar, lausn í stakskammtaílláti		940088	SANTEN OY	IS
EQUITON 5mg/ml + 10mg/ml COLLIRIO, SOLUZIONE		026064016	BRUSCHETTINI S.R.L	IT

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/20 mg/ml akių lašai (tirpalas)		LT/1/96/1924/001	SANTEN OY	LT
Fotil 5 mg/ml + 20 mg/ml acu pilieni, šķīdums		97-0400	SANTEN OY	LV
Fotil 5 mg/ml + 20 mg/ml, øyedråper, oppløsning		7849	SANTEN OY	NO
Fotil 5 mg/ml + 20 mg/ml, øyedråper, oppløsning i endosebeholdere		03-2103	SANTEN OY	NO
Fotil forte 5 mg/mg + 40 mg/ml, øyedråper, oppløsning i endosebeholdere		03-2104	SANTEN OY	NO
Fotil forte 5 mg/mg + 40 mg/ml, øyedråper, oppløsning		8146	SANTEN OY	NO
Fotil 5 mg/ml + 20 mg/ml øgondroppar, lösning		11655	SANTEN OY	SE
Fotil forte 5 mg/ml + 40 mg/ml øgondroppar, lösning		11763	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 ögondroppar, lösning i endosbehållare		11964	SANTEN OY	SE
Fotil 5 mg/ml + 20 mg/ml ögondroppar, lösning i endosbehållare		11963	SANTEN OY	SE