



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2025
EMA/PRAC/21370/2025
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): tafluprost

Procedure No. PSUSA/00002843/202404



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
Safluround 15 microgrammi/ml collirio, soluzione	DE/H/5250/001	046050086	SANTEN OY	IT
Safluround 15 microgrammi/ml collirio, soluzione	DE/H/5250/001	046050074	SANTEN OY	IT
Safluround 15 microgrammi/ml collirio, soluzione	DE/H/5250/001	046050023	SANTEN OY	IT
Safluround 15 microgrammi/ml collirio, soluzione	DE/H/5250/001	046050011	SANTEN OY	IT
Saflutan 15 microgram/ml oogdruppels, oplossing	DE/H/5250/001	BE530346	SANTEN OY	BE
Saflutan 15 microgram/ml oogdruppels, oplossing	DE/H/5250/001	RVG 122004	SANTEN OY	NL
SAFLUTAN 15 microgram/ml oogdruppels, oplossing, verpakking voor eenmalig gebruik	DE/H/0991/002	RVG 103823	SANTEN OY	NL
SAFLUTAN 15 microgramas/ml colírio, solução em recipiente unidose	DE/H/0991/02	5193149	SANTEN OY	PT
SAFLUTAN 15 microgramas/ml colírio, solução em recipiente unidose	DE/H/0991/02	5193156	SANTEN OY	PT
Saflutan 15 micrograme/ml picături oftalmice, soluție	DE/H/5250/001	15215/2023/03	SANTEN OY	RO
Saflutan 15 micrograme/ml picături	DE/H/5250/001	15215/2023/04	SANTEN OY	RO

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oftalmice, soluție				
Saflutan 15 micrograme/ml picături oftalmice, soluție	DE/H/5250/001	15215/2023/01	SANTEN OY	RO
Saflutan 15 micrograme/ml picături oftalmice, soluție	DE/H/5250/001	15215/2023/02	SANTEN OY	RO
SAFLUTAN 15 micrograme/ml picături oftalmice, soluție în fiolă unidoză	DE/H/0991/02	6131/2014/01	SANTEN OY	RO
SAFLUTAN 15 micrograme/ml picături oftalmice, soluție în fiolă unidoză	DE/H/0991/02	6131/2014/02	SANTEN OY	RO
Saflutan 15 microgrammes/ml collyre en solution	DE/H/5250/001	BE530346	SANTEN OY	BE
Saflutan 15 microgrammes/ml collyre en solution en récipient unidose	DE/H/0991/002	BE384474	SANTEN OY	BE
Saflutan 15 microgrammes/ml collyre en solution en récipient unidose	DE/H/0991/002	2011080052	SANTEN OY	LU
SAFLUTAN 15 microgrammes/ml, collyre en solution en récipient unidose	DE/H/0991/02	34009 415 299 4 8	SANTEN OY	FR
SAFLUTAN 15 microgrammes/ml, collyre en solution en récipient unidose	DE/H/0991/02	34009 579 363 7 2	SANTEN OY	FR
SAFLUTAN 15 microgrammi/ml collirio, soluzione	DE/H/0991/001	038926010	SANTEN ITALY S.R.L.	IT
SAFLUTAN 15 microgrammi/ml collirio,	DE/H/0991/001	038926022	SANTEN ITALY S.R.L.	IT

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soluzione				
SAFLUTAN 15 microgrammi/ml collirio, soluzione in contenitore monodose	DE/H/0991/002	038926034	SANTEN OY	IT
SAFLUTAN 15 microgrammi/ml collirio, soluzione in contenitore monodose	DE/H/0991/002	038926046	SANTEN OY	IT
SAFLUTAN 15 microgramos/ml colirio en solución en envase unidosis	DE/H/0991/002	70.063	SANTEN OY	ES
Saflutan 15 micrograms/ml eye drops, solution	DE/H/5250/001	PA0879/008/001	SANTEN OY	IE
Saflutan 15 micrograms/ml eye drops, solution	DE/H/5250/001	PL 16058/0026	SANTEN OY	XI
Saflutan 15 micrograms/ml eye drops, solution in single-dose container	DE/H/0991/002	20905	VIANEX S.A.	CY
SAFLUTAN 15 micrograms/ml eye drops, solution in single-dose container	DE/H/0991/002	PA 0879/006/001	SANTEN OY	IE
Saflutan 15 micrograms/ml eye drops, solution in single-dose container	DE/H/0991/02	MA1068/00201	SANTEN OY	MT
SAFLUTAN 15 micrograms/ml οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μιας δόσης	DE/H/0991/002	128391/30-10-2019	VIANEX S.A.	GR
SAFLUTAN 15 micrograms/ml οφθαλμικές σταγόνες,	DE/H/0991/002	20905	VIANEX S.A.	CY

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διάλυμα,σε περιέκτη μιας δόσης				
SAFLUTAN 15 mikrograma/ml kapi za oko, otopina u jednodoznom spremniku	not available	HR-H-499250915	SANTEN OY	HR
Saflutan 15 Mikrogramm/ml Augentropfen im Einzeldosisbehältnis	DE/H/0991/002	1-27557	SANTEN OY	AT
Saflutan 15 Mikrogramm/ml Augentropfen, Lösung	DE/H/5250/001	138325	SANTEN OY	AT
Saflutan 15 Mikrogramm/ml Augentropfen, Lösung	DE/H/5250/001	BE530346	SANTEN OY	BE
Saflutan 15 Mikrogramm/ml Augentropfen, Lösung	DE/H/5250/001	2018110354	SANTEN OY	LU
Saflutan 15 mikrogramov/ml kapljice za oko, raztopina	DE/H/5250/001	H/18/02471/001	SANTEN OY	SI
Saflutan 15 mikrogramov/ml kapljice za oko, raztopina	DE/H/5250/001	H/18/02471/002	SANTEN OY	SI
Saflutan 15 mikrogramov/ml kapljice za oko, raztopina	DE/H/5250/001	H/18/02471/003	SANTEN OY	SI
Saflutan 15 mikrogramov/ml kapljice za oko, raztopina	DE/H/5250/001	H/18/02471/004	SANTEN OY	SI
SAFLUTAN 15 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	DE/H/0991/002	H/11/01389/001	SANTEN OY	SI
SAFLUTAN 15 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	DE/H/0991/002	H/11/01389/002	SANTEN OY	SI

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SAFLUTAN® 15 microgram/ml oogdruppels, oplossing in verpakking voor eenmalig gebruik	DE/H/0991/02	BE384474	SANTEN OY	BE
SAFLUTAN® 15 micrograms/ml eye drops, solution, in single-dose container	DE/H/0991/002	PL 16058/0017	SANTEN OY	XI
SAFLUTAN® 15 Mikrogramm/ml Augentropfen im Einzeldosisbehältnis	DE/H/0991/02	BE384474	SANTEN OY	BE
Satlutan 15 mikrograma/ml kapi za oko, otopina	DE/H/5250/001	HR-H-485560365	SANTEN OY	HR
SOMINGA 15 microgrammi/ml collirio, soluzione in contenitore monodose	DE/H/7120/001	049786015	SANTEN OY	IT
Taflotan	DE/H/0991/002	43230	SANTEN OY	DK
Taflotan 15 microgramas/ml colírio, solução	DE/H/5250/001	5747241	SANTEN OY	PT
Taflotan 15 microgramas/ml colírio, solução	DE/H/5250/001	5747233	SANTEN OY	PT
Taflotan 15 microgramos/ml colirio en solución	DE/H/5250/001	83137	SANTEN OY	ES
Taflotan 15 micrograms/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/5250/001	022835	VIANEX S.A.	CY
Taflotan 15 micrograms/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/5250/001	96013/15-09-2023	VIANEX S.A.	GR
Taflotan 15	DE/H/5250/001	56968	SANTEN OY	SE

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mikrogram/ml ögondroppar, lösning				
Taflotan 15 mikrogram/ml ögondroppar, lösning i endosbehållare	DE/H/0991/002	25329	SANTEN OY	SE
Taflotan 15 mikrogram/ml øyedråper, oppløsning i endosebeholder	DE/H/0991/002	07-4894	SANTEN OY	NO
TAFLOTAN 15 mikrogrami/ml acu pilieni, šķīdums	DE/H/5250/001	18-0067	SANTEN OY	LV
TAFLOTAN 15 mikrogrami/ml acu pilieni, šķīdums, vienreizējās devas trauciņā	DE/H/0991/02	09-0234	SANTEN OY	LV
TAFLOTAN 15 Mikrogramm/ml Augentropfen	DE/H/0991/001	67940.00.00	SANTEN OY	DE
TAFLOTAN 15 Mikrogramm/ml Augentropfen	DE/H/0991/001	67940.00.00	SANTEN OY	DE
Taflotan 15 mikrogramm/ml oldatos szemcsepp	DE/H/5250/001	OGYI-T-21851/05	SANTEN OY	HU
Taflotan 15 mikrogramm/ml oldatos szemcsepp	DE/H/5250/001	OGYI-T-21851/06	SANTEN OY	HU
Taflotan 15 mikrogramm/ml oldatos szemcsepp	DE/H/5250/001	OGYI-T-21851/08	SANTEN OY	HU
Taflotan 15 mikrogramm/ml oldatos szemcsepp	DE/H/5250/001	OGYI-T-21851/07	SANTEN OY	HU
Taflotan 15 mikrogramm/ml oldatos szemcsepp egyadagos	DE/H/0991/002	OGYI-T-21851/01	SANTEN OY	HU

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tartályban				
Taflotan 15 mikrogramm/ml oldatos szemcsepp egyadagos tartályban	DE/H/0991/002	OGYI-T-21851/02	SANTEN OY	HU
TAFLOTAN 15 mikrogramov/ml očná roztoková instilácia	DE/H/5250/001	64/0302/18-S	SANTEN OY	SK
TAFLOTAN 15 mikrogramų/ml akių lašai (tirpalas vienadozėje talpyklėje)	DE/H/0991/02	LT/1/09/1603/001	SANTEN OY	LT
TAFLOTAN 15 mikrogramų/ml akių lašai (tirpalas vienadozėje talpyklėje)	DE/H/0991/02	LT/1/09/1603/002	SANTEN OY	LT
TAFLOTAN 15 mikrogramų/ml akių lašai (tirpalas)	DE/H/5250/001	LT/1/18/4301/001	SANTEN OY	LT
TAFLOTAN 15 mikrogramų/ml akių lašai (tirpalas)	DE/H/5250/001	LT/1/18/4301/002	SANTEN OY	LT
TAFLOTAN 15 mikrogramų/ml akių lašai (tirpalas)	DE/H/5250/001	LT/1/18/4301/003	SANTEN OY	LT
TAFLOTAN 15 mikrogramų/ml akių lašai (tirpalas)	DE/H/5250/001	LT/1/18/4301/004	SANTEN OY	LT
Taflotan 15 mikrogramů/ml oční kapky, roztok	DE/H/5250/001	64/411/17-C	SANTEN OY	CZ
TAFLOTAN 15 mikrogramů/ml oční kapky, roztok v jednodávkovém obalu	DE/H/0991/002	64/314/08-C	SANTEN OY	CZ
TAFLOTAN 15 míkrogrömm/ml augndropar, lausn í stakskammtaíláti	DE/H/0991/002	IS/1/09/032/01	SANTEN OY	IS

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Taflotan Multi, 15 mikrogramów/ml, krople do oczu, roztwór	DE/H/5250/001	24730	SANTEN OY	PL
Taflotan Sine	DE/H/5250/001	60174	SANTEN OY	DK
Taflotan sine 15 mikrogram/ml ögondroppar, lösning	DE/H/5250/001	35552	SANTEN OY	FI
Taflotan sine 15 mikrogram/ml øyedråper, oppløsning	DE/H/5250/001	17-11904	SANTEN OY	NO
TAFLOTAN sine 15 Mikrogramm/ml Augentropfen im Einzeldosisbehältnis	DE/H/0991/002	67942.00.00	SANTEN OY	DE
TAFLOTAN sine 15 Mikrogramm/ml Augentropfen, Lösung	DE/H/5250/001	67941.00.00	SANTEN OY	DE
Taflotan sine 15 mikrogrammaa/ml silmätipat, liuos	DE/H/5250/001	35552	SANTEN OY	FI
Taflotan sine 15 míkrogrömm/ml augndropar, lausn	DE/H/5250/001	IS/1/18/037/01	SANTEN OY	IS
TAFLOTAN 15 mikrogramov/ml očná roztoková instilácia v jednodávkovom obale	DE/H/0991/002	64/0460/09-S	SANTEN OY	SK
Taflotan, 15 mikrogrammi/ml silmatilgad, lahus	DE/H/5250/001	963218	SANTEN OY	EE
TAFLOTAN, 15 mikrogrammi/ml silmatilgad, lahus üheannuselises kontaineris	DE/H/0991/02	630509	SANTEN OY	EE
TAFLOTAN, 15 mikrogramów/ml krople do oczu, roztwór w pojemniku	DE/H/0991/002	15023	SANTEN OY	PL

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jednodawkowym				
Taflotan® 15 mikrogram/ml ögondroppar, lösning i endosbehållare	DE/H/0991/02	23420	SANTEN OY	FI
Taflotan® 15 mikrogrammaa/ml silmätipat, liuos kerta-annospipetissä	DE/H/0991/02	23420	SANTEN OY	FI
Tafluprost "Santen", øjendråber, opløsning, enkelt dosisbeholder	DE/H/7120/001	66173	SANTEN OY	DK
Tafluprost Micro Labs 15 µg/ml Augentropfen, Lösung im Einzeldosisbehältnis	DE/H/7765/001	7012203.00.00	MICRO LABS GMBH	DE
Tafluprost Micro Labs 15 µg/ml Augentropfen, Lösung im Einzeldosisbehältnis	DE/H/7765/001	7012203.00.00	MICRO LABS GMBH	DE
Tafluprost Santen 15 mikrog/ml ögondroppar, lösning	DE/H/0991/001	23419	SANTEN OY	FI
Tafluprost Santen 15 mikrogram/ml ögondroppar, lösning i endosbehållare	DE/H/7120/001	62154	SANTEN OY	SE
Tafluprost Santen 15 Mikrogramm/ml Augentropfen, Lösung im Einzeldosisbehältnis	DE/H/7120/001	7004975.00.00	SANTEN OY	DE
Tafluprost Santen® 15 mikrog/ml silmätipat, liuos	DE/H/0991/001	23419	SANTEN OY	FI
Тафлотан 15 микрограма/мл капки за очи, разтвор	DE/H/5250/001	20180222	SANTEN OY	BG
ТАФЛОТАН 15 микрограма/мл капки	DE/H/0991/02	20090329	SANTEN OY	BG

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за очи, разтвор в еднодозова опаковка				