



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 July 2018  
EMA/497430/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: tafluprost / timolol

Procedure no.: PSUSA/00010324/201712



| 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 |
|---|------------------------------|-------------------------------|------------------------------------|--|
| Taptiqom  | DE/H/3869/001/DC             | 52804                         | SANTEN OY                          | DK                                       |
| Taptiqom 15 microgram/ml + 5 mg/ml oogdruppels, oplossing in verpakking voor eenmalig gebruik | DE/H/3869/001                | BE465680                      | SANTEN OY                          | BE                                       |
| Taptiqom 15 Mikrogramm/ml + 5 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis              | DE/H/3869/001                | BE465680                      | SANTEN OY                          | BE                                       |
| Taptiqom 15 microgrammes/ml + 5 mg/ml collyre en solution en récipient unidose                | DE/H/3869/001/DC             | BE465680                      | SANTEN OY                          | BE                                       |
| Taptiqom 15 míkrogrömm/ml + 5 mg/ml augndropar, lausn í stakskammtailáti                      | DE/H/3869/001/DC             | IS/1/14/090/01                | SANTEN OY                          | IS                                       |
| Taptiqom 15 mikrogram/ml + 5 mg/ml ögondroppar, lösning i endosbehållare                      | DE/H/3869/001                | 49602                         | SANTEN OY                          | SE                                       |
| Taptiqom 15 mikrogram/ml + 5 mg/ml øyedråper, oppløsning i endosebeholder                     | DE/H/3869/001/DC             | 13-9628                       | SANTEN OY                          | NO                                       |
| Taptiqom 15 Mikrogramm/ml + 5 mg/ml Augentropfen im Einzeldosisbehältnis                      | DE/H/3869/001/DC             | 89952.00.00                   | SANTEN OY                          | DE                                       |
| Taptiqom 15 microgram/ml + 5 mg/ml oogdruppels, oplossing in verpakking voor eenmalig gebruik | DE/H/3869/001/DC             | RVG 113881                    | SANTEN OY                          | NL                                       |

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|--|-------------------------------------|--------------------------------------|---|---|
| Taptiqom 15 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container | DE/H/3869/001                       | PA0879/003/001                       | SANTEN OY                                 | IE  |
| Taptiqom 15 mikrogrammi/5 mg/ml silmatilgad, lahus üheannuselises konteineris    | DE/H/3869/001                       | 860414                               | SANTEN OY                                 | EE  |
| Taptiqom 15 mikrog/ml + 5 mg/ml silmätipat, liuos kerta-annospakkaus             | DE/H/3869/001/DC                    | 31641                                | SANTEN OY                                 | FI  |
| Taptiqom 15 mikrogram/ml + 5 mg/ml Ögondroppar, lösning i endosbehållare         | DE/H/3869/001/DC                    | 31641                                | SANTEN OY                                 | FI  |
| Taptiqom 15 mikrogramų/ 5 mg/ml akių lašai (tirpalas vienadozėje talpyklėje)     | DE/H/3869/001                       | LT/1/14/3657/001                     | SANTEN OY                                 | LT  |
| Taptiqom 15 mikrogramų/ 5 mg/ml akių lašai (tirpalas vienadozėje talpyklėje)     | DE/H/3869/001                       | LT/1/14/3657/002                     | SANTEN OY                                 | LT  |
| Taptiqom 0.015 mg /ml + 5 mg/ml colírio, solução em recipiente unidose           | DE/H/3869/001/DC                    | 5628433                              | SANTEN OY                                 | PT  |
| Taptiqom 0.015 mg /ml + 5 mg/ml colírio, solução em recipiente unidose           | DE/H/3869/001/DC                    | 5628441                              | SANTEN OY                                 | PT  |

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| Taptiqom 15 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container  | DE/H/3869/001/DC             | PL 16058/0012                 | SANTEN OY                          | UK                                       |
| Taptiqom 0,015 mg /ml + 5 mg/ml oldatos szemcsepp egyadagos tartályban  | DE/H/3869/001/DC             | OGYI-T22751/01                | SANTEN OY                          | HU                                       |
| ТАПТИКОМ 15 микрограма/ml + 5 mg/ml капки за очи, разтвор в едnodозова опаковка<br>TARTIQOM 15 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container | DE/H/3869/001                | 20150020                      | SANTEN OY                          | BG                                       |
| TARTIQOM 15 mikrogramov/ml + 5 mg/ml očná roztoková instilácia v jednodávkovom obale  | DE/H/3869/001/DC             | 64/0038/15-S                  | SANTEN OY                          | SK                                       |
| Taptiqom 15 microgrammes/ml + 5 mg/ml collyre en solution en récipient unidose  | DE/H/3869/001/DC             | 2014120435                    | SANTEN OY                          | LU                                       |
| Taptiqom 15 Mikrogramm/ml + 5 mg/ml Augentropfen im Einzeldosisbehältnis  | DE/H/3869/001                | 136041                        | SANTEN OY                          | AT                                       |

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| Taptiqom 15 mikrogrami/ 5 mg/ml acu pilieni, šķīdums vienas devas iepakojumā            | DE/H/3869/001                | 15-0024                       | SANTEN OY                          | LV                                       |
| Taptiqom 15 mikrogramů/ml + 5 mg/ml oční kapky, roztok v jednodávkovém obalu            | DE/H/3869/001/DC             | 64/017/15-C                   | SANTEN OY                          | CZ                                       |
| Taptiqom 15 mikrograma/ml + 5 mg/ml, kapi za oko, otopina u jednodoznom spremniku       | DE/H/3869/001/DC             | HR-H-552420076                | SANTEN OY                          | HR                                       |
| Loyada 15 microgrammi/ml + 5 mg/ml collirio, soluzione in contenitore monodose          | DE/H/3869/001                | 043622024                     | SANTEN ITALY S.R.L.                | IT                                       |
| Loyada 15 microgrammi/ml + 5 mg/ml collirio, soluzione in contenitore monodose          | DE/H/3869/001                | 043622012                     | SANTEN ITALY S.R.L.                | IT                                       |
| Taptiqom 15 mikrogramów/ml + 5 mg/ml, krople do oczu, roztwór w pojemniku jednodawkowym | DE/H/3869/001/DC             | 22453                         | SANTEN OY                          | PL                                       |
| Taptiqom 15 microgramos /ml + 5 mg/ml, colirio en solución en envase unidosis           | DE/H/3869/001/DC             | 80037                         | SANTEN OY                          | ES                                       |

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| TAPTIQOM 15 microgrammes/ml + 5 mg/ml, collyre en solution en récipient unidose.            | DE/H/3869/001/DC             | 34009 300 086 6 9             | SANTEN OY                          | FR                                       |
| TAPTIQOM 15 microgrammes/ml + 5 mg/ml, collyre en solution en récipient unidose.            | DE/H/3869/001/DC             | 34009 550 036 7 0             | SANTEN OY                          | FR                                       |
| Taptiqom 0,015 mg/5 mg v 1 ml kapljice za oko, raztopina v enoodmernem vsebniku             | DE/H/3869/001                | H/15/02062/001                | SANTEN OY                          | SI                                       |
| Taptiqom 0,015 mg/5 mg v 1 ml kapljice za oko, raztopina v enoodmernem vsebniku             | DE/H/3869/001                | H/15/02062/002                | SANTEN OY                          | SI                                       |
| TAPTIQOM 15 μικρογραμμάρια/ml + 5 mg/ml οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης | DE/H/3869/001                | 7732/22-3-2017                | VIANEX S.A.                        | GR                                       |
| TAPTIQOM 15 μικρογραμμάρια/ml + 5 mg/ml οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης | DE/H/3869/001                | ML 022246                     | VIANEX S.A.                        | CY                                       |