



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 October 2020  
EMA/536230/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: influenza vaccine (split virion, inactivated) (non centrally authorised products)

Procedure no.: PSUSA/00010298/202003

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| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|---|-------------------------------------|--------------------------------------|---|---|
| VAXIGRIP ENFANTS, suspension injectable en seringue préremplie<br>Vaccin grippal (inactivé, à virion fragmenté) | FR/H/0139/001                       | NL 22 390                            | SANOFI PASTEUR                            | FR  |
| AFLURIA Suspensie voor injectie, in een voorgevulde spuit.<br>Influenzavaccin (split virus, geïnactiveerd)      | DE/H/1938/001                       | BE285284                             | SEQIRUS GMBH                              | BE  |
| AFLURIA, suspension injectable en seringue préremplie Vaccin grippal (virion fragmenté, inactivé)               | DE/H/1938/001                       | BE285284                             | SEQIRUS GMBH                              | BE  |
| AFLURIA, injekční suspenze v predplnené injekční strikacce Vakcína proti chripce (štepový virion, inaktivovaná) | DE/H/1938/001                       | 59/241/14-C                          | SEQIRUS GMBH                              | CZ  |
| Afluria, injektionsvæske, suspension, fyldt injektionssprøjte   | DE/H/1938/001                       | 37439                                | SEQIRUS GMBH                              | DK  |
| AFLURIA, injektioneste, suspensio, esitäytetty ruisku.<br>Influenssarokote (pilkottu, inaktivoitu)              | DE/H/1938/001                       | 20234                                | SEQIRUS GMBH                              | FI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| AFLURIA®, Suspension zur Injektion in Fertigspritzen Influenza-Impfstoff (Spaltvirus, inaktiviert)                    | DE/H/1938/001                       | PEI.H.03523.01.1                     | SEQIRUS GMBH                              | DE  |
| AFLURIA ???s?μ? e?a????μα se p???εμ?σμ??? s?????a ?μβ????o ???p?? (τμ?μα ???, ad?a??p???μ???)                         | DE/H/1938/001                       | 21056                                | SEQIRUS GMBH                              | GR  |
| Enzira Suspension for injection, pre-filled syringe Influenza vaccine (Split Virion, inactivated)                     | DE/H/1938/001                       | PA1373/001/001                       | SEQIRUS GMBH                              | IE  |
| AFLURIA Sospensione iniettabile, in siringa pre-riempita. Vaccino influenzale (virus split (frammentato), inattivato) | DE/H/1938/001                       | 043216011                            | SEQIRUS GMBH                              | IT  |
| AFLURIA Sospensione iniettabile, in siringa pre-riempita. Vaccino influenzale (virus split (frammentato), inattivato) | DE/H/1938/001                       | 043216023                            | SEQIRUS GMBH                              | IT  |
| AFLURIA Sospensione iniettabile, in siringa pre-riempita. Vaccino   | DE/H/1938/001                       | 043216035                            | SEQIRUS GMBH                              | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| influenzale (virus split (frammentato), inattivato)   |                                     |                                      |   |   |
| AFLURIA Sospensione iniettabile, in siringa pre-riempita. Vaccino influenzale (virus split (frammentato), inattivato) | DE/H/1938/001                       | 043216047                            | SEQIRUS GMBH                              | IT  |
| AFLURIA Suspension injectable dans une seringue préremplie. Vaccin contre l'influenza (virion fragmenté, inactivé)    | DE/H/1938/001                       | 1716/06040039                        | SEQIRUS GMBH                              | LU  |
| AFLURIA Suspensie voor injectie, in een voorgevulde spuit.  Influenzavaccin (split virus, geïnactiveerd)              | DE/H/1938/001                       | RVG 31924                            | SEQIRUS GMBH                              | NL  |
| AFLURIA suspensie injectabilă, în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)                     | DE/H/1938/001                       | 7123/2014/01                         | SEQIRUS GMBH                              | RO  |
| AFLURIA suspensie injectabilă, în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)                     | DE/H/1938/001                       | 7123/2014/02                         | SEQIRUS GMBH                              | RO  |

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| AFLURIA suspensie injectabilă, în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)       | DE/H/1938/001                       | 7123/2014/03                         | SEQIRUS GMBH                              | RO  |
| AFLURIA suspensie injectabilă, în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)       | DE/H/1938/001                       | 7123/2014/04                         | SEQIRUS GMBH                              | RO  |
| Afluria Suspensión inyectable en jeringa precargada Vacuna antigripal (virus fraccionados, inactivados) | DE/H/1938/001                       | 705470 – 2                           | SEQIRUS GMBH                              | ES  |
| Afluria Suspensión inyectable en jeringa precargada Vacuna antigripal (virus fraccionados, inactivados) | DE/H/1938/001                       | 705471 – 9                           | SEQIRUS GMBH                              | ES  |
| Afluria Suspensión inyectable en jeringa precargada Vacuna antigripal (virus fraccionados, inactivados) | DE/H/1938/001                       | 702570 – 2                           | SEQIRUS GMBH                              | ES  |
| Afluria Suspensión inyectable en jeringa precargada Vacuna antigripal (virus                            | DE/H/1938/001                       | 702573 – 3                           | SEQIRUS GMBH                              | ES  |

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|--|-------------------------------------|--------------------------------------|---|---|
| fraccionados, inactivados)   |                                     |                                      |   |   |
| Afluria Suspensión inyectable en jeringa precargada Vacuna antigripal (virus fraccionados, inactivados)  | DE/H/1938/001                       | 715322 - 1                           | SEQIRUS GMBH                              | ES  |
| Afluria Suspensión inyectable en jeringa precargada Vacuna antigripal (virus fraccionados, inactivados)  | DE/H/1938/001                       | 715321 - 4                           | SEQIRUS GMBH                              | ES  |
| ENZIRA® Suspension for injection, pre-filled syringe Influenza vaccine (split virion, inactivated)       | DE/H/1938/001                       | PL 22236/0001                        | SEQIRUS GMBH                              | UK  |
| Influenza vaccine (split virion, inactivated) Suspension for injection, pre-filled syringe               | DE/H/1938/001                       | PL 22236/0001                        | SEQIRUS GMBH                              | UK  |
| Afluria injektionsvätska, suspension i förfylld spruta Vaccin mot influensa (spjälkat virus inaktiverat) | DE/H/1938/001                       | 20546                                | SEQIRUS GMBH                              | SE  |
| AFLURIA Suspensão injetável, em seringa pré-cheia  | DE/H/1938/001                       | 5643325                              | SEQIRUS GMBH                              | PT  |

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| Vacina contra a gripe (virião fragmentado, inativado)   |                                     |                                      |   |   |
| AFLURIA Suspensão injetável, em seringa pré-cheia<br>Vacina contra a gripe (virião fragmentado, inativado)            | DE/H/1938/001                       | 5643317                              | SEQIRUS GMBH                              | PT  |
| AFLURIA Suspensão injetável, em seringa pré-cheia<br>Vacina contra a gripe (virião fragmentado, inativado)            | DE/H/1938/001                       | 5643333                              | SEQIRUS GMBH                              | PT  |
| AFLURIA Suspensão injetável, em seringa pré-cheia<br>Vacina contra a gripe (virião fragmentado, inativado)            | DE/H/1938/001                       | 5643309                              | SEQIRUS GMBH                              | PT  |
| AFLURIA Sospensione iniettabile, in siringa pre-riempita. Vaccino influenzale (virus split (frammentato), inattivato) | DE/H/1938/001                       | 043216050                            | SEQIRUS GMBH                              | IT  |
| AFLURIA Sospensione iniettabile, in siringa pre-riempita. Vaccino   | DE/H/1938/001                       | 043216062                            | SEQIRUS GMBH                              | IT  |

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| influenzale (virus split (frammentato), inattivato)  |                                     |                                      |   |   |
| Afluria Injektionsvätska, suspension i förfylld spruta. Vaccin mot influensa (spjälkat virus, inaktiverat) | DE/H/1938/001                       | 20234                                | SEQIRUS GMBH                              | FI  |
| AFLURIA Suspension zur Injektion in Fertigspritzen. Influenza-Impfstoff (Spaltvirus, inaktiviert)          | DE/H/1938/001                       | BE285284                             | SEQIRUS GMBH                              | BE  |
| AFLURIA Suspension zur Injektion in Fertigspritzen. Influenza-Impfstoff (Spaltvirus, inaktiviert)          | DE/H/1938/001                       | 1716/06040039                        | SEQIRUS GMBH                              | LU  |
| AFLURIA suspensie injectabilă, în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)          | DE/H/1938/001                       | 7123/2014/05                         | SEQIRUS GMBH                              | RO  |
| AFLURIA suspensie injectabilă, în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)          | DE/H/1938/001                       | 7123/2014/06                         | SEQIRUS GMBH                              | RO  |
| a-RIX Injektionssuspension in einer Fertigspritze  | DE/H/0124/001                       | BE147244                             | GLAXOSMITHKLINE BIOLOGICALS S.A.          | BE  |



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|---|-------------------------------------|--------------------------------------|---|---|
| Grippeimpfung<br>(fragmentiertes,<br>inaktiviertes Virion)  |                                     |                                      |   |   |
| a-RIX, suspension<br>injectable en seringue<br>préremplie Vaccin grippal<br>(virion fragmenté,<br>inactivé)                 | DE/H/0124/001                       | BE147244                             | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | BE  |
| a-RIX, suspensie voor<br>injectie in een<br>voorgevulde spuit<br>Griepvaccin<br>(gefragmenteerd,<br>geïnactiveerd virion)   | DE/H/0124/001                       | BE147244                             | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | BE  |
| Influsplit SSW®<br>2014/2015<br>Injektionssuspension in<br>einer Fertigspritze<br>Influenza-Spaltimpfstoff<br>(inaktiviert) | DE/H/0124/001                       | PEI.H.11676.01.1                     | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | DE  |
| Fluarix Tetraqsuspension<br>for injection in pre-filled<br>syringe<br>Influenza vaccine (split<br>virion, inactivated)      | DE/H/1939/001                       | PL 10592/0302                        | SMITHKLINE BEECHAM LTD                    | UK  |
| Fluarix Tetra<br>Injektionssuspension in<br>einer Fertigspritze<br>Influenza-Spaltimpfstoff                                 | DE/H/1939/001                       | 235552                               | GLAXOSMITHKLINE PHARMA<br>GMBH.           | AT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| (inaktiviert)   |                                     |                                      |   |   |
| Fluarix Tetra injekční suspenze v předplněné injekční stříkačce<br>Vakcína proti chřipce (štěpený virion, inaktivovaný) | DE/H/1939/001                       | 59/145/14-C                          | GLAXOSMITHKLINE BIOLOGICALS S.A.          | CZ  |
| Influsplit Tetra®<br>2014/2015<br>Injektionssuspension in Fertigspritze<br>Influenza-Spaltimpfstoff (inaktiviert)       | DE/H/1939/001                       | PEI.H.11629.01.1                     | GLAXOSMITHKLINE GMBH & CO. KG             | DE  |
| Fluarix Tetra suspensión inyectable en jeringa precargada<br>Vacuna antigripal (de virus fraccionados e inactivados)    | DE/H/1939/001                       | 78.568                               | GLAXOSMITHKLINE BIOLOGICALS S.A.          | ES  |
| FLUARIXTETRA<br>suspension injectable en seringue préremplie<br>Vaccin grippal inactivé à virion fragmenté              | DE/H/1939/001                       | NL42097                              | LABORATOIRE GLAXOSMITHKLINE               | FR  |
| Fluarix Tetra sospensione iniettabile in siringa<br>priempita Vaccino influenzale (virus split                          | DE/H/1939/001                       | 043132036                            | GLAXOSMITHKLINE BIOLOGICALS S.A.          | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| (frammentato), inattivato)  |                                     |                                      |   |   |
| Fluarix Tetra injekčná suspenzia naplnená v injekčnej striekacke<br>Ockovacia látka proti chrípke (štiepený virión, inaktivovaná) | DE/H/1939/001                       | 59/0114/14-S                         | GLAXOSMITHKLINE BIOLOGICALS S.A.          | SK  |
| Fluarix Tetra sospensione iniettabile in siringa preimpita Vaccino influenzale (virus split (frammentato), inattivato)            | DE/H/1939/001                       | 043132048                            | GLAXOSMITHKLINE BIOLOGICALS S.A.          | IT  |
| a-RIX-Tetra, suspensie voor injectie in een voorgevulde spuit<br>Griepvaccin (gefragmenteerd, geïnactiveerd virion)               | DE/H/1939/001                       | BE456924                             | GLAXOSMITHKLINE BIOLOGICALS S.A.          | BE  |
| a-RIX-Tetra Injektionssuspension in Fertigspritze<br>Grippeimpfung (Spalt-Virion, inaktiviert)                                    | DE/H/1939/001                       | BE456924                             | GLAXOSMITHKLINE BIOLOGICALS S.A.          | BE  |
| α-RIX-Tetra, suspension injectable en seringue préremplie Vaccin antigrippal (virion  | DE/H/1939/001                       | 2014090216                           | GLAXOSMITHKLINE BIOLOGICALS S.A.          | LU  |

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|---|-------------------------------------|--------------------------------------|---|---|
| fragmenté, inactivé)  |                                     |                                      |   |   |
| a-RIX-Tetra<br>Injektionssuspension in<br>Fertigspritze<br>Grippeimpfung (Spalt-<br>Virion, inaktiviert)                            | DE/H/1939/001                       | 2014090216                           | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | LU  |
| Fluarix Tetra sospensione<br>iniettabile in siringa<br>prerimpita Vaccino<br>influenzale (virus split<br>(frammentato), inattivato) | DE/H/1939/001                       | 043132051                            | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | IT  |
| Fluarix Tetra sospensione<br>iniettabile in siringa<br>prerimpita Vaccino<br>influenzale (virus split<br>(frammentato), inattivato) | DE/H/1939/001                       | 043132063                            | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | IT  |
| Fluarix Tetra sospensione<br>iniettabile in siringa<br>prerimpita Vaccino<br>influenzale (virus split<br>(frammentato), inattivato) | DE/H/1939/001                       | 043132075                            | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | IT  |
| Fluarix Tetra, ενέσιμο<br>εναιώρημα σε<br>προγεμισμένη σύριγγα<br>Αντιγριπικό εμβόλιο<br>(τμήμα ιού,<br>αδρανοποιημένο)             | DE/H/1939/001                       | 3062501                              | GLAXOSMITHKLINE<br>BIOLOGICALS S.A.       | GR  |

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| Fluarix Tetra suspension for injection in pre-filled syringe Influenza vaccine (split virion, inactivated)                  | DE/H/1939/001                       | PA 1077/134/001                      | SMITHKLINE BEECHAM LTD                        | IE  |
| Fluarix Tetra suspenzija za injekciju u napunjenoj štrcaljki, cjepivo protiv influence (fragmentirani virion), inaktivirano | DE/H/1939/001                       | HR-H-048213854                       | GLAXOSMITHKLINE D.O.O.                        | HR  |
| Fluarix Tetra, suspensão injetável em seringa pré-cheia<br>Vacina contra a gripe (virião fragmentado, inativado)            | DE/H/1939/001                       | 5751078                              | GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA | PT  |
| Fluarix Tetra süstesuspensioon süstlis<br>Gripivaktsiin (inaktiveeritud purustatud virus)                                   | DE/H/1939/001                       | 966018                               | GLAXOSMITHKLINE EESTI OÜ                      | EE  |
| Fluarix Tetra, injektionsvæske, suspension i fyldt injektionssprøjte  | DE/H/1939/001                       | 60754                                | GLAXOSMITHKLINE PHARMA A/S                    | DK  |
| Fluarix Tetra suspensija injekcijam pilnširce<br>Gripas vakcina (škelts, inaktivets virions)                                | DE/H/1939/001                       | 18-0098                              | GLAXOSMITHKLINE LATVIA SIA                    | LV  |

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| Vaccinum influenzae inactivatum ex virorum fragmentis praeparatum  |                                     |                                      |   |   |
| Fluarix Tetra, stungulyf, dreifa í áfylltri sprautu<br>Inflúensubóluefni<br>(veiruhlutar, deyddir)                   | DE/H/1939/001                       | IS/1/18/068/01                       | GLAXOSMITHKLINE PHARMA A/S                | IS  |
| Fluarix Tetra, suspensie voor injectie in een voorgevulde spuit<br>Influenzavaccin (gesplitst virion, geïnactiveerd) | DE/H/1939/001                       | RVG 122632                           | GLAXOSMITHKLINE B.V.                      | NL  |
| Fluarix Tetra injekcine suspensija užpildytame švirkšte Vakcina nuo gripo (iš virionu fragmentu, inaktyvuota)        | DE/H/1939/001                       | LT/1/18/4236/001                     | GLAXOSMITHKLINE LIETUVA UAB               | LT  |
| Fluarix Tetra injekcine suspensija užpildytame švirkšte Vakcina nuo gripo (iš virionu fragmentu, inaktyvuota)        | DE/H/1939/001                       | LT/1/18/4236/002                     | GLAXOSMITHKLINE LIETUVA UAB               | LT  |
| Fluarix Tetra injekcine suspensija užpildytame švirkšte Vakcina nuo gripo (iš virionu fragmentu, inaktyvuota)        | DE/H/1939/001                       | LT/1/18/4236/003                     | GLAXOSMITHKLINE LIETUVA UAB               | LT  |

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| Fluarix Tetra injekcine suspensija užpildytame švirkšte Vakcina nuo gripo (iš virionu fragmentu, inaktyvuota)             | DE/H/1939/001                       | LT/1/18/4236/004                     | GLAXOSMITHKLINE LIETUVA UAB               | LT  |
| Fluarix Tetra injekcine suspensija užpildytame švirkšte Vakcina nuo gripo (iš virionu fragmentu, inaktyvuota)             | DE/H/1939/001                       | LT/1/18/4236/005                     | GLAXOSMITHKLINE LIETUVA UAB               | LT  |
| Fluarix Tetra injektioneste, suspensio, esitäytetyssä ruiskussa Influenssarokote (virusfragmentit, inaktivoitu)           | DE/H/1939/001                       | 35880                                | GLAXOSMITHKLINE OY                        | FI  |
| Fluarix Tetra suspensija za injiciranje v napolnjeni injekcijski brizgi cepivo proti gripi z delci virionov, inaktivirano | DE/H/1939/001                       | H/18/02481/001                       | GLAXOSMITHKLINE D.O.O.                    | SI  |
| Fluarix Tetra suspensija za injiciranje v napolnjeni injekcijski brizgi cepivo proti gripi z delci virionov, inaktivirano | DE/H/1939/001                       | H/18/02481/002                       | GLAXOSMITHKLINE D.O.O.                    | SI  |
| Fluarix Tetra suspensija za injiciranje v napolnjeni injekcijski brizgi cepivo  | DE/H/1939/001                       | H/18/02481/003                       | GLAXOSMITHKLINE D.O.O.                    | SI  |

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| proti gripi z delci virionov, inaktivirano  |                                     |                                      |   |   |
| Fluarix Tetra suspenzija za injiciranje v napolnjeni injekcijski brizgi cepivo proti gripi z delci virionov, inaktivirano       | DE/H/1939/001                       | H/18/02481/004                       | GLAXOSMITHKLINE D.O.O.                    | SI  |
| Fluarix Tetra suspenzija za injiciranje v napolnjeni injekcijski brizgi cepivo proti gripi z delci virionov, inaktivirano       | DE/H/1939/001                       | H/18/02481/005                       | GLAXOSMITHKLINE D.O.O.                    | SI  |
| Fluarix Tetra injekcijsvæske, suspensjon i ferdigfylt sprøyte<br>Vaksine mot influensa (inaktivert, splittvirus)                | DE/H/1939/001                       | 18-12139                             | GLAXOSMITHKLINE AS                        | NO  |
| Fluarix Tetra, zawiesina do wstrzykiwan w ampulko-strzykawce<br>Szczepionka przeciw grypie (rozszczepiony wirion, inaktywowana) | DE/H/1939/001                       | 24888                                | GLAXOSMITHKLINE BIOLOGICALS S.A.          | PL  |
| Fluarix Tetra szuszpenziós injekció előretöltött fecskendőben<br>Influenza vakcina (split-vírus,                                | DE/H/1939/001                       | OGYI-T-23435/01                      | GLAXOSMITHKLINE KFT.                      | HU  |



| <b>Product Name (in authorisation country)</b>   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| inaktivált)  |                                     |                                      |   |   |
| Флуарикс Тетра<br>инжекционна суспензия<br>в предварително<br>напълнена спринцовка<br>Ваксина срещу грип<br>(фрагментиран вирион,<br>инактивирана) | DE/H/1939/001                       | 20180166                             | GLAXOSMITHKLINE EOOD                      | BG  |
| Fluarix Tetra szuszpenziós<br>injekció eloretöltött<br>fecskendoben Influenza<br>vakcina (split-vírus,<br>inaktivált)                              | DE/H/1939/001                       | OGYI-T-23435/02                      | GLAXOSMITHKLINE KFT.                      | HU  |
| Fluarix Tetra szuszpenziós<br>injekció eloretöltött<br>fecskendoben Influenza<br>vakcina (split-vírus,<br>inaktivált)                              | DE/H/1939/001                       | OGYI-T-23435/03                      | GLAXOSMITHKLINE KFT.                      | HU  |
| Fluarix Tetra szuszpenziós<br>injekció eloretöltött<br>fecskendoben Influenza<br>vakcina (split-vírus,<br>inaktivált)                              | DE/H/1939/001                       | OGYI-T-23435/04                      | GLAXOSMITHKLINE KFT.                      | HU  |
| Fluarix Tetra szuszpenziós<br>injekció eloretöltött<br>fecskendoben<br>Influenza vakcina (split-   | DE/H/1939/001                       | OGYI-T-23435/05                      | GLAXOSMITHKLINE KFT.                      | HU  |

| <b>Product Name (in authorisation country)</b>   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| vírus, inaktivált)   |                                     |                                      |   |   |
| Fluarix Tetra suspension for injection in pre-filled syringe Influenza vaccine (split virion, inactivated) | DE/H/1939/001                       | MA170/01101                          | GLAXOSMITHKLINE BIOLOGICALS S.A.          | MT  |
| Fluarix Tetra, ενέσιμο εναιώρημα σε προγεμισμένη σύριγγα Αντιγριπικό εμβόλιο (τμήμα ιού, αδραντοποιημένο)  | DE/H/1939/001                       | 022907                               | GLAXOSMITHKLINE (CYPRUS) LIMITED          | CY  |
| Fluarix Tetra suspensie injectabilă în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)     | DE/H/1939/001                       | 11294/2018/01                        | GLAXOSMITHKLINE (GSK) S.R.L.              | RO  |
| Fluarix Tetra suspensie injectabilă în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)     | DE/H/1939/001                       | 11294/2018/02                        | GLAXOSMITHKLINE (GSK) S.R.L.              | RO  |
| Fluarix Tetra suspensie injectabilă în seringă preumplută Vaccin gripal (virion fragmentat, inactivat)     | DE/H/1939/001                       | 11294/2018/04                        | GLAXOSMITHKLINE (GSK) S.R.L.              | RO  |

| <b>Product Name (in authorisation country)</b>   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| Fluarix Tetra suspensie injectabilă în seringă preumplută<br>Vaccin gripal (virion fragmentat, inactivat)            | DE/H/1939/001                       | 11294/2018/03                        | GLAXOSMITHKLINE (GSK)<br>S.R.L.           | RO  |
| Fluarix Tetra suspensie injectabilă în seringă preumplută<br>Vaccin gripal (virion fragmentat, inactivat)            | DE/H/1939/001                       | 11294/2018/05                        | GLAXOSMITHKLINE (GSK)<br>S.R.L.           | RO  |
| Fluarix Tetra,<br>injektionsvätska,<br>suspension i förfylld spruta<br>Influensavaccin (spjälkat virus, inaktiverat) | DE/H/1939/001                       | 35880                                | GLAXOSMITHKLINE OY                        | FI  |
| FLUARIXTETRA<br>suspension injectable en seringue préremplie<br>Vaccin grippal inactivé à virion fragmenté           | DE/H/1939/001                       | 34009 300 291 9 0                    | LABORATOIRE<br>GLAXOSMITHKLINE            | FR  |
| FLUARIXTETRA<br>suspension injectable en seringue préremplie<br>Vaccin grippal inactivé à virion fragmenté           | DE/H/1939/001                       | 34009 300 292 2 0                    | LABORATOIRE<br>GLAXOSMITHKLINE            | FR  |
| FLUARIXTETRA<br>suspension injectable en seringue préremplie   | DE/H/1939/001                       | 34009 300 291 6 9                    | LABORATOIRE<br>GLAXOSMITHKLINE            | FR  |

| <b>Product Name (in authorisation country)</b>   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| Vaccin grippal inactivé à virion fragmenté   |                                     |                                      |   |   |
| FLUARIXTETRA<br>suspension injectable en seringue préremplie<br>Vaccin grippal inactivé à virion fragmenté | DE/H/1939/001                       | 34009 274 425 9 9                    | LABORATOIRE<br>GLAXOSMITHKLINE            | FR  |
| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado)   | FR/H/0122/001                       | 8650309                              | SANOFI PASTEUR EUROPE                     | PT  |
| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado)   | FR/H/0122/001                       | 2638286                              | SANOFI PASTEUR EUROPE                     | PT  |
| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado)   | FR/H/0122/001                       | 2638385                              | SANOFI PASTEUR EUROPE                     | PT  |
| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado)   | FR/H/0122/001                       | 4317186                              | SANOFI PASTEUR EUROPE                     | PT  |

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| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0122/001                       | 4316980                              | SANOFI PASTEUR EUROPE                     | PT  |
| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0122/001                       | 4317285                              | SANOFI PASTEUR EUROPE                     | PT  |
| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0122/001                       | 4317087                              | SANOFI PASTEUR EUROPE                     | PT  |
| ISTIVAC, suspensão injetável em seringa pré-cheia. Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0122/001                       | 2638484                              | SANOFI PASTEUR EUROPE                     | PT  |
| MUTAGRIP, suspension injectable en seringue préremplie. Vaccin grippal (inactivé, à virion fragmenté).   | FR/H/0122/001                       | 34009 352 300 0 3                    | SANOFI PASTEUR EUROPE                     | FR  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza           | DE/H/1949/001                       | OGYI-T-23068/01                      | SANOFI PASTEUR                            | HU  |

| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| vakcina (hasított vírus, inaktivált)  |                                     |                                      |   |   |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/02                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/03                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/04                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/05                      | SANOFI PASTEUR                            | HU  |

| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/06                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/07                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/08                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/09                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/10                      | SANOFI PASTEUR                            | HU  |

| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| inaktivált)   |                                     |                                      |   |   |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/11                      | SANOFI PASTEUR                            | HU  |
| Vaxigrip Tetra<br>szuszpenziós injekció<br>előretöltött fecskendőben<br>kvadrivalens influenza<br>vakcina (hasított vírus,<br>inaktivált) | DE/H/1949/001                       | OGYI-T-23068/12                      | SANOFI PASTEUR                            | HU  |
| VaxigripTetra suspensija<br>injekcijam pilnšlirce<br>Cetrvertiga gripas vakcina<br>(škelts virions, inaktiveta)                           | DE/H/1949/001                       | 16-0141                              | SANOFI PASTEUR                            | LV  |
| VaxigripTetra suspensie<br>injectabila în seringă<br>preumpluta<br>Vaccin gripal tetravalent<br>(virion fragmentat,<br>inactivat)         | DE/H/1949/001                       | 9198/2016/01                         | SANOFI PASTEUR                            | RO  |
| VaxigripTetra suspensie<br>injectabilă în seringă<br>preumplută<br>Vaccin gripal tetravalent  | DE/H/1949/001                       | 9198/2016/02                         | SANOFI PASTEUR                            | RO  |



| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| (virion fragmentat, inactivat)  |                                     |                                      |   |   |
| VaxigripTetra suspensie injectabilă în seringă preumplută<br>Vaccin gripal tetravalent (virion fragmentat, inactivat) | DE/H/1949/001                       | 9198/2016/03                         | SANOFI PASTEUR                            | RO  |
| VaxigripTetra suspensie injectabilă în seringă preumplută<br>Vaccin gripal tetravalent (virion fragmentat, inactivat) | DE/H/1949/001                       | 9198/2016/04                         | SANOFI PASTEUR                            | RO  |
| VaxigripTetra suspensie injectabila în seringa preumpluta<br>Vaccin gripal tetravalent (virion fragmentat, inactivat) | DE/H/1949/001                       | 9198/2016/05                         | SANOFI PASTEUR                            | RO  |
| VaxigripTetra suspensie injectabilă în seringă preumplută<br>Vaccin gripal tetravalent (virion fragmentat, inactivat) | DE/H/1949/001                       | 9198/2016/06                         | SANOFI PASTEUR                            | RO  |

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| VaxigripTetra, suspenzija za injekciju u napunjenoj štrcaljki<br>Četverovalentno cjepivo protiv influence (fragmentirani virion, inaktivirano) | DE/H/1949/001                       | HR-H-888872987                       | SANOFI PASTEUR                            | HR  |
| Vaxigrip Tetra injekční suspenze v predplněné injekční strikacce<br>Tetravalentní vakcína proti chripce (štepěný virion, inaktivovaný)         | DE/H/1949/001                       | 59/370/16-C                          | SANOFI PASTEUR                            | CZ  |
| VaxigripTetra, süstesuspensioon süstlis<br>Neljavalentne gripivaktsiin (purustatud viirus, inaktiveeritud)                                     | DE/H/1949/001                       | 919416                               | SANOFI PASTEUR                            | EE  |
| VaxigripTetra, suspension injectable en seringue<br>préremplie Vaccin grippal quadrivalent (inactivé, à virion fragmenté)                      | DE/H/1949/001                       | NL46320                              | SANOFI PASTEUR                            | FR  |
| Vaxigrip Tetra injekčná suspenzia naplnená v injekčnej striekačke<br>tetravalentná očkovacia látka proti chrípke                               | DE/H/1949/001                       | 59/0415/16-S                         | SANOFI PASTEUR                            | SK  |

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| (štiepený viri3n,<br>inaktivovaná)  |                                     |                                      |   |   |
| VaxigripTetra injekcinė suspensija užpildytame švirksšte Keturvalente vakcina nuo gripo (iš virionu fragmentu, inaktyvuota) | DE/H/1949/001                       | LT/1/16/3975/001                     | SANOFI PASTEUR                            | LT  |
| VaxigripTetra injekcinė suspensija užpildytame švirksšte Keturvalentė vakcina nuo gripo (iš virionų fragmentų, inaktyvuota) | DE/H/1949/001                       | LT/1/16/3975/002                     | SANOFI PASTEUR                            | LT  |
| VaxigripTetra injekcinė suspensija užpildytame švirksšte Keturvalentė vakcina nuo gripo (iš virionų fragmentų, inaktyvuota) | DE/H/1949/001                       | LT/1/16/3975/003                     | SANOFI PASTEUR                            | LT  |
| VaxigripTetra injekcinė suspensija užpildytame švirksšte Keturvalentė vakcina nuo gripo (iš virionų fragmentų, inaktyvuota) | DE/H/1949/001                       | LT/1/16/3975/004                     | SANOFI PASTEUR                            | LT  |

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| VaxigripTetra injekcinė suspensija užpildytame švirkšte Keturvalentė vakcina nuo gripo (iš virionų fragmentų, inaktyvuota)                   | DE/H/1949/001                       | LT/1/16/3975/005                     | SANOFI PASTEUR                            | LT  |
| VaxigripTetra injekcinė suspensija užpildytame švirkšte Keturvalentė vakcina nuo gripo (iš virionų fragmentų, inaktyvuota)                   | DE/H/1949/001                       | LT/1/16/3975/006                     | SANOFI PASTEUR                            | LT  |
| ВаксигрипТетра инжекционна суспензия в предварително напълнена спринцовка Четирирлентна ваксина срещу грип (фрагментиран инактивиран вирион) | DE/H/1949/001                       | 20160310                             | SANOFI PASTEUR                            | BG  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/001                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi  | DE/H/1949/001                       | H/16/02251/002                       | SANOFI PASTEUR                            | SI  |

| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano)  |                                     |                                      |   |   |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/003                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/004                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/005                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/006                       | SANOFI PASTEUR                            | SI  |

| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/007                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/008                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/009                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/010                       | SANOFI PASTEUR                            | SI  |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/011                       | SANOFI PASTEUR                            | SI  |

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| inaktivirano)   |                                     |                                      |   |   |
| VaxigripTetra suspenzija za injiciranje v napolnjeni injekcijski brizgi<br>Štirivalentno cepivo proti gripi (razcepljeni virioni, inaktivirano) | DE/H/1949/001                       | H/16/02251/012                       | SANOFI PASTEUR                            | SI  |
| Vaxigriptetra, injektionsvæske, suspension i fylt injektionsprøjte  | DE/H/1949/001                       | 56583                                | SANOFI PASTEUR EUROPE                     | DK  |
| Vaxigriptetra, injeksjonsvæske, suspensjon i ferdigfylt sprøyte.<br>Kvadrivalent vaksine mot influensa (inaktivert, splittvirus)                | DE/H/1949/001                       | 15-10871                             | SANOFI PASTEUR EUROPE                     | NO  |
| VaxigripTetra, stungulyf, dreifa í áfylltri sprautu.<br>Fjörgilt inflúensubóluefni (klofin veiruögn, deydd)                                     | DE/H/1949/001                       | IS/1/16/068/01                       | SANOFI PASTEUR EUROPE                     | IS  |
| Quadrivalent Influenza Vaccine (split virion, inactivated), suspension for injection in pre-filled syringe Quadrivalent                         | DE/H/1949/001                       | PA 2131/013/001                      | SANOFI PASTEUR EUROPE                     | IE  |

| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|---|-------------------------------------|--------------------------------------|---|---|
| influenza vaccine (split virion, inactivated)   |                                     |                                      |   |   |
| Quadrivalent Influenza Vaccine (split virion, inactivated), suspension for injection in pre-filled syringe Quadrivalent influenza vaccine (split virion, inactivated) | DE/H/1949/001                       | PL 46602/0017                        | SANOPI PASTEUR EUROPE                     | UK  |
| VaxigripTetra, injektioneste, suspensio, esitytetty ruisku. Nelivalenttinen influenssarokote (virusfragmentit, inaktivoitu)  | DE/H/1949/001                       | 33654                                | SANOPI PASTEUR EUROPE                     | FI  |
| VaxigripTetra injektionsvatska, suspension i forfylld spruta Quadrivalent influensavaccin (spjalkat virus, inaktiverat)  | DE/H/1949/001                       | 33654                                | SANOPI PASTEUR EUROPE                     | FI  |
| Vaxigrip Tetra, suspensie voor injectie in een voorgevulde spuit Quadrivalent griepvaccin (gesplitst virion, geinactieveerd)  | DE/H/1949/001                       | RVG 117963                           | SANOPI PASTEUR EUROPE                     | NL  |



| <b>Product Name (in authorisation country)</b>  | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| VaxigripTetra, zawiesina do wstrzykiwan w ampulko-strzykawce Czterowalentna szczepionka przeciw grypie (rozszczepiony wirion), inaktywowana | DE/H/1949/001                       | 23540                                | SANOFI PASTEUR                            | PL  |
| VaxigripTetra, injektionsvätska, suspension i förfylld spruta Fyrvalent influensavaccin (spjälkat virus, inaktiverat)                       | DE/H/1949/001                       | 53400                                | SANOFI PASTEUR EUROPE                     | SE  |
| Vaxigrip Tetra, suspension inyectable en jeringa precargada Vacuna antigripal tetravalente (virus fraccionados, inactivados)                | DE/H/1949/001                       | 81098                                | SANOFI PASTEUR EUROPE                     | ES  |
| Vaxigrip Tetra Injektionssuspension in einer Fertigspritze Tetravalenter Influenza-Spaltimpfstoff (inaktiviert)                             | DE/H/1949/001                       | PEI.H.11808.01.1                     | SANOFI PASTEUR EUROPE                     | DE  |
| Vaxigrip Tetra, suspensie voor injectie in een voorgevulde spuit Quadrivalent griepvaccin   | DE/H/1949/001                       | BE501511                             | SANOFI PASTEUR EUROPE                     | BE  |

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| (gesplitst virion, geïnactiveerd)   |                                     |                                      |   |   |
| Vaxigrip Tetra, Injektionssuspension in einer Fertigspritze Quadrivalenter Influenza-Impfstoff (inaktiviert, gespalten)   | DE/H/1949/001                       | BE501511                             | SANOFI PASTEUR EUROPE                     | BE  |
| Vaxigrip Tetra, suspension injectable en seringue préremplie Vaccin grippal quadrivalent (virion fragmenté, inactivé)     | DE/H/1949/001                       | BE501511                             | SANOFI PASTEUR EUROPE                     | BE  |
| VaxigripTetra Injektionssuspension in einer Fertigspritze Tetravalenter Influenza-Impfstoff (Spaltvirus, inaktiviert)     | DE/H/1949/001                       | 137203                               | SANOFI PASTEUR EUROPE                     | AT  |
| Vaxigrip Tetra, suspension for injection in pre-filled syringe Quadrivalent influenza vaccine (split virion, inactivated) | DE/H/1949/001                       | MA573/00103                          | SANOFI PASTEUR                            | MT  |
| VaxigripTetra, ενέσιμο εναιώρημα σε προγεμισμένη σύριγγα Τετραδύναμο αντιγριπικό  | DE/H/1949/001                       | 104433/11-09-2019                    | SANOFI PASTEUR EUROPE                     | GR  |

| <b>Product Name (in authorisation country)</b>   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| εμβόλιο (split virion, αδραντοποιημένο)  |                                     |                                      |   |   |
| Vaxigrip Tetra,<br>sospensione iniettabile in siringa preriempita<br>Vaccino influenzale quadrivalente preparato con virus frammentati "split", inattivati | DE/H/1949/001                       | 044898017                            | SANOFI PASTEUR EUROPE                     | IT  |
| Vaxigrip Tetra,<br>sospensione iniettabile in siringa preriempita<br>Vaccino influenzale quadrivalente preparato con virus frammentati "split", inattivati | DE/H/1949/001                       | 044898029                            | SANOFI PASTEUR EUROPE                     | IT  |
| Vaxigrip Tetra,<br>sospensione iniettabile in siringa preriempita<br>Vaccino influenzale quadrivalente preparato con virus frammentati "split", inattivati | DE/H/1949/001                       | 044898031                            | SANOFI PASTEUR EUROPE                     | IT  |
| Vaxigrip Tetra,<br>sospensione iniettabile in siringa preriempita<br>Vaccino influenzale quadrivalente preparato   | DE/H/1949/001                       | 044898043                            | SANOFI PASTEUR EUROPE                     | IT  |

| <b>Product Name (in authorisation country)</b>   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
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| con virus frammentati<br>"split", inattivati   |                                     |                                      |   |   |
| Vaxigrip Tetra,<br>sospensione iniettabile in<br>siringa preimpita<br>Vaccino influenzale<br>quadrivalente preparato<br>con virus frammentati<br>"split", inattivati | DE/H/1949/001                       | 044898056                            | SANOFI PASTEUR EUROPE                     | IT  |
| Vaxigrip Tetra,<br>sospensione iniettabile in<br>siringa preimpita<br>Vaccino influenzale<br>quadrivalente preparato<br>con virus frammentati<br>"split", inattivati | DE/H/1949/001                       | 044898068                            | SANOFI PASTEUR EUROPE                     | IT  |
| Vaxigrip Tetra, suspensão<br>injetável em seringa pré-<br>cheia.<br>Vacina quadrivalente<br>contra a gripe (virião<br>fragmentado, inativado).                       | DE/H/1949/001                       | 5686852                              | SANOFI PASTEUR EUROPE                     | PT  |
| Vaxigrip Tetra, suspensão<br>injetável em seringa pré-<br>cheia.<br>Vacina quadrivalente<br>contra a gripe (virião<br>fragmentado, inativado).                       | DE/H/1949/001                       | 5686928                              | SANOFI PASTEUR EUROPE                     | PT  |

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| Vaxigrip Tetra, suspensão injetável em seringa pré-cheia.<br>Vacina quadrivalente contra a gripe (virião fragmentado, inativado). | DE/H/1949/001                       | 5686878                              | SANOFI PASTEUR EUROPE                     | PT  |
| Vaxigrip Tetra, suspensão injetável em seringa pré-cheia.<br>Vacina quadrivalente contra a gripe (virião fragmentado, inativado)  | DE/H/1949/001                       | 5686860                              | SANOFI PASTEUR EUROPE                     | PT  |
| Vaxigrip Tetra, suspensão injetável em seringa pré-cheia.<br>Vacina quadrivalente contra a gripe (virião fragmentado, inativado). | DE/H/1949/001                       | 5686910                              | SANOFI PASTEUR EUROPE                     | PT  |
| Vaxigrip Tetra, suspensão injetável em seringa pré-cheia.<br>Vacina quadrivalente contra a gripe (virião fragmentado, inativado). | DE/H/1949/001                       | 5686902                              | SANOFI PASTEUR EUROPE                     | PT  |
| Vaxigrip Tetra, suspension injectable en seringue préremplie<br>Vaccin grippal quadrivalent (virion                               | DE/H/1949/001                       | 2017040149                           | SANOFI PASTEUR EUROPE                     | LU  |

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| fragmenté, inactivé)  |                                     |                                      |   |   |
| Vaxigrip Tetra,<br>Injektionssuspension in<br>einer Fertigspritze<br>Quadrivalenter Influenza-<br>Impfstoff (inaktiviert,<br>gespalten) | DE/H/1949/001                       | 2017040149                           | SANOFI PASTEUR EUROPE                     | LU  |
| VaxigripTetra, ενέσιμο<br>εναιώρημα σε<br>προγεμισμένη σύριγγα<br>Τετραδύναμο αντιγριπικό<br>εμβόλιο (split virion,<br>αδρανοποιημένο)  | DE/H/1949/001                       | 22512                                | SANOFI PASTEUR                            | CY  |
| VAXIGRIP, suspension<br>injectable en flacon<br>multidose<br>Vaccin grippal (inactivé, à<br>virion fragmenté)                           | FR/H/0121/002                       | NL 11 155-2                          | SANOFI PASTEUR                            | FR  |
| VaxigripTetra, suspension<br>injectable en flacon<br>multidose<br>Vaccin grippal<br>quadrivalent (inactivé, à<br>virion fragmenté)      | DE/H/1949/002                       | NL51341                              | SANOFI PASTEUR                            | FR  |
| Vaxigrip Tetra<br>Injektionssuspension in<br>einer Durchstechflasche  | DE/H/1949/002                       | PEI.H.11808.02.1                     | SANOFI PASTEUR                            | DE  |

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| zur Mehrfachentnahme<br>Tetravalenter Influenza-<br>Spaltimpfstoff (inaktiviert)  |                                     |                                      |   |   |
| Trivalent Influenza<br>Vaccine (Split Virion,<br>Inactivated) High Dose,<br>suspension for injection in<br>pre-filled syringe | not available                       | PL 04425/0756                        | AVENTIS PHARMA LTD                        | UK  |
| VAXIGRIP, suspension<br>injectable en seringue<br>préremplie.<br>Vaccin grippal (inactivé, à<br>virion fragmenté).            | FR/H/0121/001                       | NL 11 155-1                          | SANOFI PASTEUR                            | FR  |
| VAXIGRIP, suspensie voor<br>injectie in een<br>voorgevulde spuit.<br>Griepvaccin (gesplitst<br>virion, geïnactiveerd)         | FR/H/0121/001                       | RVG 22306                            | SANOFI PASTEUR EUROPE                     | NL  |
| VAXIGRIP, suspensión<br>inyectable en jeringa<br>precargada Vacuna<br>antigripal (virus<br>fraccionados, inactivados)         | FR/H/0121/001                       | 61108                                | SANOFI PASTEUR EUROPE                     | ES  |
| VAXIGRIP, suspensão<br>injetável em seringa pré-<br>cheia Vacina contra a<br>gripe (virião fragmentado,<br>inativado)         | FR/H/0121/001                       | 2637882                              | SANOFI PASTEUR EUROPE                     | PT  |

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| VAXIGRIP, suspensão injetável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0121/001                       | 2637981                              | SANOFI PASTEUR EUROPE                     | PT  |
| VAXIGRIP, suspensão injetável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0121/001                       | 2638088                              | SANOFI PASTEUR EUROPE                     | PT  |
| VAXIGRIP, suspensão injetável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0121/001                       | 4317780                              | SANOFI PASTEUR EUROPE                     | PT  |
| VAXIGRIP, suspensão injetável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0121/001                       | 4317681                              | SANOFI PASTEUR EUROPE                     | PT  |
| VAXIGRIP, suspensão injetável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0121/001                       | 2638187                              | SANOFI PASTEUR EUROPE                     | PT  |
| VAXIGRIP, suspensão injetável em seringa pré-cheia Vacina contra a gripe (virião fragmentado,            | FR/H/0121/001                       | 4317988                              | SANOFI PASTEUR EUROPE                     | PT  |



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| inativado)  |                                     |                                      |   |   |
| VAXIGRIP, suspensão injetável em seringa pré-cheia<br>Vacina contra a gripe (virião fragmentado, inativado) | FR/H/0121/001                       | 4317889                              | SANOFI PASTEUR EUROPE                     | PT  |