



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021
EMA/50004/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: diphtheria / tetanus vaccines (adsorbed), diphtheria vaccines (adsorbed)

Procedure no.: PSUSA/00001128/202005

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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
DIFTETALL Sospensione iniettabile in siringa pre-riempita Vaccino difterico e tetanico, adsorbito (a contenuto ridotto di antigeni)	not available	003671070	ASTRO-PHARMA GMBH	IT
Td-pur suspenzija za injiciranje cepivo proti davici in tetanusu (z zmanjšano vsebnostjo antigena(ov), adsorbirano)	not available	H/03/01500/002	GSK VACCINES GMBH	SI
Td-pur suspenzija za injiciranje cepivo proti davici in tetanusu (z zmanjšano vsebnostjo antigena(ov), adsorbirano)	not available	H/03/01500/001	GSK VACCINES GMBH	SI
Td-pur® Injektionssuspension in Fertigspritze Tetanus und Diphtherie-Adsorbat-Impfstoff (inaktiviert) mit reduziertem Antigengehalt	not available	167A/96	ASTRO-PHARMA GMBH	DE
D.T.VAX® Adults	not available	40181/25-6-2015 & 63436/21-09-2016	SANOFI PASTEUR EUROPE	GR

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IMOVAX d.T. ADULT suspensija injekcijām pilnšjircē Adsorbēta difterijas un stingumkrampju vakcīna Vaccinum diphtheriae et tetani adsorbatum	not available	06-0098	SANOFI PASTEUR SA	LV
Td-pur für Erwachsene und Heranwachsende Tetanus-Diphtherie-Impfstoff (inaktiviert, adsorbiert, reduzierter Antigengehalt) Injektionssuspension in Fertigspritze	not available	2-00234	ASTRO-PHARMA GMBH	AT
Diftavax stungulyf, dreifa í áfylltri sprautu	not available	950018	SANOFI PASTEUR EUROPE	IS
IMOVAX d.T. ADULT, 2 RÜ+20 RÜ/0,5 ml süstesuspensioon Adsorbeeritud difteeria ja teetanuse vaktsiin	not available	409103	SANOFI PASTEUR	EE
DIFTAVAX, suspenzija za injekciju u napunjenoj štrcaljki, cjepivo protiv difterije sa smanjenim sadržajem antigena i tetanusa, adsorbirano	not available	HR-H-126128199	SANOFI PASTEUR	HR

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DTVAX, suspension injectable en multidose Vaccin diphtérique et tétanique (adsorbé)	not available	V04021-2	SANOFI PASTEUR SA	FR
DTVAX, suspension injectable en seringue préremplie, Vaccin diphtérique et tétanique adsorbé	not available	V 04021-3	SANOFI PASTEUR SA	FR
IMOVAX D.T. ADULT, injekčná suspenzia naplnená v injekčnej striekačke Adsorbovaná vakcína proti záškrtu a tetanu	not available	59/0936/96-S	SANOFI PASTEUR	SK
Cjepivo protiv difterije i tetanusa sa smanjenim sadržajem antigena, adsorbirano, Imunološki zavod, 1 doza, suspenzija za injekciju; Vaccinum diphtheriae et tetani, antigeni-o(-is) minutum, adsorbatum	not available	UP/I-530-09/11-02/655	IMUNOLOŠKI ZAVOD D.D.	HR
Cjepivo protiv difterije i tetanusa sa smanjenim sadržajem antigena, adsorbirano, Imunološki zavod, 1 doza, suspenzija	not available	UP/I-530-09/11-02/655	IMUNOLOŠKI ZAVOD D.D.	HR

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za injekciju; Vaccinum diphtheriae et tetani, antigeni-o(-is) minutum, adsorbatum				
Cjepivo protiv difterije i tetanusa sa smanjenim sadržajem antigena, adsorbirano, Imunološki zavod, 10 doza, suspenzija za injekciju; Vaccinum diphtheriae et tetani, antigeni-o(-is) minutum, adsorbatum	not available	UP/I-530-09/11-02/656	IMUNOLOŠKI ZAVOD D.D.	HR
Cjepivo protiv difterije i tetanusa sa smanjenim sadržajem antigena, adsorbirano, Imunološki zavod, 10 doza, suspenzija za injekciju; Vaccinum diphtheriae et tetani, antigeni-o(-is) minutum, adsorbatum	not available	UP/I-530-09/11-02/656	IMUNOLOŠKI ZAVOD D.D.	HR
Td-Impfstoff Mérieux Injektionssuspension Diphtherie-Tetanus-Adsorbat-Impfstoff (reduzierter Antigengehalt) Für Kinder ab 5 Jahren und	not available	53A/91	SANOFI PASTEUR EUROPE	DE

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Erwachsene				
DIFTAVAX, suspension injectable en seringue préremplie Vaccin diphtérique et tétanique adsorbé	not available	NL 20 122	SANOFI PASTEUR	FR
IMOVAX d.T. adult injekcinė suspensija užpildytame švirkšte Vakcina nuo difterijos ir stabligės (adsorbuota)	not available	LT/1/95/2444/002	SANOFI PASTEUR SA	LT
D.T.Vax Adulto 2 U.I./0,5 ml + 20 U.I./0,5 ml Suspensão injectável Vacina contra a difteria e tétano, adsorvida	not available	4261780	SANOFI PASTEUR EUROPE	PT
D.T.Vax Adulto 2 U.I./0,5 ml + 20 U.I./0,5 ml Suspensão injectável Vacina contra a difteria e tétano, adsorvida	not available	4261889	SANOFI PASTEUR EUROPE	PT
dT-reduct „Mérieux“ – Injektionssuspension in einer Fertigspritze	not available	2-00144	SANOFI PASTEUR EUROPE	AT
IMOVAX DT Adult, suspension for injection in prefilled syringe	not available	MA573/01001	SANOFI PASTEUR	MT

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Adsorbed diphtheria and tetanus vaccine				
DIFTAVAX suspensión inyectable en jeringa precargada. Vacuna antidiftero-tetánica (adsorbida) para adultos y adolescentes	not available	61.025	SANOFI PASTEUR EUROPE	ES
diTeBooster, ενέσιμο εναιώρημα σε προγεμισμένες σύριγγες μίας δόσης Εμβόλιο κατά της διφθερίτιδας και του τετάνου (προσοφημένο, μειωμένη ποσότητα αντιγόνου)	DK/H/0200/002	84384/26-11-09	STATENS SERUM INSTITUT	GR
diTeBooster - Injektionssuspension in einer Fertigspritze Diphtherie- und Tetanus-Impfstoff (adsorbiert, mit reduziertem Antigengehalt)	DK/H/0200/002	2-00320	AJ VACCINES A/S	AT
diTeBooster, injektionsvæske, suspension, fyldt injektionssprøjte	DK/H/0200/002	36480	AJ VACCINES A/S	DK

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
diTeBooster, suspension for injection in pre-filled syringe Diphtheria and tetanus vaccine (adsorbed, reduced antigen content)	DK/H/0200/002	PA2160/001/001	AJ VACCINES A/S	IE
diTeBooster, injeksjonsvæske, suspensjon i ferdigfylt sprøyte Vaksine mot difteri og tetanus (adsorbent, redusert innhold av antigen)	DK/H/0200/002	06-4098	AJ VACCINES A/S	NO
diTeBooster, suspensión inyectable en jeringa monodosis precargada Vacuna contra la difteria y el tétanos (adsorbida, contenido en antígeno reducido)	DK/H/0200/002	68579	AJ VACCINES A/S	ES
diTeBooster injektionsvätska, suspension i förfylld spruta Difteri och tetanusvaccin (adsorberad, reducerat innehåll av antigen)	DK/H/0200/002	23830	AJ VACCINES A/S	SE

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diTeBooster, injektionsvæske, suspension, hætteglas Difteri-tetanusvaccine (adsorberet, reduceret indhold af antigen).	DK/H/0200/001	14827	AJ VACCINES A/S	DK
diTeBooster, suspensão injetável em seringas unidose pré-cheias. Vacina para difteria e tétano (adsorvida, reduzido conteúdo antigénico).	DK/H/0200/002	5002605	AJ VACCINES A/S	PT
Td-IMMUN, Injektionssuspension, Einzeldosis-Fertigspritze Diphtherie- und Tetanus- Impfstoff (adsorbiert, mit reduziertem Antigenhalt)	DK/H/0200/002	PEI.H.02357.01.2	AJ VACCINES A/S	DE
diTeBooster, suspensão injetável em seringas unidose pré-cheias. Vacina para difteria e tétano (adsorvida, reduzido conteúdo antigénico).	DK/H/0200/002	5002571	AJ VACCINES A/S	PT
diTeBooster, suspensão injetável em seringas unidose pré-cheias.	DK/H/0200/002	5002563	AJ VACCINES A/S	PT

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
Vacina para difteria e tétano (adsorvida, reduzido conteúdo antigénico).				
diTeBooster, suspensão injetável em seringas unidose pré-cheias. Vacina para difteria e tétano (adsorvida, reduzido conteúdo antigénico).	DK/H/0200/002	5002555	AJ VACCINES A/S	PT
diTeBooster Injektionsvätska, suspension, förfylld spruta. Difteri- och tetanusvaccin (adsorberad, reducerat innehåll av antigen)	DK/H/0200/002	22158	AJ VACCINES A/S	FI
diTeBooster Injektioneste, suspensio, esitäytetyissä ruiskuissa Kurkkumätä- ja jäykkäkouristusrokote (adsorboitu, vähennetty antigeenimäärä)	DK/H/0200/002	22158	AJ VACCINES A/S	FI
DIFTAVAX, suspension injectable en multidose Vaccin diphtérique et tétanique adsorbé	not available	NL 20 832	SANOFI PASTEUR	FR