



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31, October 2018
EMA/800973/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: BCG (bacillus calmette-guérin) for Immunotherapy

Procedure no.: PSUSA/00000303/201803



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
BCG Kultur "SSI", pulver til blæreskyllevæske	not available	14785	AJ VACCINES A/S	DK
IMMUCYST 81 mg, poudre pour suspension intravésicale B.C.G. pour immunothérapie	not available	NL17980	SANOFI PASTEUR SA	FR
ImmuCyst® 81 mg powder for intravesical suspension	not available	PL 16853/0120	ALLIANCE PHARMACEUTICALS LTD	UK
ImmuCyst® 81 mg powder for intravesical suspension	not available	PL 16853/0120	ALLIANCE PHARMACEUTICALS LTD	UK
ImmuCyst® 81 mg powder for intravesical suspension	not available	PL 16853/0120	ALLIANCE PHARMACEUTICALS LTD	UK
OncoTICE – zur intravesikalen Instillation	not available	2-00074	MERCK SHARP & DOHME GES.M.B.H.	AT
OncoTICE 12,5 mg pulver till lösning för intravesikal användning	not available	11614	MERCK SHARP & DOHME BV	SE
OncoTICE 2-8 x 10 ⁸ UFC polvo para suspensión intravesical BCG cepa Tice	not available	61.377	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
OncoTICE 2-8 x10e8 UFC Tice BCG pó para líquido para irrigação vesical	not available	3073087	MERCK SHARP & DOHME, LDA.	PT
OncoTICE 2-8 x10e8 UFC Tice BCG pó para líquido para irrigação vesical	not available	3072881	MERCK SHARP & DOHME, LDA.	PT
OncoTICE 2-8 x10e8 UFC Tice BCG pó para líquido para irrigação vesical	not available	3072980	MERCK SHARP & DOHME, LDA.	PT
OncoTICE BCG ad immunocurationem BCG do immunoterapii 2-8 x	not available	R/6711	MSD POLSKA SP. Z O.O.	PL

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10 ⁸ CFU, żywych atenuowanych pratków BCG (Bacillus Calmette-Guerin), podszczep TICE Proszek do sporządzania zawiesiny do podawania do pecherza moczowego				
OncoTICE polvere per sospensione per uso endovesicale	not available	028346029	NV ORGANON	IT
OncoTICE pulver til suspensjon til intravesikal bruk	not available	7941	MERCK SHARP & DOHME BV	NO
OncoTICE, jauhe rakonsisäisesti tiputettavaa liuosta varten	not available	10438	MERCK SHARP & DOHME BV	FI
OncoTICE, poeder voor instillatievloestof voor intravesicaal gebruik	not available	RVG 17509	NV ORGANON	NL
OncoTICE, PULVER FÖR BEREDNING AV LÖSNING FÖR INSTALLATION I URINBLÅSAN	not available	10438	MERCK SHARP & DOHME BV	FI
OncoTICE® 2-8 x 10 ⁸ vermehrungsfähige Einheiten Pulver zur Herstellung einer Suspension zur intravesikalen Instillation	not available	177A/89	MSD SHARP & DOHME GMBH	DE
OncoTICE® powder for instillation fluid for intravesical use containing 2-8 X 10 ⁸	not available	PL 05003/0046	NV ORGANON	UK

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CFU Tice BCG				
OncoTICE®, poeder voor oplossing voor intravesicaal gebruik	not available	BE 155653	MSD BELGIUM BVBA/SPRL	BE
OncoTICE®, poudre pour solution intravésicale	not available	BE 155653	MSD BELGIUM BVBA/SPRL	BE
OncoTICE®, poudre pour solution intravésicale	not available	2007079368	MSD BELGIUM BVBA/SPRL	LU
OncoTICE®, Pulver zur Herstellung einer Lösung zur intravesikalen Anwendung	not available	BE 155653	MSD BELGIUM BVBA/SPRL	BE
OncoTICE®, s???? ??a ???? e?d???st???? ????s?? t? ?p??? pe????e? 2-8 x 10^8 CFU Tice BCG	not available	19017	MSD GREECE	CY
OncoTICE®, s???? ??a ???? e?d???st???? ????s?? t? ?p??? pe????e? 2-8 x 10^8 CFU Tice BCG	not available	26185/11-4-2012	MSD GREECE	GR