



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2023
EMA/299583/2023
Human Medicines Division

List of nationally authorised medicinal products

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

Procedure No. PSUSA/00000303/202303



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
OncoTICE – zur intravesikalen Instillation	not available	2-00074	MERCK SHARP & DOHME GES.M.B.H.	AT
OncoTICE, Pulver zur Herstellung einer Lösung zur intravesikalen Anwendung	not available	BE155653	MSD BELGIUM BVBA/SPRL	BE
OncoTICE, poeder voor oplossing voor intravesicaal gebruik	not available	BE155653	MSD BELGIUM BVBA/SPRL	BE
OncoTICE, poudre pour solution intravésicale	not available	BE155653	MSD BELGIUM BVBA/SPRL	BE
OncoTICE®, σκόνη για υγρό ενδοκυστικής έγχυσης το οποίο περιέχει 2-8 x 10 ⁸ CFU Tice BCG	not available	19017	MSD GREECE	CY
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
Vesiculture, pulver til blæreskyllevæske	not available	14785	AJ VACCINES A/S	DK
OncoTICE 2-8 x 10 ⁸ UFC polvo para suspensión intravesical BCG cepa Tice	not available	61377	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
OncoTICE, pulver till intravesikal suspension	not available	10438	MERCK SHARP & DOHME BV	FI
OncoTICE, jauhe suspensiota varten, virtsarakkoon	not available	10438	MERCK SHARP & DOHME BV	FI
IMMUCYST 81 mg, poudre pour suspension	not available	34009 492 524 9 7	SANOFI PASTEUR	FR

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intravésicale B.C.G. pour immunothérapie				
OncoTICE®, σκόνη για υγρό ενδοκυστικής έγχυσης το οποίο περιέχει 2-8 x 10 ⁸ CFU Tice BCG	not available	47783/14-10-2008	MSD GREECE	GR
OncoTICE polvere per sospensione per uso endovesicale	not available	028346029	MSD ITALIA S.R.L.	IT
OncoTICE, poudre pour solution intravésicale	not available	2007079368	MSD BELGIUM BVBA/SPRL	LU
OncoTICE, poeder voor instillatievloestof voor intravesicaal gebruik	not available	RVG 17509	MERCK SHARP & DOHME BV	NL
OncoTICE pulver til suspensjon til intravesikal bruk.	not available	7941	MERCK SHARP & DOHME BV	NO
OncoTICE BCG ad immunocurationem BCG do immunoterapii 2-8 x 10 ⁸ CFU żywych, atenuowanych prątków BCG (Bacillus Calmette- Guerin), podszczep TICE Proszek do sporządzania zawiesiny do podawania do pęcherza moczowego	not available	R/6711	MSD POLSKA SP. Z O.O.	PL
OncoTICE 2-8 x10 ⁸ UFC Tice BCG pó para líquido para irrigação vesical	not available	3073087	MERCK SHARP & DOHME, LDA.	PT
OncoTICE 2-8 x10 ⁸ UFC Tice BCG pó para líquido para irrigação vesical	not available	3072881	MERCK SHARP & DOHME, LDA.	PT
OncoTICE 2-8 x10 ⁸	not available	3072980	MERCK SHARP & DOHME,	PT

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UFC Tice BCG pó para líquido para irrigação vesical			LDA.	
OncoTICE 12,5 mg pulver till lösning för intravesikal användning	not available	11614	MERCK SHARP & DOHME BV	SE
OncoTICE® powder for instillation fluid for intravesical use containing 2-8 x 10 ⁸ CFU Tice BCG.	not available	PL 53095/0003	MERCK SHARP & DOHME (UK) LIMITED	XI