



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2018
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: BCG vaccine (freeze-dried)

Procedure no.: PSUSA/00000304/201803



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 Szczepionka AJVaccines, proszek i rozpuszczalnik do sporządzania zawiesiny do wstrzykiwań.	DK/H/0367/001	12176	AJ VACCINES A/S	PL
BCG vaccin SSI, 0,75 mg per ml, poeder en oplosmiddel voor suspensie voor injectie	not available	RVG 17661	AJ VACCINES A/S	NL
BCG Vaccine "AJ Vaccines", pulver og solvens til injektionsvæske, suspension	DK/H/0367/001	14762	AJ VACCINES A/S	DK
BCG Vaccine "SSI", σκόνη και διαλύτης για ενέσιμο εναιώρημα	DK/H/0367/001	17557/5-3-2009	STATENS SERUM INSTITUT	GR
BCG Vaccine AJV, powder and solvent for suspension for injection	DK/H/0367/001	PL 46796/0001	AJ VACCINES A/S	UK
BCG Vaccine AJVaccines pulveris un šķīdinātājs injekciju suspensijas pagatavošanai	not available	95-0281	AJ VACCINES A/S	LV
BCG Vaccine AJVaccines, injektiokuiva-aine ja liuotin suspensiota varten.	DK/H/0367/001	18550	AJ VACCINES A/S	FI
BCG Vaccine AJVaccines, Pulver och vätska till injektionsvätska, suspension	DK/H/0367/001	18550	AJ VACCINES A/S	FI

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 vaccine SSI milteliai ir tirpiklis injekcinei suspensijai Vakcina nuo tuberkuliozės (BCG), liofilizuota	not available	LT/1/96/2510/001	AJ VACCINES A/S	LT
BCG vaccine SSI milteliai ir tirpiklis injekcinei suspensijai Vakcina nuo tuberkuliozės (BCG), liofilizuota	not available	LT/1/96/2510/002	AJ VACCINES A/S	LT
BCG VACCINE SSI Powder and solvent for suspension for injection	not available	PA2160/003/001	AJ VACCINES A/S	IE
BCG VACCINE SSI, 0,75 mg süstesuspensiooni pulber ja lahusti	not available	312400	AJ VACCINES A/S	EE
BCG Vacina SSI, 0,75 mg/1 ml, Pó e veículo para suspensão injetável	not available	4472189	AJ VACCINES A/S	PT
BCG-vaccin AJVaccines, pulver och vätska till injektionsvätska, suspension.	DK/H/0367/001	19853	AJ VACCINES A/S	SE
BCG-vaksine AJVaccines, pulver og væske til injeksjonsvæske, suspensjon. Vaksine mot tuberkulose (BCG) (frysetørret).	DK/H/0367/001	03-1989	AJ VACCINES A/S	NO
SSI BCG por és oldószer szuszpenziós injekcióhoz	not available	OGYI-T-9001/01	STATENS SERUM INSTITUT	HU
SSI BCG por és oldószer szuszpenziós injekcióhoz	not available	OGYI-T-9001/02	STATENS SERUM INSTITUT	HU

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
VACCIN BCG SSI, poudre et solvant pour suspension injectable	DK/H/0367/001	34009 364 661 3 5	STATENS SERUM INSTITUT	FR
VACCIN BCG SSI, poudre et solvant pour suspension injectable	DK/H/0367/001	34009 364 664 2 5	STATENS SERUM INSTITUT	FR
VACCIN BCG SSI, poudre et solvant pour suspension injectable	DK/H/0367/001	34009 364 660 7 4	STATENS SERUM INSTITUT	FR
VACCIN BCG SSI, poudre et solvant pour suspension injectable	DK/H/0367/001	34009 364 663 6 4	STATENS SERUM INSTITUT	FR