



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2018
EMA/496103/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fludeoxyglucose (18f)

Procedure no.: PSUSA/00001437/201711



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
Fluor-18-FDG, solution for injection	not available	DK R 14	PET & CYCLOTRON UNIT, RIGHOSPITALET, SECTION 3982	DK
Fludeoxyglucose (18F) Life Radiopharma Bonn, Injektionslösung, 300-2800 MBq/ml	not available	57818.00.00	LIFE RADIOPHARMA BERLIN GMBH	DE
GLUCOTRACE 185 MBq/ml, oplossing voor injectie	BE/H/0110/001	BE241132	UNIVERSITÉ DE LIÈGE	BE
GLUCOTRACE 185 MBq/ml solution injectable	BE/H/0110/001	BE241132	UNIVERSITÉ DE LIÈGE	BE
GLUCOTRACE, 185 MBq/ml solution injectable	BE/H/0110/001	2004090012	UNIVERSITÉ DE LIÈGE	LU
GLUCOTRACE, oplossing voor injectie 185 MBq/ml (185 tot 1850 MBq per flacon voor meervoudig gebruik)	BE/H/0110/001	RVG 30437	UNIVERSITÉ DE LIÈGE	NL
GLUCOTRACE 185 MBq/ml, Injektionslösung	BE/H/0110/001	59605.00.00	UNIVERSITÉ DE LIÈGE	DE
GLUCOTRACE 185 MBq/mL solution injectable	BE/H/0110/001	564 460-1	UNIVERSITÉ DE LIÈGE	FR
FDG Life Radiopharma Bonn, 300-2800 MBq/ml, Injektionslösung	not available	57819.00.00	LIFE RADIOPHARMA BERLIN GMBH	DE
Fludeoxyglucose (18F) Life Radiopharma Bonn, Injektionslösung, 300-2800 MBq/ml	not available	57818.00.00	LIFE RADIOPHARMA BERLIN GMBH	DE

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
PCA (18F) Fludeoxyglucose injection	not available	2165	PET-CENTRET ÅRHUS SYGEHUS	DK
Steripet 250 MBq/ml Solution for injection	NL/H/3528/001	05-3635	GE HEALTHCARE LIMITED	NO
Steripet 250 MBq/ml Injektionslösung	NL/H/3528/001	86228.00.00	GE HEALTHCARE BUCHLER GMBH & CO. KG	DE
Steripet 250 MBq/ml Oplossing voor injectie	NL/H/3528/001	RVG 33033	GE HEALTHCARE B.V.	NL
Steripet 250 MBq/ml injektioneste, liuos	NL/H/3528/001	30177	GE HEALTHCARE LIMITED	FI
Steripet, solution for injection	NL/H/3528/001	DK R. 2233	GE HEALTHCARE LIMITED	DK
Steripet 250 MBq/ml, injektionsvätska, lösning	NL/H/3528/001	46873	GE HEALTHCARE LIMITED	SE
Steripet 250 MBq/ml Soluzione iniettabile	NL/H/3528/001	37119017	GE HEALTHCARE S.R.L.	IT
Steripet, 250 MBq/ml süstelahus	NL/H/3528/001	781912	GE HEALTHCARE LIMITED	EE
Steripet 250 mg/ml injektionsvätska, lösning	NL/H/3528/001	30177	GE HEALTHCARE LIMITED	FI
Steripet 250 MBq/ml injekčný roztok	NL/H/3528/001	88/0271/12-S	GE HEALTHCARE LIMITED	SK
Steripet, 250 MBq/ml, roztwór do wstrzykiwań	NL/H/3528/001	20437	GE HEALTHCARE LIMITED	PL
Steripet 250 MBq/ml Injekční roztok	NL/H/3528/001	88/548/12-C	GE HEALTHCARE LIMITED	CZ
2-[18F]-FDG Injekční roztok	not available	88/463/99-C	RADIOMEDIC S.R.O.	CZ
2-[18F]-FDG, injekcia	not available	88/0295/00-S	RADIOMEDIC S.R.O.	SK