



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 July 2023
EMA/275473/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance: sodium fluoride (^{18}F)

Procedure no.: PSUSA/00010706/202211



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
[18F] NaF/ΒΙΟΚΟΣΜΟΣ	not available	86796/13-11-2013	ΒΙΟΚΟΣΜΟΣ SA	GR
CISNAF 100 MBq/mL, solution injectable	not available	34009-577-318-4-7	CIS BIO INTERNATIONAL	FR
Fluorid (18F) sodný RadioMedic 1-10 GBq injekční roztok	not available	88/396/06-C	RADIOMEDIC S.R.O.	CZ
Fluorid (18F) sodný UJV 100 – 1500 MBq/ml Injekční roztok	not available	88/394/16-C	ÚSTAV JADERNÉHO VÝZKUMU ŘEŽ A.S	CZ
IASOflu 2,0 GBq/mL Injektionslösung	FR/H/0394/001	76609.00.00	CURIUM AUSTRIA GMBH	AT
IASOflu 2,0 GBq/mL Injektionslösung	FR/H/0394/001	76609.00.00	CURIUM AUSTRIA GMBH	AT
IASOflu 2,0 GBq/mL Injektionslösung	FR/H/0394/001	1523/11050028	IASON GMBH	LU
IASOflu 2,0 GBq/mL, solution for injection	FR/H/0394/001	II-11061/22.10.2010	IASON GMBH	BG
IASOflu 2,0 GBq/mL, solution injectable	not available	34009 578 426 5 9	CURIUM AUSTRIA GMBH	FR
IASOflu 2,0 GBq/mL, solution injectable	not available	34009 573 228 0 9	CURIUM AUSTRIA GMBH	FR
IASOflu 2.0 GBq/mL, solution injectable	FR/H/0394/001	34009 573 228 0 9	IASON GMBH	FR
IASOfluorid 2,0 GBq/mL Injektionslösung	FR/H/0394/001	4-00043	CURIUM AUSTRIA GMBH	AT
IASONfluoride 2,0 GBq/ml, soluzione iniettabile	FR/H/0394/001	040986010	IASON GMBH	IT
IASONfluoride 2,0 GBq/ml, soluzione iniettabile	FR/H/0394/001	040986022	IASON GMBH	IT
METAFLU 2,0 GBq/ml injekčný roztok	FR/H/0647/001	88/0098/19-S	SYNEKTİK S.A.	SK
METAFLU 2,0 GBq/mL, solution injectable	not available	34009 550 226 4 0	SYNEKTİK S.A.	FR
METAFLU 2,0 GBq/mL, solution injectable	not available	34009 550 226 5 7	SYNEKTİK S.A.	FR
NaF MetaTrace 2 000	not available	34009 585 676 3 6	SIEMENS HEALTHCARE GMBH	FR

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MBq/mL, solution injectable NaFRos Injektionslösung	not available	79232.00.00	HELMHOLTZ-ZENTRUM DRESDEN-ROSSENDORF FWP	DE
Natrii fluoridum (18F) Synektik 2,0 GBq/ml injekcinis tirpalas	FR/H/0647/001	LT/1/19/4428/001	SYNEKTIK S.A.	LT
Natrii fluoridum (18F) Synektik 2,0 GBq/ml injekcinis tirpalas	FR/H/0647/001	LT/1/19/4428/002	SYNEKTIK S.A.	LT
Natrii fluoridum (18F) Synektik 2,0 GBq/mL, roztwór do wstrzykiwań	FR/H/0647/001	25284	SYNEKTIK S.A.	PL
Natrio fluoridas (18F) Life Radiopharma 0,1-4 GBq/ml injekcinis tirpalas	DE/H/3517/001	LT/1/14/3649/001	LIFE RADIOPHARMA BERLIN GMBH	LT
Natriumfluorid (18F) NMS 0,2-2,7 GBq/ml, injeksjonsvæske, oppløsning	not available	18-12191	NORSK MEDISINSK SYKLOTRONSENTER AS	NO
Natriumfluorid(F-18) Life Radiopharma 0,1-4 GBq/ml injektionsvätska, lösning	DE/H/3517/001	48563	LIFE RADIOPHARMA BERLIN GMBH	SE
Radio-Flu	DE/H/3517/001	86605.00.00	LIFE RADIOPHARMA BERLIN GMBH	DE
Radio-Flu	DE/H/3517/001	2015040071	LIFE RADIOPHARMA BERLIN GMBH	LU
Radio-Flu 0,1 - 4 GBq/ml oplossing voor injectie	DE/H/3517/001	RVG 126583	LIFE RADIOPHARMA BERLIN GMBH	NL
Radio-Flu, 0,1-4 GBq/ml roztwór do wstrzykiwań	DE/H/3517/001	22309	LIFE RADIOPHARMA BERLIN GMBH	PL
Sodio Fluoruro (18F) ITEL 2,0 GBq/mL soluzione iniettabile	not available	047433014	ITEL TELECOMUNICAZIONI SRL	IT
Sodium Fluoride (18F) Life Radiopharma 0,1 - 4 GBq/ml solution injectable	DE/H/3517/001	BE571822	LIFE RADIOPHARMA BERLIN GMBH	BE