



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 March 2026
EMADOC-1700519818-2996574
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): fosphenytoin

EURD list No. PSUSA/00001476/202508

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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
PRODILANTIN 75 mg/mL, solution à diluer pour perfusion / solution injectable	IE/H/0640/001	34009 561 095 0 0	PFIZER HOLDING FRANCE	FR
PRODILANTIN 75 mg/mL, solution à diluer pour perfusion / solution injectable	IE/H/0640/001	34009 562 027 9 9	PFIZER HOLDING FRANCE	FR
PRODILANTIN 75 mg/mL, solution à diluer pour perfusion / solution injectable	IE/H/0640/001	34009 562 029 1 1	PFIZER HOLDING FRANCE	FR
PRODILANTIN 75 mg/mL, solution à diluer pour perfusion / solution injectable	IE/H/0640/001	34009 562 026 2 1	PFIZER HOLDING FRANCE	FR
PRODILANTIN 75 mg/mL, solution à diluer pour perfusion / solution injectable	IE/H/0640/001	34009 561 094 4 9	PFIZER HOLDING FRANCE	FR
PRODILANTIN 75 mg/mL, solution à diluer pour	IE/H/0640/001	34009 562 028 5 0	PFIZER HOLDING FRANCE	FR

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
perfusion / solution injectable				
PRODILANTIN 75 mg/mL, solution à diluer pour perfusion / solution injectable	IE/H/0640/001	34009 562 025 6 0	PFIZER HOLDING FRANCE	FR
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska, lösning/injektionsvätska, lösning	IE/H/0640/001	13578	PFIZER OY	FI
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska, lösning/injektionsvätska, lösning	IE/H/0640/001	14441	PFIZER AB	SE
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska, lösning/injektionsvätska, lösning	IE/H/0640/001	14441	PFIZER AB	SE
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska,	IE/H/0640/001	14441	PFIZER AB	SE

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lösning/injektionsvätska, lösning				
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska, lösning/injektionsvätska, lösning	IE/H/0640/001	14441	PFIZER AB	SE
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska, lösning/injektionsvätska, lösning	IE/H/0640/001	14441	PFIZER AB	SE
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska, lösning/injektionsvätska, lösning	IE/H/0640/001	14441	PFIZER AB	SE
Pro-Epanutin 75 mg/ml koncentrat till infusionsvätska, lösning/injektionsvätska, lösning	IE/H/0640/001	14441	PFIZER AB	SE
Pro-Epanutin 75 mg/ml koncentrat til injeksjons-	not available	98-3075	PFIZER AS	NO

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
/infusjonsvæske, oppløsning				
Pro-Epanutin 75 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO
Pro-Epanutin 75 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO
Pro-Epanutin 75 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO
Pro-Epanutin 75 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO
Pro-Epanutin 75 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO
Pro-Epanutin 75 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO
Pro-Epanutin 75 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO

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
/infusjonsvæske, oppløsning				
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED	IE

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
for infusion/Solution for injection			COMPANY	
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI

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for infusion/Solution for injection				
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	XI
Pro-Epanutin 75 mg/ml, stungulyf, lausn/innrennslispykkni, lausn.	not available	980132	PFIZER APS	IS
Pro-Epanutin 75 mg/ml, stungulyf, lausn/innrennslispykkni, lausn.	not available	980132	PFIZER APS	IS
Pro-Epanutin 75 mg/ml, stungulyf, lausn/innrennslispykkni, lausn.	not available	980132	PFIZER APS	IS
Pro-Epanutin 75 mg/ml, stungulyf,	not available	980132	PFIZER APS	IS

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lausn/innrennslispykkni, lausn.				
Pro-Epanutin 75 mg/ml, stungulyf, lausn/innrennslispykkni, lausn.	not available	980132	PFIZER APS	IS
Pro-Epanutin 75 mg/ml, stungulyf, lausn/innrennslispykkni, lausn.	not available	980132	PFIZER APS	IS
Pro-Epanutin 75 mg/ml, stungulyf, lausn/innrennslispykkni, lausn.	not available	980132	PFIZER APS	IS
Pro-Epanutin, injektionsvæske/koncentrat til infusionsvæske, opløsning	IE/H/0640/001	30073	PFIZER APS	DK
Pro-Epanutin, injektionsvæske/koncentrat til infusionsvæske, opløsning	IE/H/0640/001	30073	PFIZER APS	DK
Pro-Epanutin, injektionsvæske/koncentrat til infusionsvæske, opløsning	IE/H/0640/001	30073	PFIZER APS	DK

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rat til infusionsvæske, opløsning				
Pro-Epanutin, injektionsvæske/koncentrat til infusionsvæske, opløsning	IE/H/0640/001	30073	PFIZER APS	DK
Pro-Epanutin, injektionsvæske/koncentrat til infusionsvæske, opløsning	IE/H/0640/001	30073	PFIZER APS	DK
Pro-Epanutin, injektionsvæske/koncentrat til infusionsvæske, opløsning	IE/H/0640/001	30073	PFIZER APS	DK
Pro-Epanutin, injektionsvæske/koncentrat til infusionsvæske, opløsning	IE/H/0640/001	30073	PFIZER APS	DK