



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2021
EMA/246760/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fosphenytoin

Procedure no.: PSUSA/00001476/202008

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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 perfusion / solution injectable	IE/H/0640/001	34009 562 028 5 0	PFIZER HOLDING FRANCE	FR
PRODILANTIN 75 mg/ml, solution à diluer pour perfusion / solution injectable	IE/H/0640/001	34009 562 025 6 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
Pro-Epanutin 75 mg/ml infuusiokonsentraatti, liuosta varten/injektioneste, liuos	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, lösning/injektionsvätska, lösning	IE/H/0640/001	14441	PFIZER AB	SE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND	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	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
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PA 0822/019/001	PFIZER HEALTHCARE IRELAND	IE
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	UK
Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection	IE/H/0640/001	PL 00057/0551	PFIZER LIMITED	UK
Pro-Epanutin 75 mg/ml, innrennslisþykkni/stungul yfsþykkni, lausn.	not available	980132	PFIZER APS	IS
Pro-Epanutin 75 mg/ml, innrennslisþykkni/stungul yfsþykkni, lausn.	not available	980132	PFIZER APS	IS
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
Pro-Epanutin 75 mg/ml, konsentrat til injeksjons-/infusjonsvæske, oppløsning	not available	98-3075	PFIZER AS	NO
Pro-Epanutin, konsentrat til infusions-/injeksjonsvæske, oppløsning	IE/H/0640/001	30073	PFIZER APS	DK
Pro-Epanutin, konsentrat til infusions-/injeksjonsvæske, oppløsning	IE/H/0640/001	30073	PFIZER APS	DK
Pro-Epanutin, konsentrat til infusions-/injeksjonsvæske, oppløsning	IE/H/0640/001	30073	PFIZER APS	DK