



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2021
EMA/305569/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: phenytoin

Procedure no.: PSUSA/00002392/202008

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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
AURANTIN 250 mg/5 ml soluzione iniettabile	not available	028823021	PFIZER ESTABLISHED MEDICINE ITALY S.R.L.	IT
DILANTIN 250 mg/5 ml, solution injectable	not available	560 554-1	KEOCYT	FR
DILANTIN 250 mg/5 ml, solution injectable	not available	560 553-5	KEOCYT	FR
Dintoina 100 mg compresse rivestite	not available	002129017	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Diphantoïne IV 250 mg Injektionslösung	not available	BE095207	KELA PHARMA NV	BE
Diphantoïne IV 250 mg oplossing voor injectie	not available	BE095207	KELA PHARMA NV	BE
Diphantoïne IV 250 mg solution injectable	not available	170/01/02/6275	KELA PHARMA NV	LU
Diphantoïne IV 250 mgsolution injectable	not available	BE095207	KELA PHARMA NV	BE
Epanutin 100 mg cápsulas duras	not available	45.695	PFIZER GEP, S.L.	ES

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
EPANUTIN 100 mg Hard Capsules	not available	PA 822/11/3	PFIZER HEALTHCARE IRELAND	IE
EPANUTIN 100 mg Hard Capsules	not available	MA1396/00702	UPJOHN HELLAS L.T.D.	MT
Epanutin 100 mg hårda kapslar	not available	1982	PFIZER AB	SE
EPANUTIN 25 mg Hard Capsules.	not available	PA 822/11/1	PFIZER HEALTHCARE IRELAND	IE
Epanutin 250 mg oldatos injekció	not available	OGYI-T-797/01	UPJOHN EESV	HU
EPANUTIN 30 mg/5 ml Oral Suspension	not available	PL 00057/0528	PFIZER LIMITED	UK
EPANUTIN 300 mg Hard Capsules.	not available	PA 822/11/4	PFIZER HEALTHCARE IRELAND	IE
EPANUTIN 50 mg Hard Capsules	not available	PA 822/11/2	PFIZER HEALTHCARE IRELAND	IE
EPANUTIN 50 mg Hard Capsules	not available	MA1396/00701	UPJOHN HELLAS L.T.D.	MT

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
EPANUTIN INFATABS 50 MG CHEWABLE TABLETS	not available	PL 00057/0526	PFIZER LIMITED	UK
Epanutin Parenteral 250 mg/5 ml injekční roztok	not available	21/239/75-C	PFIZER, SPOL. S R.O.	CZ
Epanutin parenteral, 50 mg/ml, roztwór do wstrzykiwań	not available	R/2043	UPJOHN EESV	PL
Epanutin Ready Mixed Parenteral 250 mg/5 ml Solution for Injection or Infusion	not available	PL 00057/0527	PFIZER LIMITED	UK
Epanutin Ready Mixed Parenteral 250 mg/5 ml Solution for Injection or Infusion.	not available	PA 822/11/6	PFIZER HEALTHCARE IRELAND	IE
Epanutin ready mixed, injectievloeistof 250 mg/5ml	not available	RVG 10573	PFIZER B.V.	NL
Epanutin® 250 mg/5 ml - Injektionslösung	not available	15.958	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
EPANUTIN® Ενέσιμο διάλυμα, 250 mg/5 ml	not available	42519/25-9-2008	UPJOHN HELLAS L.T.D.	GR
EPANUTIN® Καψάκιο, σκληρό, 100 mg/cap	not available	7521	UPJOHN HELLAS L.T.D.	CY

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
EPANUTIN® Καψάκιο, σκληρό, 100 mg/cap	not available	42517/25-09-2008	UPJOHN HELLAS L.T.D.	GR
Fenantoin RPH Pharma 100 mg tableter	SE/H/1627/001	8796	RPH PHARMACEUTICALS AB	SE
Fenantoin RPH Pharmaceuticals 100 mg tableter	SE/H/1627/001	16-11234	RPH PHARMACEUTICALS AB	NO
Hidantina 100 mg comprimido revestido	not available	9913723	LABORATÓRIOS VITÓRIA, SA	PT
Hidantina 100 mg comprimido revestido	not available	9913715	LABORATÓRIOS VITÓRIA, SA	PT
Hydantin 100 mg tablett	not available	3112	ORION OYJ	FI
Hydantin 100 mg tabletti	not available	3112	ORION OYJ	FI
PHENHYDAN 250 mg/5 ml solutie injectabilă	not available	2334/2010/01	DESITIN ARZNEIMITTEL GMBH	RO
Sinergina 100 mg comprimidos	not available	5970	FAES FARMA, S.A.	ES