



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2024
EMA/144701/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): phenytoin

Procedure No. PSUSA/00002392/202308



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	VIATRIS PHARMA S.R.L.	IT
DILANTIN 250 mg/5 ml, solution injectable	not available	3400956055418	ESTEVE PHARMACEUTICALS S.A.S.	FR
DILANTIN 250 mg/5 ml, solution injectable	not available	3400956055357	ESTEVE PHARMACEUTICALS S.A.S.	FR
Dintoina 100 mg compresse rivestite	not available	002129017	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Epanutin 100 mg cápsulas duras	not available	45.695	VIATRIS HEALTHCARE S.L.	ES
EPANUTIN 100 mg Hard Capsules	not available	PA 23055/003/003	UPJOHN EESV	IE
EPANUTIN 100 mg Hard Capsules	not available	MA1396/00702	VIATRIS HELLAS LTD.	MT
Epanutin 100 mg hårda kapslar	not available	1982	VIATRIS AB	SE
EPANUTIN 25 mg Hard Capsules.	not available	PA 23055/003/001	UPJOHN EESV	IE
Epanutin 250 mg oldatos injekció	not available	OGYI-T-797/01	UPJOHN EESV	HU
EPANUTIN 30 mg/5 ml Oral Suspension	not available	PA 23055/003/007	UPJOHN EESV	IE
EPANUTIN 30 mg/5 ml Oral Suspension	not available	MA1396/01502	VIATRIS HELLAS LTD.	MT
EPANUTIN 30 mg/5 ml Oral Suspension	not available	PL 50622/0023	UPJOHN UK LIMITED	XI
EPANUTIN 300 mg Hard Capsules.	not available	PA 23055/003/004	UPJOHN EESV	IE
EPANUTIN 50 mg Hard Capsules	not available	PA 23055/003/002	UPJOHN EESV	IE
EPANUTIN 50 mg Hard Capsules	not available	MA1396/00701	VIATRIS HELLAS LTD.	MT
EPANUTIN INFATABS 50	not available	PA 23055/003/005	UPJOHN EESV	IE

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MG CHEWABLE TABLETS				
EPANUTIN INFATABS 50 MG CHEWABLE TABLETS	not available	PL 50622/0024	UPJOHN UK LIMITED	XI
Epanutin Parenteral 250 mg/5 ml injekční roztok	not available	21/239/75-C	UPJOHN EESV	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 50622/0025	UPJOHN UK LIMITED	XI
Epanutin Ready Mixed Parenteral 250 mg/5 ml Solution for Injection or Infusion.	not available	PA 23055/003/006	UPJOHN EESV	IE
Epanutin Ready Mixed Parenteral 250 mg/5 ml Solution for Injection or Infusion.	not available	MA1396/01501	VIATRIS HELLAS LTD.	MT
Epanutin ready mixed, injectievloeistof 250 mg/5ml	not available	RVG 10573	VIATRIS NETHERLANDS B.V.	NL
Epanutin® 250 mg/5 ml - Injektionslösung	not available	15.958	MYLAN ÖSTERREICH GMBH	AT
EPANUTIN® Ενέσιμο διάλυμα, 250 mg/5 ml	not available	42519/25-9-2008	VIATRIS HELLAS LTD.	GR
EPANUTIN® Καψάκιο, σκληρό, 100 mg/cap	not available	7521	VIATRIS HELLAS LTD.	CY
EPANUTIN® Καψάκιο, σκληρό, 100 mg/cap	not available	42517/25-09-2008	VIATRIS HELLAS LTD.	GR
EPANUTIN® Πόσιμο εναιώρημα, 30 mg/5 ml	not available	42521/25-09-2008	VIATRIS HELLAS LTD.	GR
Hidantina 100 mg comprimido revestido	not available	9913723	LABORATÓRIOS VITÓRIA, SA	PT
Hidantina 100 mg comprimido revestido	not available	9913715	LABORATÓRIOS VITÓRIA, SA	PT

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Hydantin 100 mg tablett	not available	3112	ORION CORPORATION	FI
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PHENHYDAN 250 mg/5 ml solutie injectabilă	not available	2334/2010/01	DESITIN ARZNEIMITTEL GMBH	RO
Sinergina 100 mg comprimidis	not available	5970	FAES FARMA, S.A.	ES