



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15 October 2020  
EMA/273764/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: phenobarbital\*

Procedure no.: PSUSA/00002370/202001

*\*MAHs of medicinal products containing the active substance phenobarbital should also refer to the outcome of the dedicated PSUR follow-up (PSUFU) procedure for phenobarbital (EE/H/PSUFU/00002370/202001):*

[https://www.hma.eu/fileadmin/dateien/Human\\_Medicines/CMD\\_h\\_/Pharmacovigilance\\_Legislation/PSUR/PSUFU/Phenobarbital\\_PSUFU\\_AR\\_2021\\_04x.pdf](https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/PSUR/PSUFU/Phenobarbital_PSUFU_AR_2021_04x.pdf)

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
BIALMINAL FORTE, 200 mg, comprimidos	not available	9901249	BIAL - PORTELA & C <sup>a</sup> , SA	PT
BIALMINAL, 100 mg, comprimidos	not available	9901231	BIAL - PORTELA & C <sup>a</sup> , SA	PT
BIALMINAL, 100 mg, comprimidos	not available	9901207	BIAL - PORTELA & C <sup>a</sup> , SA	PT
Fenemal Meda 100 mg tableter	not available	8853	MEDA AB	SE
Fenemal Meda 100 mg töflur	not available	IS/1/04/118/03	MEDA AB	IS
Fenemal Meda 15 mg tableter	not available	8851	MEDA AB	SE
Fenemal Meda 15 mg töflur	not available	IS/1/04/118/01	MEDA AB	IS
Fenemal Meda 200 mg/ml injektionsvätska, lösning	not available	9151	MEDA AB	SE
Fenemal Meda 50 mg tableter	not available	8852	MEDA AB	SE
Fenemal Meda 50 mg töflur	not available	IS/1/04/118/02	MEDA AB	IS
GARDENAL 10 mg,	not available	34009 304 250 7 7	SANOFI-AVENTIS FRANCE	FR

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comprimé				
GARDENAL 100 mg comprimés	not available	0047833	SANOFI BELGIUM	LU
GARDENAL 100 mg tabletten	not available	BE002195	SANOFI BELGIUM	BE
GARDENAL 100 mg δισκία	not available	41418/07/27-5-2008	SANOFI-AVENTIS AEBE	GR
GARDENAL 100 mg, comprimé	not available	34009 550 423 1 0	SANOFI-AVENTIS FRANCE	FR
GARDENAL 100 mg, comprimé	not available	34009 304 253 6 7	SANOFI-AVENTIS FRANCE	FR
GARDENAL 100 mg, comprimé	not available	34009 550 422 5 9	SANOFI-AVENTIS FRANCE	FR
GARDENAL 100 mg, Tabletten	not available	BE002195	SANOFI BELGIUM	BE
GARDENAL 200 mg/4 ml, poudre et solvant pour solution injectable	not available	34009 550 427 7 8	SANOFI-AVENTIS FRANCE	FR
GARDENAL 200 mg/4 ml, poudre et solvant pour solution injectable	not available	34009 304 248 2 7	SANOFI-AVENTIS FRANCE	FR
GARDENAL 200 mg/4 ml,	not available	34009 339 969 8 7	SANOFI-AVENTIS FRANCE	FR

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poudre et solvant pour solution injectable				
GARDENAL 40 mg/2 ml, poudre et solvant pour solution injectable	not available	34009 550 428 3 9	SANOFI-AVENTIS FRANCE	FR
GARDENAL 40 mg/2 ml, poudre et solvant pour solution injectable	not available	34009 328 620 9 2	SANOFI-AVENTIS FRANCE	FR
GARDENAL 50 MG COMPRIMIDOS	not available	49002	SANOFI-AVENTIS, S.A.	ES
GARDENAL 50 mg, comprimé	not available	34009 550 426 0 0	SANOFI-AVENTIS FRANCE	FR
GARDENAL 50 mg, comprimé	not available	34009 304 251 3 8	SANOFI-AVENTIS FRANCE	FR
GARDENALE 100 mg compresse	not available	004556015	SANOFI S.P.A	IT
GARDENALE 50 mg compresse	not available	004556027	SANOFI S.P.A	IT
Luminal 100 mg comprimidos	not available	9908400	BAYER PORTUGAL LDA	PT
LUMINAL® 0,1, comprimidos	not available	35.052	KERN PHARMA, S.L.	ES

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LUMINAL®, solución inyectable	not available	3.905	KERN PHARMA, S.L.	ES
LUMINALE	not available	002860017	DOMPÉ FARMACEUTICI S.P.A.	IT
LUMINALE 15 mg compresse	not available	002860043	DOMPÉ FARMACEUTICI S.P.A.	IT
Luminaletas 15 mg comprimidos	not available	9980706	BAYER PORTUGAL LDA	PT
LUMINALETAS®, comprimidos	not available	3.275	KERN PHARMA, S.L.	ES
PHENOBARBITAL ACCORD TABLETS BP 30mg	not available	PL 0142/0418	ACTAVIS UK LIMITED	UK
PHENOBARBITAL ACCORD TABLETS BP 60mg	not available	PL 0142/0419	ACTAVIS UK LIMITED	UK