



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 February 2023
EMA/76569/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: flecainide

Procedure no.: PSUSA/00001396/202206

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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
Flecainide Acetate 50 mg tablets	NL/H/2428/001	MA807/05301	AUROBINDO PHARMA (MALTA) LIMITED	MT
FLEIDERINA 200 mg, capsule rigide a rilascio prolungato	NL/H/2503/004	042864076	BRUNO FARMACEUTICI	IT
FLEIDERINA 50 mg, capsule rigide a rilascio prolungato	NL/H/2503/001	042864013	BRUNO FARMACEUTICI	IT
FLEIDERINA 100 mg, capsule rigide a rilascio prolungato	NL/H/2503/002	042864037	BRUNO FARMACEUTICI	IT
FLEIDERINA 150 mg, capsule rigide a rilascio prolungato	NL/H/2503/003	042864052	BRUNO FARMACEUTICI	IT
FLEIDERINA 200 mg, capsule rigide a rilascio prolungato	NL/H/2503/004	042864088	BRUNO FARMACEUTICI	IT
FLEIDERINA 150 mg, capsule rigide a rilascio prolungato	NL/H/2503/003	042864064	BRUNO FARMACEUTICI	IT
FLEIDERINA 100 mg, capsule rigide a rilascio prolungato	NL/H/2503/002	042864049	BRUNO FARMACEUTICI	IT
FLEIDERINA 50 mg, capsule rigide a rilascio prolungato	NL/H/2503/001	042864025	BRUNO FARMACEUTICI	IT
Apocard 100 mg Comprimidos	not available	8674101	TEVA PHARMA – PRODUTOS FARMACÉUTICOS LDA	PT
Apocard 100 mg Comprimidos	not available	4531489	TEVA PHARMA – PRODUTOS FARMACÉUTICOS LDA	PT
ALMARYTM 100 mg compresse	not available	025728015	VIATRIS HEALTHCARE LTD	IT
ALMARYTM 100 mg compresse	not available	025728066	VIATRIS HEALTHCARE LTD	IT
ALMARYTM 100 mg compresse	not available	025728155	VIATRIS HEALTHCARE LTD	IT
Aristocor 10 mg/ml- Injektionslösung	not available	1-20061	MYLAN ÖSTERREICH GMBH	AT
Tambocor 100 mg tabletti	not available	9282	VIATRIS OY	FI
Tambocor 100 mg tablett	not available	9282	VIATRIS OY	FI
APOCARD Retard 100 mg, Hartkapsel, retardiert	not available	BE255001	MYLAN EPD BVBA/SPRL	BE
APOCARD Retard 150 mg,	not available	BE255017	MYLAN EPD BVBA/SPRL	BE

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Hartkapsel, retardiert				
APOCARD Retard 200 mg, Hartkapsel, retardiert	not available	BE255026	MYLAN EPD BVBA/SPRL	BE
APOCARD Retard 100 mg, Hartkapsel, retardiert	not available	2009100574	MYLAN EPD BVBA/SPRL	LU
APOCARD Retard 150 mg, Hartkapsel, retardiert	not available	2009100575	MYLAN EPD BVBA/SPRL	LU
APOCARD Retard 200 mg, Hartkapsel, retardiert	not available	2009100576	MYLAN EPD BVBA/SPRL	LU
Apocard Retard 100 mg capsules met verlengde afgifte.	not available	BE255001	MYLAN EPD BVBA/SPRL	BE
APOCARD Retard 150 mg gélules à libération prolongée	not available	BE255017	MYLAN EPD BVBA/SPRL	BE
APOCARD Retard 200 mg, gélules à libération prolongée	not available	BE255026	MYLAN EPD BVBA/SPRL	BE
APOCARD Retard 100 mg gélules à libération prolongée	not available	2009100574	MYLAN EPD BVBA/SPRL	LU
APOCARD Retard 100 mg gélules à libération prolongée	not available	BE255001	MYLAN EPD BVBA/SPRL	BE
Apocard Retard 150 mg capsules met verlengde afgifte.	not available	BE255017	MYLAN EPD BVBA/SPRL	BE
APOCARD Retard 200 mg, gélules à libération prolongée	not available	2009100576	MYLAN EPD BVBA/SPRL	LU
APOCARD Retard 150 mg gélules à libération prolongée	not available	2009100575	MYLAN EPD BVBA/SPRL	LU
Apocard Retard 200 mg, capsules met verlengde afgifte.	not available	BE255026	MYLAN EPD BVBA/SPRL	BE
Tambocor 100 mg tabletter	not available	10441	MEDA AB	SE
Aristocor 100 mg - Tabletten	not available	1-20057	MYLAN ÖSTERREICH GMBH	AT
Tambocor Retard 100 mg hårda depotkapslar	not available	17411	VIATRIS OY	FI
Tambocor Retard 200 mg hårda depotkapslar	not available	17412	VIATRIS OY	FI

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
Tambocor Retard 100 mg kovat depotkapselit	not available	17411	VIATRIS OY	FI
Tambocor Retard 200 mg kovat depotkapselit	not available	17412	VIATRIS OY	FI
Tambocor 100 mg töflur	not available	843293	VIATRIS APS	IS
Tambocor 10 mg/ml injeksjonsvæske	not available	7126	VIATRIS AS	NO
FLECAINE 100 mg, comprimé sécable	not available	34009 326 362 2 8	MEDA PHARMA SAS	FR
FLECAINE 100 mg, comprimé sécable	not available	34009 326 363 9 6	MEDA PHARMA SAS	FR
Tambocor 100 mg tabletter	not available	7127	VIATRIS AS	NO
Tambocor Retard 200 mg depotkapsel, hard	not available	03-1818	VIATRIS AS	NO
Tambocor 10 mg/ml Injektionslösung	not available	2088.00.01	VIATRIS HEALTHCARE GMBH	DE
FLECAINE 10 mg/ml, solution injectable	not available	34009 563 745 2 6	MEDA PHARMA SAS	FR
Apocard 10 mg/ml, solución inyectable	not available	57514	MEDA PHARMA S.L.	ES
Apocard 100 mg, comprimidos	not available	57532	MEDA PHARMA S.L.	ES
Tambocor 10 mg/ml injektionsvätska, lösning	not available	9281	VIATRIS OY	FI
Tambocor 10 mg/ml injektioneste, liuos	not available	9281	VIATRIS OY	FI
Tambocor 50 mg Tablets	not available	PA2010/026/002	MYLAN IRE HEALTHCARE LIMITED	IE
Tambocor 100 mg Tablets	not available	PA2010/026/003	MYLAN IRE HEALTHCARE LIMITED	IE
FLECAINE 100 mg, comprimé sécable	not available	34009 326 362 2 8	MEDA PHARMA SAS	FR
FLECAINE 100 mg, comprimé sécable	not available	34009 326 363 9 6	MEDA PHARMA SAS	FR
Tambocor 100 mg Tablets	not available	MA1187/01701	MYLAN IRE HEALTHCARE	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
			LIMITED	
Tambocor Retard 100 mg hårda depotkapslar	not available	19587	VIATRIS AB	SE
Tambocor Retard 200 mg hårda depotkapslar	not available	19588	VIATRIS AB	SE
Tambocor, injectievloeistof 10 mg/ml	not available	RVG 10099	MYLAN HEALTHCARE B.V.	NL
Tambocor 100 mg, comprimate	not available	12760/2019/01	VIATRIS HEALTHCARE LTD	RO
Tambocor 100 mg, comprimate	not available	12760/2019/02	VIATRIS HEALTHCARE LTD	RO
Tambocor 100 mg, comprimate	not available	12760/2019/03	VIATRIS HEALTHCARE LTD	RO
Tambocor 50 mg, comprimate	not available	12759/2019/02	VIATRIS HEALTHCARE LTD	RO
Tambocor 50 mg, comprimate	not available	12759/2019/03	VIATRIS HEALTHCARE LTD	RO
Tambocor 50 mg, comprimate	not available	12759/2019/01	VIATRIS HEALTHCARE LTD	RO
Tambocor 100 mg Tabletten	not available	2088.00.00	VIATRIS HEALTHCARE GMBH	DE
Tambocor mite 50 mg Tabletten	not available	17505.00.00	VIATRIS HEALTHCARE GMBH	DE
Tambocor 10 mg/ml Solution for Injection or Infusion	not available	PA2010/026/001	MYLAN IRE HEALTHCARE LIMITED	IE
FLECAINE L.P. 50 mg, gélule à libération prolongée	not available	34009 358 052 9 4	MEDA PHARMA SAS	FR
FLECAINE L.P. 100 mg, gélule à libération prolongée	not available	34009 358 056 4 5	MEDA PHARMA SAS	FR
FLECAINE L.P. 200 mg, gélule à libération prolongée	not available	34009 358 058 7 4	MEDA PHARMA SAS	FR
FLECAINE L.P. 150 mg, gélule à libération prolongée	not available	34009 358 054 1 6	MEDA PHARMA SAS	FR
TAMBOCOR 100 mg Tabletten	not available	BE 126061	MYLAN EPD BVBA/SPRL	BE
TAMBOCOR 150mg/15 ml Injektionslösung	not available	BE 126077	MYLAN EPD BVBA/SPRL	BE
TAMBOCOR 100 mg Tabletten	not available	2008110055	MYLAN EPD BVBA/SPRL	LU
TAMBOCOR 150mg/15 ml, Injektionslösung	not available	2008119054	MYLAN EPD BVBA/SPRL	LU
TAMBOCOR 100 mg comprimés	not available	BE 126061	MYLAN EPD BVBA/SPRL	BE

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
TAMBOCOR 150 mg/15 ml solution injectable	not available	BE 126077	MYLAN EPD BVBA/SPRL	BE
TAMBOCOR 150 mg/15 ml oplossing voor injectie	not available	BE 126077	MYLAN EPD BVBA/SPRL	BE
Tambocor 150 mg/15 ml solution injectable	not available	2008119054	MYLAN EPD BVBA/SPRL	LU
Tambocor 100 mg comprimés	not available	2008110055	MYLAN EPD BVBA/SPRL	LU
TAMBOCOR 100 mg tabletten	not available	BE 126061	MYLAN EPD BVBA/SPRL	BE
APOCARD Retard 100 mg gélules à libération prolongée	not available	BE255001	MYLAN EPD BVBA/SPRL	BE
Apocard Retard 150 mg capsules met verlengde afgifte.	not available	BE255017	MYLAN EPD BVBA/SPRL	BE
Tambocor CR 100, capsules met gereguleerde afgifte 100 mg	not available	RVG 27132	MYLAN HEALTHCARE B.V.	NL
Tambocor CR 150, capsules met gereguleerde afgifte 150 mg	not available	RVG 27133	MYLAN HEALTHCARE B.V.	NL
Tambocor CR 200, capsules met gereguleerde afgifte 200 mg	not available	RVG 27134	MYLAN HEALTHCARE B.V.	NL
Tambocor CR 50, capsules met gereguleerde afgifte 50 mg	not available	RVG 27131	MYLAN HEALTHCARE B.V.	NL
Tambocor 50 , tabletten 50 mg	not available	RVG 15854	MYLAN HEALTHCARE B.V.	NL
Tambocor 100 , tabletten 100 mg	not available	RVG 10098	MYLAN HEALTHCARE B.V.	NL
ALMARYTM 150 mg/15 ml soluzione iniettabile per uso endovenoso	not available	025728027	VIATRIS HEALTHCARE LTD	IT