



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 March 2018
EMA/156863/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): flecainide

Procedure No.: PSUSA/00001396/201706



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	MA80705301	AUROBINDO PHARMA (MALTA) LIMITED	MT
Tambocor	not available	11396	MEDA AS	DK
Tambocor 100 mg Tablets	not available	PA1332/018/003	MEDA HEALTH SALES IRELAND LIMITED	IE
Tambocor, injectievloeistof 10 mg/ml	not available	10099	MEDA PHARMA B.V.	NL
Tambocor 50 , tabletten 50 mg	not available	RVG 15854	MEDA PHARMA B.V.	NL
Tambocor 100 mg tabletter	not available	104410	MEDA AB	SE
Tambocor 100 mg tabletter	not available	7127	MEDA AS	NO
Tambocor 100 , tabletten 100 mg	not available	RVG 10098	MEDA PHARMA B.V.	NL
Tambocor® 100 mg Tabletten Wirkstoff: Flecainidacetat	not available	2088.00.00	MEDA PHARMA GMBH & CO. KG	DE
APOCARD Retard 100 mg, Hartkapsel, retardiert	not available	BE255001	S.A. MEDA PHARMA N.V.	BE
APOCARD Retard 150 mg, Hartkapsel, retardiert	not available	BE255017	S.A. MEDA PHARMA N.V.	BE
APOCARD Retard 200 mg, Hartkapsel, retardiert	not available	BE255026	S.A. MEDA PHARMA N.V.	BE
TAMBOCOR 100 mg, Tabletten	not available	BE 126061	S.A. MEDA PHARMA N.V.	BE
TAMBOCOR 150mg/15 ml, Injektionslösung	not available	BE 126077	S.A. MEDA PHARMA N.V.	BE
APOCARD Retard 100 mg, Hartkapsel, retardiert	not available	2009/100574	S.A. MEDA PHARMA N.V.	LU
APOCARD Retard 150 mg, Hartkapsel, retardiert	not available	2009/100576	S.A. MEDA PHARMA N.V.	LU
APOCARD Retard 200 mg, Hartkapsel, retardiert	not available	2009/100575	S.A. MEDA PHARMA N.V.	LU
TAMBOCOR 100 mg, Tabletten	not available	2004/078321	S.A. MEDA PHARMA N.V.	LU
TAMBOCOR 150mg/15 ml, Injektionslösung	not available	2004/078320	S.A. MEDA PHARMA N.V.	LU
Tambocor® mite 50 mg Tabletten	not available	17505.00.00	MEDA PHARMA GMBH & CO. KG	DE
Tambocor 50 mg Tablets	not available	PA 1332/018/002	MEDA HEALTH SALES IRELAND LIMITED	IE
Tambocor® 10 mg/ml Injektionslösung	not available	2088.00.01	MEDA PHARMA GMBH & CO. KG	DE
Tambocor 10 mg/ml Solution for Injection or Infusion	not available	PA 1332/018/001	MEDA HEALTH SALES IRELAND LIMITED	IE
Tambocor 10 mg/ml injeksjonsvæske	not available	7126	MEDA AS	NO

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Tambocor Retard 200 mg depotkapsel, hard	not available	03-1818	MEDA AS	NO
APOCARD® 100 mg Comprimidos	not available	8674101	MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A.	PT
APOCARD® 100 mg Comprimidos	not available	4531489	MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A.	PT
Apocard 10 mg/ml Injetável	not available	867 42 00	MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A.	PT
FLECAINE 10 mg/ml, solution injectable	not available	563 745-2	MEDA PHARMA SAS	FR
FLECAINE 100 mg, comprimé sécable	not available	326 362-2	MEDA PHARMA SAS	FR
FLECAINE 100 mg, comprimé sécable	not available	326 363-9	MEDA PHARMA SAS	FR
FLECAÏNE L.P. 50 mg, gélule à libération prolongée	not available	358 052-9	MEDA PHARMA SAS	FR
FLECAÏNE L.P. 100 mg, gélule à libération prolongée	not available	358 056-4	MEDA PHARMA SAS	FR
FLECAÏNE L.P. 200 mg, gélule à libération prolongée	not available	358 058-7	MEDA PHARMA SAS	FR
FLECAÏNE L.P. 150 mg, gélule à libération prolongée	not available	358 054-1	MEDA PHARMA SAS	FR
TAMBOCOR 100 mg, comprimés	not available	BE 126061	S.A. MEDA PHARMA N.V.	BE
Tambocor CR 100, capsules met gereguleerde afgifte 100 mg	not available	RVG 27132	MEDA PHARMA B.V.	NL
Tambocor CR 50, capsules met gereguleerde afgifte 50 mg	not available	RVG 27131	MEDA PHARMA B.V.	NL
Tambocor CR 150, capsules met gereguleerde afgifte 150 mg	not available	RVG 27133	MEDA PHARMA B.V.	NL
Tambocor CR 200, capsules met gereguleerde afgifte 200 mg	not available	RVG 27134	MEDA PHARMA B.V.	NL
Apocard Retard 100 mg capsules met verlengde afgifte.	not available	BE255001	S.A. MEDA PHARMA N.V.	BE
APOCARD Retard 150 mg gélules à libération prolongée	not available	BE255017	S.A. MEDA PHARMA N.V.	BE
APOCARD Retard 200 mg, gélules à libération prolongée	not available	BE255026	S.A. MEDA PHARMA N.V.	BE
TAMBOCOR 150 mg/15 ml, solution injectable	not available	BE 126077	S.A. MEDA PHARMA N.V.	BE

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Tambocor, injektionsvæske, opløsning	not available	11395	MEDA AS	DK
Tambocor, tabletter	not available	14751	MEDA AS	DK
Tambocor, 50 mg tabletid	not available	238198	MEDA AB	EE
Tambocor, 10 mg/ml süstelahu	not available	327900	MEDA AB	EE
TAMBOCOR 150 mg/15 ml oplossing voor injectie.	not available	BE 126077	S.A. MEDA PHARMA N.V.	BE
TAMBOCOR 150 mg/15 ml, solution injectable	not available	2004/078320	S.A. MEDA PHARMA N.V.	LU
TAMBOCOR 100 mg, comprimés	not available	2004/078321	S.A. MEDA PHARMA N.V.	LU
Tambocor 100 mg töflur	not available	843293	MEDA AB	IS
Tambocor, 100 mg tabletid	not available	238098	MEDA AB	EE
TAMBOCOR 100 mg tabletten	not available	BE 126061	S.A. MEDA PHARMA N.V.	BE
APOCARD Retard 100 mg gélules à libération prolongée	not available	2009/100574	S.A. MEDA PHARMA N.V.	LU
Tambocor Retard 100 mg depotkapsel, hård	not available	19587	MEDA AB	SE
APOCARD Retard 100 mg gélules à libération prolongée	not available	BE255001	S.A. MEDA PHARMA N.V.	BE
Tambocor Retard 200 mg depotkapsel, hård	not available	19588	MEDA AB	SE
Apocard Retard 150 mg capsules met verlengde afgifte.	not available	BE255017	S.A. MEDA PHARMA N.V.	BE
APOCARD Retard 200 mg, gélules à libération prolongée	not available	2009/100575	S.A. MEDA PHARMA N.V.	LU
APOCARD Retard 150 mg gélules à libération prolongée	not available	2009/100576	S.A. MEDA PHARMA N.V.	LU
Apocard Retard 200 mg, capsules met verlengde afgifte.	not available	BE255026	S.A. MEDA PHARMA N.V.	BE
Tambocor 100 mg tabletti	not available	9282	MEDA OY	FI
Tambocor 100 mg tablett	not available	9282	MEDA OY	FI
Juneflecad 50 mg, capsule cu eliberare prelungită, greu	NL/H/2502/001	6186/201/01-02	LABORATORIOS LICONSA, S.A.	RO
Juneflecad 100 mg, capsule cu eliberare prelungită, greu	NL/H/2502/002	6187/201/01-02	LABORATORIOS LICONSA, S.A.	RO
Juneflecad 150 mg, capsule cu eliberare prelungită, greu	NL/H/2502/003	6188/201/01-02	LABORATORIOS LICONSA, S.A.	RO

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
Juneflecad 200 mg, capsule cu eliberare prelungită, greu	NL/H/2502/004	6189/201/01-02	LABORATORIOS LICONSA, S.A.	RO
Tambocor Retard 100 mg hård depotkapsel	not available	17411	MEDA OY	FI
Tambocor Retard 200 mg hård depotkapsel	not available	17412	MEDA OY	FI
Tambocor Retard 100 mg kovat depotkapselit	not available	17411	MEDA OY	FI
Tambocor Retard 200 mg kovat depotkapselit	not available	17412	MEDA OY	FI
Tambocor 10 mg/ml injektionsvätska, lösning	not available	9281	MEDA OY	FI
Tambocor 10 mg/ml injektioneste, liuos	not available	9281	MEDA OY	FI