



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 10 February 2022
EMA/111334/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: acenocoumarol

Procedure no.: PSUSA/00000027/202107



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
Acenocoumarol Sandoz 1 mg, tabletten	not available	RVG 04464	SANDOZ B.V.	NL
MINI-SINTROM 1 mg, comprimé	not available	34009 336 628 5 1	MERUS LABS LUXCO II S.À R.L.	FR
MINI-SINTROM 1 mg, comprimé	not available	34009 336 629 1 2	MERUS LABS LUXCO II S.À R.L.	FR
MINI-SINTROM 1 mg, comprimé	not available	34009 336 631 6 2	MERUS LABS LUXCO II S.À R.L.	FR
MINI-SINTROM 1 mg, comprimé	not available	34009 336 530 5 7	MERUS LABS LUXCO II S.À R.L.	FR
MINI-SINTROM 1 mg, comprimé	not available	34009 336 628 5 1	MERUS LABS LUXCO II S.À R.L.	FR
MINI-SINTROM 1 mg, comprimé	not available	34009 336 629 1 2	MERUS LABS LUXCO II S.À R.L.	FR
MINI-SINTROM 1 mg, comprimé	not available	34009 336 631 6 2	MERUS LABS LUXCO II S.À R.L.	FR
MINI-SINTROM 1 mg, comprimé	not available	34009 336 530 5 7	MERUS LABS LUXCO II S.À R.L.	FR

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
Sinthrome® Tablets 1mg.	not available	PL 20011/0068	NORGINE PHARMACEUTICALS LIMITED	XI
Sinthrome® Tablets 1mg.	not available	PL 20011/0068	NORGINE PHARMACEUTICALS LIMITED	XI
SINTROM 1 mg compresse	not available	011782024	MERUS LABS LUXCO II S.À R.L.	IT
SINTROM 1 mg compresse	not available	011782036	MERUS LABS LUXCO II S.À R.L.	IT
SINTROM 1 mg compresse	not available	011782024	MERUS LABS LUXCO II S.À R.L.	IT
SINTROM 1 mg compresse	not available	011782036	MERUS LABS LUXCO II S.À R.L.	IT
SINTROM 1 mg comprimidos	not available	58.994	MERUS LABS LUXCO II S.À R.L.	ES
SINTROM 1 mg comprimidos	not available	58.994	MERUS LABS LUXCO II S.À R.L.	ES
Sintrom 1 mg Tabletten	not available	BE085355	MERUS LABS LUXCO II S.À R.L.	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
Sintrom 1 mg Tabletten	not available	BE085355	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom 1 mg, comprimés	not available	BE085355	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom 1 mg, comprimés	not available	BE085355	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom 1 mg, comprimés	not available	0252624	MERUS LABS LUXCO II S.À R.L.	LU
Sintrom 1 mg, comprimés	not available	0252624	MERUS LABS LUXCO II S.À R.L.	LU
Sintrom 1 mg, tabletten	not available	BE085355	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom 1 mg, tabletten	not available	BE085355	MERUS LABS LUXCO II S.À R.L.	BE
SINTROM 4 mg compresse	not available	011782012	MERUS LABS LUXCO II S.À R.L.	IT
SINTROM 4 mg compresse	not available	011782012	MERUS LABS LUXCO II S.À R.L.	IT

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
SINTROM 4 mg comprimate	not available	2606/2010/01	MERUS LABS LUXCO II S.À R.L.	RO
SINTROM 4 mg comprimate	not available	2606/2010/01	MERUS LABS LUXCO II S.À R.L.	RO
SINTROM 4 mg comprimidos	not available	25.670	MERUS LABS LUXCO II S.À R.L.	ES
SINTROM 4 mg comprimidos	not available	25.670	MERUS LABS LUXCO II S.À R.L.	ES
Sintrom 4 mg comprimidos	not available	9893503	MERUS LABS LUXCO II S.À R.L.	PT
Sintrom 4 mg comprimidos	not available	9893503	MERUS LABS LUXCO II S.À R.L.	PT
Sintrom 4 mg Tabletten	not available	9828	MERUS LABS LUXCO II S.À R.L.	AT
Sintrom 4 mg Tabletten	not available	9828	MERUS LABS LUXCO II S.À R.L.	AT
Sintrom 4 mg Tabletten	not available	BE086685	MERUS LABS LUXCO II S.À R.L.	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
Sintrom 4 mg Tabletten	not available	BE086685	MERUS LABS LUXCO II S.À R.L.	BE
SINTROM 4 mg, comprimé quadrisécable	not available	34009 335 580 9 3	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 309 657 8 8	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 335 581 5 4	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 335 643 0 8	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 309 658 4 9	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 335 580 9 3	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 309 657 8 8	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 335 581 5 4	MERUS LABS LUXCO II S.À R.L.	FR

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
SINTROM 4 mg, comprimé quadrisécable	not available	34009 335 643 0 8	MERUS LABS LUXCO II S.À R.L.	FR
SINTROM 4 mg, comprimé quadrisécable	not available	34009 309 658 4 9	MERUS LABS LUXCO II S.À R.L.	FR
Sintrom 4 mg, comprimés	not available	BE086685	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom 4 mg, comprimés	not available	BE086685	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom 4 mg, comprimés	not available	0105291	MERUS LABS LUXCO II S.À R.L.	LU
Sintrom 4 mg, comprimés	not available	0105291	MERUS LABS LUXCO II S.À R.L.	LU
Sintrom 4 mg, tabletten	not available	BE086685	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom 4 mg, tabletten	not available	BE086685	MERUS LABS LUXCO II S.À R.L.	BE
Sintrom, 4 mg, tabletki	not available	R/1739	MERUS LABS LUXCO II S.À R.L.	PL

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
Sintrom, 4 mg, tabletki	not available	R/1739	MERUS LABS LUXCO II S.À R.L.	PL
Sintrom® 4 mg δισκία	not available	39860/24-05-2016	MERUS LABS LUXCO II S.À R.L.	GR
Sintrom® 4 mg δισκία	not available	39860/24-05-2016	MERUS LABS LUXCO II S.À R.L.	GR
Syncumar mite 1 mg tabletta	not available	OGYI-T-5965/01	BAUSCH HEALTH IRELAND LIMITED	HU
Syncumar mite 1 mg tabletta	not available	OGYI-T-5965/02	BAUSCH HEALTH IRELAND LIMITED	HU
Syncumar mite 1 mg tabletta	not available	OGYI-T-5965/03	BAUSCH HEALTH IRELAND LIMITED	HU
Синтром 4 mg таблетки	not available	20000293	MERUS LABS LUXCO II S.À R.L.	BG
Синтром 4 mg таблетки	not available	20000293	MERUS LABS LUXCO II S.À R.L.	BG