



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2023
EMA/66072/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): theophylline

Procedure no.: PSUSA/00002921/202206



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
Xanthium 200 mg Gélules à libération prolongée	not available	BE138573	LABORATOIRES SMB S.A.	BE
Xanthium 200 mg harde capsules met verlengde afgifte	not available	BE138573	LABORATOIRES SMB S.A.	BE
Xanthium 200 mg Hartkapseln, retardiert	not available	BE138573	LABORATOIRES SMB S.A.	BE
Xanthium 300 mg Gélules à libération prolongée	not available	BE158365	LABORATOIRES SMB S.A.	BE
Xanthium 300 mg harde capsules met verlengde afgifte	not available	BE158365	LABORATOIRES SMB S.A.	BE
Xanthium 300 mg Hartkapseln, retardiert	not available	BE158365	LABORATOIRES SMB S.A.	BE
Xanthium 400 mg Gélules à libération prolongée	not available	BE138564	LABORATOIRES SMB S.A.	BE
Xanthium 400 mg harde capsules met verlengde afgifte	not available	BE138564	LABORATOIRES SMB S.A.	BE
Xanthium 400 mg Hartkapseln, retardiert	not available	BE138564	LABORATOIRES SMB S.A.	BE
THEO-DUR®	not available	20099	LAVIPHARM S.A	CY
THEO-DUR®	not available	20100	LAVIPHARM S.A	CY
Afonilum SR 125 mg tvrdé tobolky s prodlouženým uvolňováním	not available	14/468/95-A/C	VIATRIS HEALTHCARE LTD	CZ
Afonilum SR 250 mg tvrdé tobolky s	not available	14/468/95-B/C	VIATRIS HEALTHCARE LTD	CZ

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
prodlouženým uvolňováním				
Euphyllin CR N 100 mg tvrdé tobolky s prodlouženým uvolňováním	not available	14/078/99-C	ZR PHARMA& GMBH	CZ
Euphyllin CR N 200 mg tvrdé tobolky s prodlouženým uvolňováním	not available	14/079/99-C	ZR PHARMA& GMBH	CZ
Euphyllin CR N 300 mg tvrdé tobolky s prodlouženým uvolňováním	not available	14/080/99-C	ZR PHARMA& GMBH	CZ
Euphyllin CR N 400 mg tvrdé tobolky s prodlouženým uvolňováním	not available	14/081/99-C	ZR PHARMA& GMBH	CZ
Theophyllin STADA® 400 mg Hartkapseln, retardiert	not available	31200.00.00	STADAPHARM GMBH	DE
Theo-Dur, depottabletter	not available	10044	KARO PHARMA AB	DK
Theo-Dur, depottabletter	not available	10045	KARO PHARMA AB	DK
Unixan, depottabletter	not available	14101	MUNDIPHARMA A/S	DK
Unixan, depottabletter	not available	11640	MUNDIPHARMA A/S	DK
Eufilina Venosa 200 mg solución inyectable	not available	1.891	ZR PHARMA& GMBH	ES
Theo-Dur 100 mg comprimidos de liberación prolongada.	not available	56.199	VEGAL FARMACEUTICA, S.L.	ES
Theo-Dur 200 mg comprimidos de liberación prolongada.	not available	56.165	VEGAL FARMACEUTICA, S.L.	ES
Theo-Dur 300 mg comprimidos de liberación prolongada.	not available	56.166	VEGAL FARMACEUTICA, S.L.	ES
DILATRANE 1 POUR	not available	34009 303 178 0 8	SOCIETE D'ETUDES ET DE	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
CENT, sirop			RECHERCHES PHARMACEUTIQUES (SERP)	
DILATRANE 100 mg, gélule à libération prolongée	not available	34009 303 177 4 7	SOCIETE D'ETUDES ET DE RECHERCHES PHARMACEUTIQUES (SERP)	FR
DILATRANE 200 mg, gélule à libération prolongée	not available	34009 303 176 8 6	SOCIETE D'ETUDES ET DE RECHERCHES PHARMACEUTIQUES (SERP)	FR
DILATRANE 300 mg, gélule à libération prolongée	not available	34009 327 879 9 9	SOCIETE D'ETUDES ET DE RECHERCHES PHARMACEUTIQUES (SERP)	FR
DILATRANE 50 mg, gélule à libération prolongée	not available	34009 327 878 2 1	SOCIETE D'ETUDES ET DE RECHERCHES PHARMACEUTIQUES (SERP)	FR
TEDRALAN 200 mg, gélule à libération prolongée	not available	34009 303 176 8 6	SOCIETE D'ETUDES ET DE RECHERCHES PHARMACEUTIQUES (SERP)	FR
THÉOSTAT 100 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 326 913 9 5	PIERRE FABRE MEDICAMENT	FR
THÉOSTAT 100 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 326 914 5 6	PIERRE FABRE MEDICAMENT	FR
THÉOSTAT 100 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 326 915 1 7	PIERRE FABRE MEDICAMENT	FR
THÉOSTAT 100 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 327 138 9 9	PIERRE FABRE MEDICAMENT	FR
THÉOSTAT 100 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 554 701 6 8	PIERRE FABRE MEDICAMENT	FR

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THEOSTAT 100 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 556 814 2 7	PIERRE FABRE MEDICAMENT	FR
THEOSTAT 300 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 326 021 0 0	PIERRE FABRE MEDICAMENT	FR
THEOSTAT 300 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 327 314 1 1	PIERRE FABRE MEDICAMENT	FR
THEOSTAT 300 mg A LIBERATION PROLONGEE, comprimé sécable	not available	34009 554 187 0 2	PIERRE FABRE MEDICAMENT	FR
THEO-DUR®	not available	42686/09/12-2-2010	LAVIPHARM S.A	GR
THEO-DUR®	not available	42687/09/12-2-2010	LAVIPHARM S.A	GR
UNIPHYLLIN Κάψουλες βραδείας αποδέσμευσης 350mg/cap	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Ενέσιμο διάλυμα 240(218)mg/4ml Amp.	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Δισκία βραδείας αποδέσμευσης 100mg/tab	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Δισκία βραδείας αποδέσμευσης 200mg/tab	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Δισκία βραδείας αποδέσμευσης 300mg/tab	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Ελιξίριο 50mg/5ml	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Κάψουλες	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS	GR

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βραδείας αποδέσμευσης 100mg/cap			PHARMACEUTICAL LABORATORIES S.A.	
UNIPHYLLIN® Σιρόπι 50mg/5ml	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Υπόθετα 100mg/supp	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® Υπόθετα 350mg/supp	not available	8570/06.02.2007	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
UNIPHYLLIN® CONTINUS® 200 mg prolonged release tablets	not available	PA 1688/11/1	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
UNIPHYLLIN® CONTINUS® 300 mg prolonged release tablets	not available	PA 1688/11/2	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
UNIPHYLLIN® CONTINUS® 400 mg prolonged release tablets	not available	PA 1688/11/3	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
AMINOMAL 0,67% soluzione orale (67 mg/10 ml)	not available	011226091	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DIFFUMAL 200 mg compresse a rilascio modificato	not available	025740085	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DIFFUMAL 350 mg compresse a rilascio modificato	not available	025740097	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Theo-dur 300 mg compresse a rilascio prolungato	not available	025267016	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Xanthium 200 mg Gélules à libération prolongée	not available	2002116791	LABORATOIRES SMB S.A.	LU
Xanthium 200 mg Hartkapseln, retardiert	not available	2002116791	LABORATOIRES SMB S.A.	LU

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Xanthium 300 mg Gélules à libération prolongée	not available	2002116792	LABORATOIRES SMB S.A.	LU
Xanthium 300 mg Hartkapseln, retardiert	not available	2002116792	LABORATOIRES SMB S.A.	LU
Xanthium 400 mg Gélules à libération prolongée	not available	2002116793	LABORATOIRES SMB S.A.	LU
Xanthium 400 mg Hartkapseln, retardiert	not available	2002116793	LABORATOIRES SMB S.A.	LU
Theo-Dur 200mg depottablett	not available	6607	KARO PHARMA AB	NO
Theo-Dur 300mg depottablett	not available	6608	KARO PHARMA AB	NO
Euphyllin long, 200 mg, kapsułki o zmodyfikowanym uwalnianiu, twarde	not available	4501	ZR PHARMA& GMBH	PL
Euphyllin long, 300 mg, kapsułki o zmodyfikowanym uwalnianiu, twarde	not available	4502	ZR PHARMA& GMBH	PL
UNICONTIN 400mg comprimidos de libertação prolongada	not available	9628719	BGP PRODUCTS UNIPESSOAL, LDA.	PT
UNICONTIN 400mg comprimidos de libertação prolongada	not available	9628727	BGP PRODUCTS UNIPESSOAL, LDA.	PT
Teofyllamin Meda 23 mg/ml injektionsvätska, lösning	not available	8801	MEDA AB	SE
Theo-Dur 200 mg depottabletter	not available	9445	KARO PHARMA AB	SE
Theo-Dur 300 mg depottabletter	not available	9446	KARO PHARMA AB	SE
EUPHYLLIN CR N 200 200 mg kapsuly s	not available	14/0135/94-S	ZR PHARMA& GMBH	SK

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predĺženým uvoľňovaním				
EUPHYLLIN CR N 300 300 mg kapsuly s predĺženým uvoľňovaním	not available	14/0003/13-S	ZR PHARMA& GMBH	SK
EUPHYLLIN CR N 400 400 mg kapsuly s predĺženým uvoľňovaním	not available	14/0004/13-S	ZR PHARMA& GMBH	SK