



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 January 2026  
EMADOC-1700519818-2988210  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): methadone

EURD list No. PSUSA/00002004/202505

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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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>
Dolmed 5 mg tabletit	not available	9475	ORIFARM HEALTHCARE A/S	FI
Dolmed 5 mg tabletit	not available	9475	ORIFARM HEALTHCARE A/S	FI
Dolmed 5 mg tabletit	not available	9475	ORIFARM HEALTHCARE A/S	FI
Dolmed 5 mg tabletter	not available	9475	ORIFARM HEALTHCARE A/S	FI
Dolmed 5 mg tabletter	not available	9475	ORIFARM HEALTHCARE A/S	FI
Dolmed 5 mg tabletter	not available	9475	ORIFARM HEALTHCARE A/S	FI
EPTADONE 1 mg/ml sciroppo	not available	006105062	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 1 mg/ml sciroppo	not available	006105050	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 10 mg/1ml soluzione iniettabile	not available	006105011	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 10 mg/20 ml sciroppo	not available	006105035	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 20 mg/20 ml sciroppo	not available	006105023	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 5 mg/20 ml sciroppo	not available	006105047	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
MEPHENON 10mg/1ml Injektionslösung	not available	BE117327	LABORATOIRES STEROP	BE
MEPHENON 10mg/1ml oplossing voor injectie	not available	BE117327	LABORATOIRES STEROP	BE
MEPHENON 10mg/1ml solution injectable	not available	BE117327	LABORATOIRES STEROP	BE
MEPHENON 10mg/1ml solution injectable	not available	1998034433	LABORATOIRES STEROP	LU
Metadon "Dne Pharma", tabletter	DK/H/2990/002	61837	DNE PHARMA AS	DK
Metadon "Dne Pharma", tabletter	DK/H/2990/004	61839	DNE PHARMA AS	DK
Metadon "Dne Pharma",	DK/H/2990/005	61840	DNE PHARMA AS	DK

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tabletter				
Metadon dne pharma 10 mg tabletter	DK/H/2990/002	36485	DNE PHARMA AS	FI
Metadon dne pharma 10 mg tabletter	DK/H/2990/002	18-12533	DNE PHARMA AS	NO
Metadon dne pharma 10 mg tabletti	DK/H/2990/002	36485	DNE PHARMA AS	FI
Metadon dne pharma 40 mg tabletter	DK/H/2990/004	36487	DNE PHARMA AS	FI
Metadon dne pharma 40 mg tabletter	DK/H/2990/004	18-12535	DNE PHARMA AS	NO
Metadon dne pharma 40 mg tabletti	DK/H/2990/004	36487	DNE PHARMA AS	FI
Metadon dne pharma 60 mg tabletter	DK/H/2990/005	36488	DNE PHARMA AS	FI
Metadon dne pharma 60 mg tabletter	DK/H/2990/005	18-12536	DNE PHARMA AS	NO
Metadon dne pharma 60 mg tabletti	DK/H/2990/005	36488	DNE PHARMA AS	FI
Metasedin 10 mg/ml solución inyectable	not available	17.128	ESTEVE PHARMACEUTICALS, S.A.	ES
Metasedin 30 mg comprimidos.	not available	62.422	ESTEVE PHARMACEUTICALS, S.A.	ES
Metasedin 40 mg comprimidos.	not available	62.423	ESTEVE PHARMACEUTICALS, S.A.	ES
Metasedin 5 mg comprimidos	not available	17.129	ESTEVE PHARMACEUTICALS, S.A.	ES
Metasedin 5 mg comprimidos	not available	17.129	ESTEVE PHARMACEUTICALS, S.A.	ES
Methadon G.L. Pharma 20 mg Tabletten	DE/H/6793/003	7000721.00.00	G.L. PHARMA GMBH	DE
Methadon G.L. Pharma 60 mg Tabletten	DE/H/6793/005	7000723.00.00	G.L. PHARMA GMBH	DE
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 114404	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 114404	AUROBINDO PHARMA B.V.	NL

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Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 118670	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 118670	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 114404	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 118670	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 114404	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 118670	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 114405	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 114405	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 118671	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 118671	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 114405	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 118671	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 114405	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 118671	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 114406	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 114406	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 118672	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 118672	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo	not available	RVG 114406	AUROBINDO PHARMA B.V.	NL

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40 mg, tabletten				
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 118672	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 114406	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 118672	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 114407	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 114407	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 118673	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 118673	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 114407	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 118673	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 114407	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 118673	AUROBINDO PHARMA B.V.	NL
Methadon HCl Teva 20 mg, tabletten	not available	RVG 127973	TEVA B.V	NL
Methadon HCl Teva 20 mg, tabletten	not available	RVG 127973	TEVA B.V	NL
Methadon HCl Teva 20 mg, tabletten	not available	RVG 127973	TEVA B.V	NL
Methadon HCl Teva 20 mg, tabletten	not available	RVG 127973	TEVA B.V	NL
Methadon HCl Teva 40 mg, tabletten	not available	RVG 127974	TEVA B.V	NL
Methadon HCl Teva 40 mg, tabletten	not available	RVG 127974	TEVA B.V	NL
Methadon HCl Teva 40 mg, tabletten	not available	RVG 127974	TEVA B.V	NL

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Methadon HCl Teva 40 mg, tabletten	not available	RVG 127974	TEVA B.V	NL
Methadon HCl Tiofarma 20 mg, tabletten	not available	RVG 117368	TIOFARMA B.V.	NL
Methadon HCl Tiofarma 30 mg, tabletten	not available	RVG 131187	TIOFARMA B.V.	NL
Methadon HCl Tiofarma 40 mg, tabletten	not available	RVG 117370	TIOFARMA B.V.	NL
Methadon HCl Tiofarma 50 mg, tabletten	not available	RVG 131188	TIOFARMA B.V.	NL
Methadon HCl Tiofarma 60 mg, tabletten	not available	RVG 131189	TIOFARMA B.V.	NL
Methadon HCl Tiofarma 70 mg, tabletten	not available	RVG 131190	TIOFARMA B.V.	NL
Methadon HCl Tiofarma 80 mg, tabletten	not available	RVG 117371	TIOFARMA B.V.	NL
Methadone 1 mg/ml Oral Solution	not available	PL 20075/0608	ACCORD HEALTHCARE LIMITED	XI
Methadone 1 mg/ml Oral Solution	not available	PL 20075/0608	ACCORD HEALTHCARE LIMITED	XI
Methadone 1 mg/ml Oral Solution	not available	PL 20416/0481	CRESCENT PHARMA LIMITED	XI
METHADONE AP-HP 1 mg, gélule	not available	34009 379 146 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 1 mg, gélule	not available	34009 379 146 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 1,33 mg/ml, sirop	not available	34009 353 197 9 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 10 mg, gélule	not available	34009 379 148 5 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 10 mg, gélule	not available	34009 379 148 5 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR

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METHADONE AP-HP 20 mg, gélule	not available	34009 379 149 1 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 20 mg, gélule	not available	34009 379 149 1 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 40 mg, gélule	not available	34009 380 508 1 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 40 mg, gélule	not available	34009 380 508 1 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 5 mg, gélule	not available	34009 379 147 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 5 mg, gélule	not available	34009 379 147 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution	not available	PL 00427/0113	ROSEMONT PHARMACEUTICALS LIMITED	XI
Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution	not available	00427/0113	ROSEMONT PHARMACEUTICALS LIMITED	XI
Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution	not available	PL 00427/0113	ROSEMONT PHARMACEUTICALS LIMITED	XI
Methadon-neuraxpharm 10 mg Tabletten	DE/H/4261/002	93817.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Methadon-neuraxpharm 40 mg Tabletten	DE/H/4261/004	93819.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Metharose Sugar Free	not available	00427/0113	ROSEMONT	XI

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Green 1mg/1ml Oral Solution			PHARMACEUTICALS LIMITED	
Metharose Sugar Free Green 1mg/1ml Oral Solution	not available	00427/0113	ROSEMONT PHARMACEUTICALS LIMITED	XI
Metharose Sugar Free Green 1mg/1ml Oral Solution	not available	00427/0113	ROSEMONT PHARMACEUTICALS LIMITED	XI
Methasan 20 mg Tabletten	DE/H/5965/003	2203042.00.00	G.L. PHARMA GMBH	DE
Methasan 20 mg Tabletten	DE/H/5965/003	2024020019	G.L. PHARMA GMBH	LU
Methasan 20 mg-Tabletten	not available	140552	G.L. PHARMA GMBH	AT
Methasan 60 mg Tabletten	DE/H/5965/005	2203044.00.00	G.L. PHARMA GMBH	DE
Methasan 60 mg Tabletten	DE/H/5965/005	2024020021	G.L. PHARMA GMBH	LU
Methasan 60 mg-Tabletten	not available	140554	G.L. PHARMA GMBH	AT
Omtisa 20 mg compresse	DE/H/6793/003	049749171	G.L. PHARMA GMBH	IT
Omtisa 20 mg compresse	DE/H/6793/003	049749183	G.L. PHARMA GMBH	IT
Omtisa 20 mg compresse	DE/H/6793/003	049749195	G.L. PHARMA GMBH	IT
Omtisa 20 mg compresse	DE/H/6793/003	049749207	G.L. PHARMA GMBH	IT
Omtisa 20 mg compresse	DE/H/6793/003	049749219	G.L. PHARMA GMBH	IT
Omtisa 20 mg compresse	DE/H/6793/003	049749221	G.L. PHARMA GMBH	IT
Omtisa 20 mg compresse	DE/H/6793/003	049749233	G.L. PHARMA GMBH	IT
Omtisa 60 mg compresse	DE/H/6793/005	049749310	G.L. PHARMA GMBH	IT
Omtisa 60 mg	DE/H/6793/005	049749322	G.L. PHARMA GMBH	IT

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compresse				
Omtisa 60 mg compresse	DE/H/6793/005	049749334	G.L. PHARMA GMBH	IT
Omtisa 60 mg compresse	DE/H/6793/005	049749346	G.L. PHARMA GMBH	IT
Omtisa 60 mg compresse	DE/H/6793/005	049749359	G.L. PHARMA GMBH	IT
Omtisa 60 mg compresse	DE/H/6793/005	049749361	G.L. PHARMA GMBH	IT
Omtisa 60 mg compresse	DE/H/6793/005	049749373	G.L. PHARMA GMBH	IT
Phymet DTF 1 mg/ml Syrup	not available	PA 1077/074/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
ZORYON 10 mg, gélule	not available	34009 301 678 5 4	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, gélule	not available	34009 301 678 7 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, gélule	not available	34009 301 678 8 5	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, gélule	not available	34009 301 678 9 2	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, gélule	not available	34009 550 614 4 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, gélule	not available	34009 550 614 5 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg/7,5 ml, sirop en récipient unidose	not available	34009 301 679 0 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg/7,5 ml, sirop en récipient unidose	not available	34009 550 614 6 5	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR

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ZORYON 20 mg, gélule	not available	34009 301 679 1 5	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, gélule	not available	34009 301 679 3 9	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, gélule	not available	34009 301 679 4 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, gélule	not available	34009 301 679 5 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, gélule	not available	34009 550 614 7 2	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, gélule	not available	34009 550 614 8 9	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg/15 ml, sirop en récipient unidose	not available	34009 301 679 6 0	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg/15 ml, sirop en récipient unidose	not available	34009 550 614 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 301 679 7 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 301 679 8 4	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 301 679 9 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 301 680 1 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 550 615 0 2	ASSISTANCE PUBLIQUE -	FR

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			HOPITAUX DE PARIS - AP-HP	
ZORYON 40 mg, gélule	not available	34009 550 615 1 9	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg/15 ml, sirop en récipient unidose	not available	34009 301 680 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg/15 ml, sirop en récipient unidose	not available	34009 550 615 2 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, gélule	not available	34009 301 678 0 9	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, gélule	not available	34009 301 678 1 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, gélule	not available	34009 301 678 2 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, gélule	not available	34009 301 678 3 0	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, gélule	not available	34009 550 614 0 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, gélule	not available	34009 550 614 2 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg/3,75 ml, sirop en récipient unidose	not available	34009 301 678 4 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg/3,75 ml, sirop en récipient unidose	not available	34009 550 614 3 4	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR