



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 January 2023  
EMA/99341/2023  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): methadone

Procedure No. PSUSA/00002004/202205



<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
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
MEPHENON 5mg comprimés	not available	BE078802	LABORATOIRES STEROP	BE
MEPHENON 5mg tabletten	not available	BE078802	LABORATOIRES STEROP	BE
MEPHENON 5mg Tabletten	not available	BE078802	LABORATOIRES STEROP	BE
MEPHENON 5mg, comprimés	not available	1998034432	LABORATOIRES STEROP	LU
Metadon G.L. 10 mg tabletter	DK/H/2990/002	18-12533	G.L. PHARMA GMBH	NO

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Metadon G.L. 40 mg tabletter	DK/H/2990/004	18-12535	G.L. PHARMA GMBH	NO
Metadon G.L. 60 mg tabletter	DK/H/2990/005	18-12536	G.L. PHARMA GMBH	NO
Metasedin 10 mg/ml solución inyectable	not available	17.128	ESTEVE PHARMACEUTICALS, S.A.	ES
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", tabletter	DK/H/2990/002	61837	G.L. PHARMA GMBH	DK
Methadon "G.L. Pharma", tabletter	DK/H/2990/004	61839	G.L. PHARMA GMBH	DK
Methadon "G.L. Pharma", tabletter	DK/H/2990/005	61840	G.L. PHARMA GMBH	DK
Methadon HCl Apotex 10 mg, tabletten	not available	RVG 118670	APOTEX EUROPE B.V.	NL
Methadon HCl Apotex 20 mg, tabletten	not available	RVG 118671	APOTEX EUROPE B.V.	NL
Methadon HCl Apotex 40 mg, tabletten	not available	RVG 118672	APOTEX EUROPE B.V.	NL
Methadon HCl Apotex 50 mg, tabletten	not available	RVG 118673	APOTEX EUROPE B.V.	NL
Methadon HCl Aurobindo 10 mg, tabletten	not available	RVG 114404	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 20 mg, tabletten	not available	RVG 114405	AUROBINDO PHARMA B.V.	NL
Methadon HCl Aurobindo 40 mg, tabletten	not available	RVG 114406	AUROBINDO PHARMA B.V.	NL

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Methadon HCl Aurobindo 50 mg, tabletten	not available	RVG 114407	AUROBINDO PHARMA B.V.	NL
Methadon HCl Teva 10 mg, tablet	not available	RVG 118662	TEVA NEDERLAND B.V.	NL
Methadon HCl Teva 20 mg, tablet	not available	RVG 118664	TEVA NEDERLAND B.V.	NL
Methadon HCl Teva 20 mg, tabletten	not available	RVG 127973	TEVA B.V	NL
Methadon HCl Teva 40 mg, tablet	not available	RVG 118665	TEVA NEDERLAND B.V.	NL
Methadon HCl Teva 40 mg, tabletten	not available	RVG 127974	TEVA B.V	NL
Methadon HCl Teva 50 mg, tablet	not available	RVG 118666	TEVA NEDERLAND B.V.	NL
Methadon HCl Tiofarma 20 mg, tabletten	not available	RVG 117368	TIOFARMA BV	NL
Methadon HCl Tiofarma 40 mg, tabletten	not available	RVG 117370	TIOFARMA BV	NL
Methadon HCl Tiofarma 80 mg, tabletten	not available	RVG 117371	TIOFARMA BV	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 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 1,33 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 20 mg, gélule	not available	34009 379 149 1 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR

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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 G.L. Pharma 10 mg tabletti	DK/H/2990/002	36485	G.L. PHARMA GMBH	FI
Methadone G.L. Pharma 40 mg tabletti	DK/H/2990/004	36487	G.L. PHARMA GMBH	FI
Methadone G.L. Pharma 60 mg tabletti	DK/H/2990/005	36488	G.L. PHARMA GMBH	FI
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
Methasan 20 mg Tabletten	DE/H/5965/003	2203042.00.00	G.L. PHARMA GMBH	DE
Methasan 20 mg Tabletten	DE/H/5965/003	2019110280	G.L. PHARMA GMBH	LU
Methasan 60 mg Tabletten	DE/H/5965/005	2203044.00.00	G.L. PHARMA GMBH	DE
Methasan 60 mg Tabletten	DE/H/5965/005	2019110282	G.L. PHARMA GMBH	LU
Methasan® 20 mg-Tabletten	not available	140552	G.L. PHARMA GMBH	AT
Methasan® 60 mg-Tabletten	not available	140554	G.L. PHARMA GMBH	AT
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

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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, 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

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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
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, 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

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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 301 680 1 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 550 615 0 2	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 550 615 1 9	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 301 680 1 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, gélule	not available	34009 550 615 0 2	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR



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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, 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

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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