



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 April 2014
EMA/223546/2014
Procedure Management and Business Support

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for all authorised methadone medicinal products for oral use containing povidone

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1395



Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Alternova A/S Lodshusvej 11 4230 Skælskør Denmark	Methadon "Alternova"	Methadone	20 mg	tablet	oral use
Denmark	Alternova A/S Lodshusvej 11 4230 Skælskør Denmark	Methadon "Alternova"	Methadone	5 mg	tablet	oral use
Denmark	Martindale Pharmaceuticals Bampton Road RM3 8UG Essex United Kingdom	Methadon "Martindale Pharma"	Methadone	2 mg/ml	oral solution	oral use
Finland	Abcur AB BOX 1452 25114 Helsingborg Sweden	METADON ABCUR	Methadone hydrochloride	5 mg	tablet	oral use
Finland	Abcur AB BOX 1452 25114 Helsingborg Sweden	METADON ABCUR	Methadone hydrochloride	20 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Martindale Pharmaceuticals Bampton Road Harold Hill Romford Essex RM3 8UG United Kingdom	METHADONE MARTINDALE PHARMA	Methadone hydrochloride	2 mg/ml	oral solution	oral use
Hungary	ExtractumPharma zrt. Megyeri út 64 Budapest 1044 Hungary	Depridol	methadone	5 mg	tablet	oral use
Hungary	ExtractumPharma zrt. Megyeri út 64 Budapest 1044 Hungary	Metadon-EP 5 mg	methadone	5 mg	tablet	oral use
Hungary	ExtractumPharma zrt. Megyeri út 64 Budapest 1044 Hungary	Metadon-EP 20 mg	methadone	20 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Iceland	Abcur AB, P.O. Box 1452 S-251 14 Helsingborg Sweden	Metadon Abcur	Metadonum INN chloride	5 mg	tablet	oral use
Iceland	Abcur AB, P.O. Box 1452 S-251 14 Helsingborg Sweden	Metadon Abcur	Metadonum INN chloride	20 mg	tablet	oral use
Malta	Martindale Pharmaceuticals Ltd. Bampton Road Harold Hill Romford, RM3 8UG United Kingdom	Methadone Martindale Pharma Oral Solution 2mg/ml	Methadone hydrochloride	2mg/ml	oral solution	oral use
Norway	Abcur AB P.O. Box 1452 25114 Helsingborg Sweden	Metadon Abcur	methadone hydrochloride	5 mg	tablet	oral use
Norway	Abcur AB P.O. Box 1452 25114 Helsingborg Sweden	Metadon Abcur	methadone hydrochloride	20 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Norway	Martindale Pharmaceuticals Ltd. Bampton Road Harold Hill Romford, RM3 8UG United Kingdom	Methadon Martindale Pharma	methadone hydrochloride	2 mg/ml	oral solution	oral use
Romania	S.C. BIO EEL S.R.L. Str. Bega Nr. 4 Târgu-Mureş 540390 România	METADON BIOEEL	methadone	5mg	tablet	oral use
Romania	S.C. BIO EEL S.R.L. Str. Bega Nr. 4 Târgu-Mureş 540390 România	METADON BIOEEL	methadone	20mg	tablet	oral use
Spain	LABORATORIO Dr. ESTEVE, S.A. Avda. Mare de Déu de Montserrat, 221 08041 Barcelona Spain	METASEDIN 5 mg comprimidos	Methadone hydrochloride	5 mg	tablet	oral use
Sweden	Abcur AB Box 1452 251 14 Helsingborg Sweden	Metadon Abcur	Methadone hydrochloride	5 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Abcur AB Box 1452 251 14 Helsingborg Sweden	Metadon Abcur	Methadone hydrochloride	20 mg	tablet	oral use
Sweden	Martindale Pharmaceuticals Ltd. Bampton Road Harold Hill, Romford, Essex, RM3 8UG United Kingdom	Methadone Martindale Pharma	Methadone hydrochloride	2 mg/ml	oral solution	oral use
United Kingdom	Martindale Pharmaceuticals Limited Bampton Road, Harold Hill, Romford Essex RM3 8UG United Kingdom	Methadone Martindale Pharma 2mg/ml Oral Solution	methadone hydrochloride	2mg/ml	oral Solution	oral use