MARTINDALE PHARMA®
Making lives better

METHADONE ORAL SOLUTION

1mg/ml Sugar Free Mixture

Martindale Pharma® is one of the leading UK suppliers of Methadone for the treatment of Opioid Drug addiction.

Our Methadone is currently registered in Ireland, Norway, Sweden, Finland, Denmark, Malta, Kenya and South Africa, with further registration applications submitted in Europe and the Middle East.

With over 15 years' experience in manufacturing Methadone to a precise and consistent formulation, all our products are manufactured under GMP conditions. Formulations include Alcohol free, Sugar free, Lycosine free and orange flavoured variants.

From 2005, Methadone has been included in the WHO Model List of Essential Medicines.

Methadone oral solution offers a consistent formulation for treating opioid dependence

Proven to relieve craving & withdrawal symptoms[1]

Favourable tolerability profile with low potential for toxicity[2]

Wealth of experience in treating opioid dependence[2]

Methadone Oral Solution improves harm-reduction outcomes[1-3]

Methadone 1mg/ml Mixture Sugar Free Prescribing Information

Prescribing information for Methadone Mixture DTF (Sugar Free) 1mg in 1ml Oral Solution.

Please refer to Summary of Product Characteristics before prescribing.

PRESENTATION: A green, clear oral solution containing 1mg/ml Methadone Hydrochloride in a sugar free base.

INDICATIONS: Treatment of opioid drug addiction as substitution or maintenance therapy, within a broader treatment protocol/ program, accompanied by regular reviews and reassessment. This treatment must be supervised by specialist services.

DOSAGE AND ADMINISTRATION: Dosing and duration should be individualised based on a careful evaluation of data and clinical status, including hepatic and renal function of the patient. Use with caution in patients with cardiac repolarisation disorders.
For oral administration only.
Adults: initially 10 - 20mg/day, increasing by 10 - 20mg/day until there is no sign of withdrawal or intoxication. Usual dose is 40-60mg/day. Adjust dose according to degree of dependence with the aim of gradual reduction.
The elderly or ill patient: repeated doses should only be given with extreme caution.
Children: not recommended.

CONTRA-INDICATIONS: Respiratory depression, obstructive airways disease and acute alcoholism. Head injury and raised intracranial pressure, risk of paralytic ileus, concurrent administration of MAOI drugs or within 2 weeks of discontinuation of treatment with them. Use during an acute asthma attack is not advisable. Use during labour and in children is not recommended. Phaeochromocytoma.

WARNINGS AND PRECAUTIONS: Cases of QT interval prolongation and torsade de pointes have been reported during treatment with methadone, particularly at high doses (>100 mg/d). Methadone should be administered with caution to patients at risk for development of prolonged QT interval, e.g. in case of:
- known history of QT prolongation
- advanced heart disease ,
- ischaemic heart disease & Liver disease,
- concomitant treatment with drugs that have a potential for QT-prolongation

Tolerance and dependence of the morphine type may occur. Use with caution in patients with a history of asthma, convulsive disorders, depressed respiratory reserve, hypotension, shock, prostatic hyperplasia, adrenocortical insufficiency, inflammatory or obstructive bowel disorders, myasthenia gravis or hypothyroidism. In cases of hepatic or renal impairment the use of methadone should be avoided or given in reduced doses.

INTERACTIONS: A wide range of interactions are possible. Methadone may interact with alcohol, analgesics e.g. buprenorphine and pentazocine, other opioids, antiarrhythmics e.g. mexiletine, antidepressants e.g. MAOIs, tricyclics and fluvoxamine, antivirals e.g. nevirapine, efavirenz, nelfinavir and zidovudine, ciprofloxacin, cytochrome P450 3A4 inhibitors e.g. cimetidine, macrolide antibiotics, azole antifungal agents. Drugs that affect cardiac conduction and electrolyte balance, carbamazepine, CNS depressants, gastrointestinal drugs e.g. metoclopramide and domperidone. Also naloxone, naltrexone, phenytoin, rifampicin and urinary acidifiers.

PREGNANCY AND LACTATION: Methadone administered to pregnant women for the management of opioid addiction has the potential for several adverse effects on the foetus and neonate. A careful benefit/ risk assessment must be made. There is an increased risk of prolonged respiratory depression in neonate, neonatal withdrawal syndrome, low birth weight and increased still birth rates. Babies born to mothers maintained on methadone may also be at risk of sudden infant death syndrome. Methadone is excreted in breast milk.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: The ability to drive or operate machinery may be severely effected during and after treatment with methadone.

UNDESIRABLE EFFECTS: Nausea, vomiting and dizziness. Methadone has the potential to increase intracranial pressure, particularly where it is already raised. Hallucinations, confusion, vertigo, mood changes, dysphoria, dependence, headache, drowsiness, sweating, postural hypotension, miosis, difficulty with micturition and hypothermia. Bradycardia, palpitations, tachycardia, facial flushing, constipation, dry mouth, ureteric or biliary spasm, antidiuretic effect, decreases libido or potency, urticaria, pruritis and rashes. Cases of QT prolongation and torsades de pointes have been rarely reported.

PRODUCT LICENCE NUMBER:
PA 361/007/006

PRODUCT LICENCE HOLDER:
Martindale Pharmaceuticals Ltd
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LEGAL CATEGORY:
Prescription Only CD

DATE OF PREPARATION:
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REFERENCES:

1. For C, Barbard J. Bury J et al.Guidance for the use of methadone for the treatment of opioid dependence in primary care. Published by thr Royal College of General Practitioners. 1st ed 2005.

2. Leavitt SB. The safety of methadone, LAAM, buprenorphine in the treatment of opioid dependency. Addiction treatment forum. Available at www.atforum.com/siteroot/pages/current_pastissues/safety_methadone.shtml

3. The National Treatment Outcome Research Study (NTORS). The Addiction Centre, 2001.

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