Unique formulations of Levomepromazine

Levorol™
levomepromazine

The Levorol Range: aims to provide confidence and flexibility in dosing[1,2]

Prescribing information is available on the last two pages.

Adverse events should be reported. For reporting within the UK, forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Galvany Pharma Ltd on Phone: +44(0) 1438310048 or Email: information@galvanypharma.com.

For more information please call +44 (0) 1438 310048 or email information@galvanypharma.com

Galvany Pharma
Innovative solutions for palliative care

Levorol 6.25 mg Tablets

Small, scored tablets aim to provide confidence in accurate dosing[1]

Levorol 6.25 mg Tablets offer you an accurate dosing solution without the need to quarter 25 mg tablets.[1]

Levorol 6.25 mg Tablets is indicated as second or third line treatment of adults with refractory nausea unassociated with chemotherapy, where other agents have failed to give adequate control.[1]

Available from Alloga and Alliance Healthcare
Levorol 6.25 mg tablets
EAN code: 5070000854380
PIP code: 5401831

Levorol 5 mg/ml Oral Solution

The Levorol Oral Solution is also available to provide you and your patients with flexible dosing[2]

Levorol 5 mg/ml Oral Solution is the first licensed oral liquid levomepromazine in the UK.[2]

Levorol 5 mg/ml Oral Solution offers an alternative for patients who have difficulty swallowing tablets.[2]

1 ml = 5 mg with 0.5ml oral syringe graduations.[2]

Available from Alloga and Alliance Healthcare
Levorol 5 mg/ml oral solution
EAN code: 5070000854304
PIP code: 5400809

Prescribing Information

Levorol™ (levomepromazine hydrochloride) 5 mg/ml Oral Solution
PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Levomepromazine hydrochloride
Please refer to Summary of Product Characteristics (SmPC) before prescribing. INDICATION(S): Levomepromazine is a neuroleptic with indications in psychiatry and general medicine, particularly in terminal illness. Clinically it is more sedative and more potent than chlorpromazine in the management of psychotic conditions and in the relief of severe chronic pain and possesses anti-emetic effects. Levorol 5 mg/ml Oral Solution is indicated: for the suppression of psychomotor restlessness and agitation within the context of psychotic disorders, for acute agitation states in manic episodes, and as an adjunct therapy for the treatment of severe and/or chronic pain. DOSAGE & ADMINISTRATION: A 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and a "Press In" Bottle Adapter (PIBA) are provided with the product. Dosage varies with the condition under treatment and the individual response of the patient. Children and adolescents under 16 years: Use not recommended. Adults: Ambulant patients: 15-30 mg levomepromazine/day (3-6 ml of Levorol oral solution) up to 75-150 mg levomepromazine/day (15-30 ml of Levorol oral solution). Bed patients with psychosis: Initially the total daily oral dosage is 75-100 mg (5 ml, 3 to 4 times), increased to 150 mg/day (10 ml, 3 times) up to 300 mg/day (20 ml, 3 times) and for severe psychoses up to 600 mg levomepromazine/day. For doses higher than 300 mg levomepromazine should be taken in the form of tablets. Bed patients with severe pain: Initially the total daily oral dosage is 25-50-75 mg/day (5-10-15 ml), gradually increased, if necessary, up to 300 mg/day (60 ml). Elderly and patients with renal or hepatic impairment: The dose must be adjusted with special caution, as there is an increased incidence of side effect. Please refer to SmPC for full details. CONTRAINDICATIONS: Hypersensitivity to the active substance, levomepromazine hydrochloride, thioxanthenes and phenothiazines or to any of the excipients. Acute alcohol-, sleeping medication-, analgesic- and psychopharmaceutical- intoxication. Shock (circulatory failure). Coma. Impairment of the haematopoietic system. SPECIAL WARNINGS & PRECAUTIONS: Levorol oral solution should be avoided or used with caution in the following conditions: hepatic failure and end stage renal disease; previous cardiac disease; prolactin-dependent tumours (such as breast tumours); severe hypotension or hypertension; postural hypotension; history of brain disease or epileptic seizures; non-drug induced Parkinson's disease; atherosclerotic cerebrovascular disease; history of Malignant Neuroleptic Syndrome; glaucoma; micturition disorder; pyloric stenosis; benign prostatic hyperplasia; congenital long QT syndrome or other clinically significant cardiac disorders (especially coronary artery disease, conduction disorders, arrythmias); and concomitant treatment with drugs that prolong the QT interval in the ECG or cause hypokalaemia. Ongoing monitoring: blood count should be checked before the initiation of treatment (including platelet and differential count) and then weekly within the first four months of initiation (leukocyte count and differential count), if after which the values are within normal ranges, a monthly monitoring will suffice. Levomepromazine must not be initiated or continued if blood values are outside the normal range or if changes in blood count occur during treatment. Initiation of treatment should be followed by ECG monitoring and liver function should be monitored every 6-12 months while on treatment. Cardiovascular events: levomepromazine may prolong the QT interval leading (rarely) to fatal arrhythmias and Torsade de Pointes. In these cases, treatment must be discontinued. Blood pressure lowering effects may occur within 10-20 minutes after intramuscular injection of levomepromazine, lasting 4-6 hours (rarely up to 12 hours). As a rule, the blood pressure-reducing effect of levomepromazine is reduced over longer treatment periods. If treatment is interrupted for several days, further administration might again lead to blood pressure reduction. After parenteral administration as well as at the initiation of administration of higher doses, the patient needs bed rest for 5-6 hours. Hospitalisation is recommended for daily doses over 150 mg. Malignant neuroleptic syndrome: if high fever and muscle stiffness occur, the possibility of malignant neuroleptic syndrome (increase in myoglobin and creatine kinase activity [CK] in the blood) should be considered, which is often misdiagnosed as catatonia. Since the re-administration of neuroleptics can have life-threatening consequences, the differentiation from catatonia is decisive in the differential diagnosis (medical history, examination for rigor, fever, as well as an increase in CK and myoglobin in the blood or urine). The following treatment options are recommended: immediate drug withdrawal; cooling employed for hypothermia; treatment for fluid and electrolyte imbalance, cardiovascular manifestations, infections, respiratory and renal complications; and treatment with dantrolene infusions (3 to 10 mg/kg/day) in combination with bromocriptine (7.5 to 30 mg/day orally). Elderly people with dementia: increased risk of mortality. The extent to which this association is attributed to the medicinal product, as opposed to being confounded by patient characteristics, has not yet been elucidated. Leverol oral solution is not indicated for the treatment of dementia-related behavioural disturbances. Cerebrovascular events: 3-fold increased risk of cerebrovascular adverse events with some atypical antipsychotics. The mechanism for this increased risk is not known. An increased risk cannot be excluded for other patient populations. Levorol oral solution must be used with caution in patients with risk factors for stroke. Venous thromboembolism (VTE) risk: reports of VTE with the use of antipsychotic drugs. All possible risk factors for VTE should be identified before and during treatment with levomepromazine solution and preventative measures should be undertaken. Propylene glycol: medical monitoring is required due to reports of various adverse events attributed to propylene glycol in patients with impaired renal or hepatic functions (such as renal dysfunction, acute renal failure and liver dysfunction). Sodium content: contains less than 1 mmol sodium (23 mg) per 40 ml of oral solution, that is to say essentially 'sodium free'. Sodium benzoate: contains 0.3 mg of sodium benzoate in each 1 ml of oral solution. Benzyl alcohol: contains 0.03 mg of benzyl alcohol in each 1 ml of oral solution. Benzyl alcohol may cause allergic reactions. High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity. Other: patients should be advised not to self-medicate in case of fever, mouth and gum inflammation, sore throat or purulent angina, and flu-like symptoms, especially if these occur within the first three months of drug treatment, but to seek medical advice immediately. Patients should be advised to avoid exposure to direct sunlight due to the risk of photosensitisation. Refer to SmPC for full details. UNDESIRABLE EFFECTS: Very common (≥ 1/10): Fatigue, orthostatic hypotension, tachycardia, ECG changes. Common: (≥ 1/100 to <1/10): Weight gain, extrapyramidal symptoms such as dyskinesia, Parkinson's disease, and akathisia, eye dystonia, blurred vision, ocular hypertension, nasal congestion, constipation, nausea, vomiting, diarrhoea, loss of appetite, xerostomia, Micturition disorder. Uncommon: (≥ 1/1000 to <1/100: Anaphylactic reaction, restlessness, agitation, drowsiness, depressed mood, lethargy, dizziness, headache, exacerbation of psychotic symptoms, confusion, seizures, disturbance of temperature regulation, anterior corneal pigmentations, liver dysfunction, bile drainage problems, jaundice, skin hypersensitivity reactions, photosensitivity. Refer to SmPC for full details on side effects. PREGNANCY: There are insufficient data on the effects of levomepromazine on human embryo or foetus and animal studies are insufficient with respect to reproductive toxicity. Levorol oral solution is not recommended during pregnancy and in women of childbearing potential and women should be advised to contact their physician in case of childbearing potential. Levorol oral solution should not be used in the first trimester and avoided in the second and third trimesters unless considered essential by the physician, in which case the lowest effective dose should be used. Neonates exposed to antipsychotics (including Levorol oral solution) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. Consequently, newborns should be carefully monitored. Levorol oral solution should not be used during the last 10 days of pregnancy to prevent extrapyramidal and/or withdrawal symptoms in the neonate. Refer to SmPC for full details on use in pregnancy. LACTATION: Levomepromazine and its metabolites are excreted to human milk. If treatment cannot be avoided, breast-feeding should be discontinued. INTERACTIONS: Concomitant administration of carbamazepine and barbiturates can induce the CYP enzyme activity resulting in decreased levomepromazine plasma concentrations. The effects of levomepromazine can be inhibited by anticholinergic medicinal products, such a biperiden. The moderate anticholinergic effects of levomepromazine can be enhanced by other anticholinergic agents or other medicinal products with anticholinergic effects. Concomitant administration of drugs known to inhibit hepatic metabolism of levomepromazine, might lead to enhanced therapeutic effects of levomepromazine. Refer to SmPC for full details of the effects of Levorol oral solution on other medicinal products, to include; analgesics, hypnotic agents, sedatives, drugs metabolised primarily by the CYP2D6 enzyme system, phenytoin, polypeptide antibiotics, tricyclic antidepressants, anaesthetics, antihypertensive drugs, dopamine agonists, gonadorelin. LEGAL CATEGORY: POM. PRESENTATIONS, PACK SIZES, PRODUCT LICENCE NUMBERS: Amber, type III glass bottle safely closed with a child-resistant, HDPE screw cap with tamper evident closure. Each bottle contains 100 ml of this medicinal product. A 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and a "press-in" syringe/bottle adapter are also provided.

PLGB 56809/0001
FURTHER INFORMATION AVAILABLE FROM THE MARKETING AUTHORISATION HOLDER: information@galvanypharma.com

Prescribing information last revised: December 2022
Item prepared: December 2022

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Prescribing Information

Levorol™ (levomepromazine maleate) 6.25 mg Tablets PRESCRIBING INFORMATION
ACTIVE INGREDIENT(S): Levomepromazine maleate
Please refer to Summary of Product Characteristics (SmPC) before prescribing.
INDICATION(S): LEVEROL™ is a neuroleptic with indications in psychiatry and general medicine, particularly in terminal illness. Clinically it is more sedative and more potent than chlorpromazine in the management of psychotic conditions and in the relief of severe chronic pain and possesses anti-emetic effects. LEVEROL™ 6.25 mg Tablets are indicated: as an alternative to chlorpromazine in schizophrenia especially when it is desirable to reduce psychomotor activity, as adjunct therapy in the relief of pain and the accompanying distress of terminal illness, and as second or third line treatment of terminally ill adults with refractory nausea unassociated with chemotherapy, where other agents have failed to give adequate control. **DOSAGE & ADMINISTRATION:** Dosage varies with the condition under treatment and the individual response of the patient. **Children and adolescents under 16 years:** Children are very susceptible to the hypotensive and soporific effects of LEVEROL™. It is advised that a total daily oral dosage of 37.5 mg (6 tablets of LEVEROL™ 6.25 mg Tablets) should not be exceeded. The average effective daily intake for a ten-year-old is 12.5 mg to 25 mg (2 to 4 tablets of LEVEROL™ 6.25 mg Tablets). **Adults:** Ambulant patients with psychiatric conditions: initially the total daily oral dose should not exceed 25 mg to 50 mg usually divided into 3 doses. Bed patients with psychiatric conditions: initially the total daily oral dosage may be 100 mg to 200 mg, usually divided into 3 doses. Terminally ill patients for the relief of pain: 12.5 mg to 50 mg every 4 to 8 hours; Terminally ill patients for the treatment of refractory nausea: 6.25 mg once daily, taken at bedtime, increased -if necessary- to 12.5-25 mg twice daily. **Elderly patients with psychiatric conditions:** It is not advised to give LEVEROL™ to ambulant patients over 50 years of age unless the risk of a hypotensive reaction has been assessed**. Patients with renal or hepatic impairment:** In patients with end-stage renal disease, initial smaller doses are recommended. There is no experience regarding the use of LEVEROL™ tablets in patients with hepatic impairment. **Please refer to SmPC for full details CONTRAINDICATIONS:** Hypersensitivity to the active substance, levomepromazine maleate or to any of the excipients. **SPECIAL WARNINGS & PRECAUTIONS:** LEVEROL™ Tablets should be avoided, or used with caution, in patients with liver dysfunction or cardiac disease. Pre-initiation of LEVEROL™ Tablets: Prior to initiation of treatment with LEVEROL™, it may be appropriate to consider an ECG with measurement of serum calcium, magnesium and potassium levels. Periodic serum electrolyte levels should be monitored and corrected if necessary, especially during long-term chronic usage. An ECG may be appropriate to assess the QT interval whenever dose escalation is proposed and when the maximum therapeutic dose is reached. Cardiovascular events: The hypotensive effects of levomepromazine should be taken into account when it is administered to patients with cardiac disease and the elderly or debilitated. Patients receiving large initial doses should be kept in bed. As with other neuroleptics, cases of QT interval prolongation have been reported with levomepromazine very rarely. Consequently, and if the clinical situation permits, absence of the following risk factors for onset of this type of arrhythmia should be verified prior to administration: Bradycardia or 2nd or 3rd degree heart block; metabolic abnormalities such as hypokalaemia, hypocalcaemia or hypomagnesaemia; starvation or alcohol abuse; a history of QT interval prolongation, ventricular arrhythmias or Torsades de Pointes; a family history of QT interval prolongation; concomitant neuroleptics; ongoing treatment with other drug(s) liable to induce marked bradycardia; electrolyte imbalance, slowed intracardiac conduction or prolonged QT interval Malignant neuroleptic syndrome: should be treated with cooling. Dantrolene sodium may be tried. Elderly people with dementia: increased risk of mortality. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of the increased risk is not known. LEVEROL™ is not licensed for the treatment of dementia-related behavioural disturbances. Cerebrovascular events: 3-fold increased risk of cerebrovascular adverse events with some atypical antipsychotics. The mechanism for this increased risk is not known. An increased risk cannot be excluded for other patient populations. LEVEROL™ tablets must be used with caution in patients with risk factors for stroke. Venous thromboembolism (VTE) risk: reports of VTE with the use of antipsychotic drugs. All possible risk factors for VTE should be identified before and during treatment with levomepromazine tablets and preventative measures undertaken. Hyperglycaemia: hyperglycaemia or intolerance to glucose has been reported in patients treated with levomepromazine. Patients with an established diagnosis of diabetes mellitus or with risk factors for the development of diabetes who are started on levomepromazine, should get appropriate glycaemic monitoring during treatment. Convulsions: levomepromazine may lower epileptic threshold and should be used with caution in epileptic patients. Sodium content: contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'. **Refer to SmPC for full details UNDESIRABLE EFFECTS: Very common (≥ 1/10):** Dry mouth, somnolence. **Common: (≥ 1/100 to <1/10):** QT prolongation, asthenia, heat stroke (in hot and humid conditions), hypotension (especially in elderly patients). **Other side effects:** Constipation, Parkinsonism, convulsions, venous thromboembolism, ventricular arrhythmias, cardiac arrest, cardiac rhythm disturbances, jaundice, sudden death/ sudden cardiac death, Torsades de Pointes, ileus paralytic, necrotizing enterocolitis, hepatocellular, cholestatic and mixed liver injury, glucose tolerance impaired, hyperglycaemia, hyponatraemia, syndrome of inappropriate antidiuretic hormone secretion (SIADH), neuroleptic malignant syndrome, confusional states, delirium, drug withdrawal syndrome neonatal, priapism, deep vein thrombosis, pulmonary embolism, photosensitivity reaction, dermatitis allergic. **Refer to SmPC for full details on side effects PREGNANCY:** Safety in pregnancy has not been established. Animal studies are insufficient with respect to reproductive toxicity. In humans, the teratogenic risk of levomepromazine has not been evaluated. Levomepromazine is not recommended during pregnancy and in women of childbearing potential not using contraception. Neonates exposed to antipsychotics (including Levorol tablets) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. Consequently, newborns should be carefully monitored. **Refer to SmPC for full details on use in pregnancy LACTATION:** LEVEROL™ is excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from levomepromazine therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **INTERACTIONS:** Co-administration of LEVEROL™ and drugs primarily metabolised by the CYP2D6 enzyme system may result in increased plasma concentrations of these drugs. The anticholinergic effect of neuroleptics may be enhanced by other anticholinergic drugs. Avoid concomitant neuroleptics and any other drugs that may cause electrolyte imbalance. There is an increased risk of arrhythmias when neuroleptics are used with drugs that prolong the QT interval such as certain Class 1A and III antiarrhythmics, certain antimicrobials, tricyclic antidepressants, tetracyclic antidepressants, other neuroleptics, antihistamines, cisapride, bretylium and antimalarials.

Refer to SmPC for full details of the effects of LEVEROL™ tablets on other medicinal products, including; nortriptyline, amitriptyline/amitriptylinoxide, diuretics, adrenaline and desferrioxamine.
LEGAL CATEGORY: POM.
PRESENTATIONS, PACK SIZES, PRODUCT LICENCE NUMBERS: PVC/PVDC/ aluminium blisters. Pack size: 28 tablets.
PL 56809/0015
FURTHER INFORMATION AVAILABLE FROM THE MARKETING AUTHORISATION HOLDER: Galvany Pharma Ltd., Business & Technology Centre, Bessemer Drive, Stevenage, SG1 2DX, UK. Email: information@galvanypharma.com.

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References

1. Levorol™ 6.25 mg Tablets Summary of Product Characteristics. August 2023.
2. Levorol™ 5 mg/ml Oral Solution Summary of Product Characteristics. June 2022.

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Galvany Pharma

Innovative solutions for palliative care

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