Oxomil®

Oxomemazine 0.33mg/mL

FORMS AND PRESENTATION

Oxomil®: Syrup: Bottle of 150 mL.

COMPOSITION

Oxomil®: Each 100 ml of oral solution contains Oxomemazine 0.033g

Excipients: Sodium benzoate, glycerol, citric acid monohydrate, sodium citrate, liquid maltitol, acesulfame potassium.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Systemic Antihistamines,
ATC code: R06AD08.

Oxomemazine:

Oxomemazine is an H1 antihistamine, phenothiazine with an aliphatic side chain, characterized by:

• A pronounced sedative effect at usual doses, originating from central histaminergic and adrenolytic action.
• An anticholinergic effect causing peripheral adverse effects.
• A peripheral adrenolytic effect, which may impact hemodynamic (risk of orthostatic hypotension).

Antihistamines share the common property of opposing, through more or less reversible competitive antagonism, the effects of histamine, particularly on the skin, bronchi, intestines, and blood vessels.

Pharmacokinetic properties

Pharmacokinetic data specific to Oxomemazine are currently unavailable. However, general characteristics of antihistamines, particularly those of the phenothiazine class, can be outlined. Bioavailability is typically moderate, and metabolism, when applicable, is often extensive, leading to the formation of numerous metabolites, which accounts for the minimal amount of unchanged drug excreted in the urine. The half-life of these agents is variable but frequently prolonged, enabling once-daily dosing. Their high liposolubility contributes to a large volume of distribution. In patients with renal or hepatic insufficiency, there is a potential risk of drug accumulation due to altered elimination pathways.

INDICATIONS

Oxomil® is indicated to soothe dry and irritative coughs in adults and children over 2 years of age, particularly when they occur in the evening or at night.

CONTRAINDICATIONS

Oxomil® is contraindicated in the following situations:

• Hypersensitivity to oxomemazine or any of the excipients listed.
• Allergy to any antihistamine, particularly those in the same family as oxomemazine.
• Administration to children under 2 years of age.
• History of significant reduction in white blood cells (agranulocytosis).
• Difficulty urinating due to prostate disorders or other urinary conditions.
• Risk of closed-angle glaucoma, characterized by increased intraocular pressure affecting vision.
• Concurrent use of medications containing cabergoline or quinagolide, which are used to reduce excessive prolactin production.

PRECAUTIONS

Special warnings

Productive coughs, which play a crucial role in bronchopulmonary defence, should not be suppressed.

It is inappropriate to combine an expectorant or mucolytic with this antitussive medication.

Prior to initiating antitussive therapy, it is essential to identify the underlying causes of the cough that may require targeted treatment.

In cases where the cough persists despite the administration of an antitussive at the recommended dosage, dose escalation is not advised; instead, the clinical situation should be re-evaluated.

Related to the presence of Oxomemazine:

Given that phenothiazines have been implicated as potential risk factors for sudden infant death syndrome (SIDS), oxomemazine should not be administered to children under 2 years of age.

Enhanced clinical and, if necessary, electroencephalographic monitoring is warranted in epileptic patients due to the potential lowering of the seizure threshold.

Although the risk of abuse and dependence is considered low, instances of misuse and dependence can occur, primarily in adults using oxomemazine for its sedative effects. Any indications of misuse or dependence should prompt careful monitoring.

Oxomemazine must be used with caution under the following conditions:

-In elderly patients, who may exhibit:
• Increased susceptibility to orthostatic hypotension, dizziness, and sedation,
• Chronic constipation (risk of paralytic ileus),
• Possible prostatic hypertrophy;
-In individuals with certain cardiovascular disorders, due to the tachycardic and hypertensive effects associated with phenothiazines;
-In cases of severe hepatic and/or renal impairment, due to the risk of drug accumulation.
-In pediatric patients, bronchial asthma or gastroesophageal reflux should be excluded before considering the use of oxomemazine as an antitussive.

Consumption of alcohol or medications containing alcohol is strongly discouraged during the treatment period.

Due to the photosensitizing properties of phenothiazines, patients should avoid exposure to direct sunlight during treatment.

H1 antihistamines should be administered with caution because of the associated risk of sedation. Concomitant use with other sedative agents is not recommended.

Related to the presence of excipients with a known effect:

This formulation contains 0.300 g of sodium benzoate per 100 mL of solution. Sodium benzoate may displace bilirubin from albumin, potentially leading to an increase in bilirubin levels and thereby heightening the risk of neonatal jaundice, which could progress to kernicterus (bilirubin deposition in the brain).

This product contains liquid maltitol and is contraindicated in patients with hereditary fructose intolerance, a rare genetic disorder.

Effects on ability to drive and use machines

Attention is drawn, particularly for drivers and machine operators, to the risk of drowsiness associated with the use of this medication, especially at the beginning of treatment. This effect is heightened by the consumption of alcoholic beverages or medications containing alcohol.

PREGNANCY AND LACTATION

Pregnancy

Teratogenic Aspect

There are no reliable data on teratogenesis in animals.

Currently, there is not enough relevant data to assess any potential malformities or fetotoxic effects of oxomemazine when administered during pregnancy.

Fetotoxic Aspect

In newborns of mothers treated long-term with high doses of anticholinergic medications, digestive signs related to atropinic properties have been rarely described (abdominal distension, meconium ileus, delayed meconium passage, difficulty initiating feeding, tachycardia, neurological disorders, etc.).

Given these data, the use of this medication is not recommended during the first trimester of pregnancy. It should only be prescribed, if necessary, thereafter, and limited to occasional use in the third trimester.

If this medication is administered at the end of pregnancy, it seems justified to observe a period of monitoring of the newborn's neurological and digestive functions.

Breastfeeding

It's not known whether Oxomemazine is excreted in breast milk. Given the potential for sedation or paradoxical excitation in the newborn, and the risk of sleep apnea associated with phenothiazines, this medication is not recommended during breastfeeding.

DRUG INTERACTIONS

Medications Lowering the Epileptogenic Threshold

The concurrent use of proconvulsant medications, or those lowering the epileptogenic threshold, should be carefully considered due to the severity of the risk involved. These medications include most antidepressants (imipramine derivatives, selective serotonin reuptake inhibitors), neuroleptics (phenothiazines and butyrophenones), mefloquine, chloroquine, bupropion, and tramadol.

Atropine Medications

It must be taken into account that atropine substances can amplify their adverse effects and lead to increased risk of urinary retention, acute glaucoma exacerbation, constipation, dry mouth, etc. Various atropine medications include imipramine antidepressants, most H1 atropine antihistamines, anticholinergic antiparkinsonian drugs, atropine antispasmodics, disopyramide, phenothiazine neuroleptics, and clozapine.

Sedative Medications

It should be noted that many medications or substances can enhance their central nervous system depressant effects and contribute to reduced alertness. This includes morphine derivatives (analgesics, antitussives, and substitution treatments), neuroleptics, barbiturates, benzodiazepines, anxiolytics other than benzodiazepines (e.g., meprobamate), hypnotics, sedative antidepressants (amitriptyline, doxepin, mianserin, mirtazapine, trimipramine), sedative H1 antihistamines, central antihypertensives, baclofen, and thalidomide.

Contraindicated Associations

Dopaminergic agents, except Parkinson's (cabergoline, quinagolide): Reciprocal antagonism between dopaminergic agonists and neuroleptics.

Discouraged Associations

Other sedative medications: Potentiation of the sedative effect of H1 antihistamines.

Alcohol consumption: Alcohol increases the sedative effect of these substances. Impaired alertness can make driving and operating machinery dangerous.

Associations Requiring Caution

Gastrointestinal topicals, antacids, and charcoal: Decreased gastrointestinal absorption of phenothiazine neuroleptics. Take gastrointestinal topicals and antacids at least 2 hours apart from phenothiazine neuroleptics, if possible.

Associations to Consider

Antihypertensives: Increased risk of hypotension, particularly orthostatic.

Beta-blockers (except esmolol and sotalol): Vasodilatory effect and risks of hypotension, particularly orthostatic (additive effect).

Beta-blockers in heart failure (bisoprolol, carvedilol, metoprolol, nebivolol): Vasodilatory effect and risks of hypotension, particularly orthostatic (additive effect).

Nitrate derivatives and related compounds: Increased risk of hypotension, particularly orthostatic.

ADVERSE EFFECTS

The pharmacological characteristics of the oxomemazine molecule are responsible for adverse effects of varying intensity, which may or may not be dose-related:

Neurovegetative effects:

• Sedation or drowsiness, more pronounced at the beginning of treatment.
• Anticholinergic effects such as dry mucous membranes, constipation, accommodation disorders, mydriasis, heart palpitations, risk of urinary retention.
• Orthostatic hypotension.
• Balance disorders, dizziness, reduced memory or concentration (more common in the elderly).
• Motor incoordination, tremors.
• Mental confusion, hallucinations.
• Less commonly, excitatory effects: agitation, nervousness, insomnia.

Psychiatric disorders:

• Drug abuse/dependence (frequency unknown).

Sensitivity reactions:

•Erythema, eczema, itching, purpura, possibly giant urticaria.
• Edema, more rarely angioedema.
• Anaphylactic shock.
• Photosensitivity.

Hematological disorders:

• Leukopenia, neutropenia, rare agranulocytosis.
• Thrombocytopenia.
• Hemolytic anemia.

DOSAGE AND ADMINISTRATION

For adults and children over 2 years old.
Oral route.
Use the measuring cup.

For adults and children over 40 kg (around 12 years old): 10 ml per dose, 4 times a day.

For children: the daily dosage depends on the child's weight (1 ml of oral solution per kg of body weight per day), as a guideline:

• Children weighing 13 to 20 kg (around 2 to 6 years old): 5 ml per dose, 2 to 3 times a day.
• Children weighing 20 to 30 kg (around 6 to 10 years old): 10 ml per dose, 2 to 3 times a day.
• Children weighing 30 to 40 kg (around 10 to 12 years old): 10 ml per dose, 3 to 4 times a day.

Doses should be repeated as needed, with a minimum interval of 4 hours. Evening doses are preferable due to the sedative effect of oxomemazine, especially at the beginning of treatment.

OVERDOSAGE

Signs of oxomemazine overdose: seizures (especially in children), altered consciousness, coma. Symptomatic treatment will be initiated in a specialized setting.

STORAGE CONDITIONS

Store below 30ºC.
Store in the original package in order to protect from light.
Store for a maximum of 6 months after first opening the bottle.
Keep out of the sight and reach of children.

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Marketing Authorization Holder
Benta S.A.L. - Lebanon

Manufacturer
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For **Benta S.A.L. – Lebanon**

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