ISMOTIC- Isosorbide solution
Alcon Laboratories, Inc.

---------

ISMOTIC®
(isosorbide solution)
45% w/v Solution

DESCRIPTION
ISMOTIC® is a 45% w/v solution of isosorbide in a vanilla-mint flavored vehicle. ISMOTIC is a caramel colored aqueous solution that is chemically stable at room temperature.

Each mL contains:
Isosorbide 45% w/v (Isosorbide Concentrate 60.6%), Alcohol 0.3% w/v, Caramel, Creme de Menthe, Malic Acid, Potassium Citrate, Potassium Sorbate, Saccharin Calcium, Sodium Citrate, Sorbitol Solution, Vanilla Concentrate Imitation #20, Potassium Hydroxide (to adjust pH), and Purified Water.

Typical analysis of electrolyte content:
4.6 meq. of Sodium/220 mL ISMOTIC Solution
0.9 meq. of Potassium/220 mL ISMOTIC Solution

Isosorbide, the osmotic agent in ISMOTIC, is a dihydric alcohol with the formula C₆H₁₀O₄ represented by the structure:

![Chemical structure of Isosorbide](image)

Established name:
Isosorbide
Chemical name:
1,4:3,6-dianhydro-D-glucitol
M.W. 146.14

CLINICAL PHARMACOLOGY
Isosorbide is rapidly absorbed after oral administration. It is essentially nonmetabolized, and in the circulation, it contributes to the tonicity of the blood until it is eliminated by the kidney unchanged. While in the blood, isosorbide acts as an osmotic agent to promote redistribution of water toward the circulation with ultimate elimination in the urine. The physical action of ISMOTIC is similar to that of other osmotic drugs.

INDICATIONS AND USAGE
For the short-term reduction of intraocular pressure. May be used prior to and after intraocular surgery. May be used to interrupt an acute attack of glaucoma.

CONTRAINDICATIONS
1. Well-established anuria
2. Severe dehydration
3. Frank or impending acute pulmonary edema
4. Severe cardiac decompensation
5. Hypersensitivity to any component of this preparation

**WARNINGS**
1. With repeated doses, consideration should be given to maintenance of adequate fluid and electrolyte balance.
2. If urinary output continues to decrease, the patient’s clinical status should be closely reviewed. Accumulation of ISMOTIC may result in overexpansion of the extracellular fluid.

**PRECAUTIONS**

**General**
For oral use only – not for injection. Repetitive doses should be used with caution particularly in patients with diseases associated with salt retention. Ensure that patient’s bladder has been emptied prior to surgery.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**
No studies have been conducted in animals or in humans to evaluate the potential of these effects.

**Pregnancy**

Pregnancy Category B
Reproduction (fertility and teratology) studies have been performed in rats at doses approximately 5 times the recommended initial human dose of 1.5 gm/kg body weight and have revealed no evidence of impaired fertility or harm to the fetus due to isosorbide. Teratology studies have been performed with rabbits and rats given daily oral doses of isosorbide at 6.5 and 10 times, respectively, the recommended initial human dose during organogenesis without evidence of harm to the fetus. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.

**Nursing Mothers**
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in breast milk, caution should be exercised when isosorbide is administered to a nursing mother.

**Pediatric Use**
Safety and effectiveness in pediatric patients have not been established.

**ADVERSE REACTIONS**
Nausea, vomiting, headache, confusion, and disorientation may occur. Occurrences of syncope, gastric discomfort, lethargy, vertigo, thirst, dizziness, hiccups, hypernatremia, hyperosmolarity, irritability, rash and light-headedness have been reported.

**DOSAGE AND ADMINISTRATION**
The recommended initial dose of isosorbide is 1.5 gm/kg body weight (equivalent to 1.5 mL /lb. of body weight). The onset of action is usually within 30 minutes while the maximum effect is expected at 1 to 1 1/2 hours. The useful dose range is 1 to 3 gm/kg body weight and the drug effect will persist up to 5 to 6 hours. Use two to four times a day as indicated. Palatability may be improved if the medication is
poured over cracked ice and sipped.

RECOMMENDED DOSAGES ARE:

<table>
<thead>
<tr>
<th>POUNDS</th>
<th>MILLILITERS</th>
<th>POUNDS</th>
<th>MILLILITERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>150</td>
<td>155</td>
<td>235</td>
</tr>
<tr>
<td>105</td>
<td>155</td>
<td>160</td>
<td>240</td>
</tr>
<tr>
<td>110</td>
<td>165</td>
<td>165</td>
<td>250</td>
</tr>
<tr>
<td>115</td>
<td>170</td>
<td>170</td>
<td>255</td>
</tr>
<tr>
<td>120</td>
<td>180</td>
<td>175</td>
<td>265</td>
</tr>
<tr>
<td>125</td>
<td>190</td>
<td>180</td>
<td>270</td>
</tr>
<tr>
<td>130</td>
<td>195</td>
<td>185</td>
<td>280</td>
</tr>
<tr>
<td>135</td>
<td>205</td>
<td>190</td>
<td>285</td>
</tr>
<tr>
<td>140</td>
<td>210</td>
<td>195</td>
<td>295</td>
</tr>
<tr>
<td>145</td>
<td>220</td>
<td>200</td>
<td>300</td>
</tr>
<tr>
<td>150</td>
<td>225</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HOW SUPPLIED
Disposable plastic bottles of 220 mL (100 gm of isosorbide/220 mL) for oral use only.

NDC 0065-0034-08
Storage: Store at 15°-30°C (59°-86°F).
CAUTION: Federal (USA) law prohibits dispensing without prescription.
Mfd. for: Alcon Laboratories, Inc.
Fort Worth, Texas 76134 USA
Mfd. by: ALCON (Puerto Rico) INC.
Humacao, Puerto Rico 00791 USA
July 1997 Printed in USA
249165-0797

ISMOTIC
isosorbide solution

<table>
<thead>
<tr>
<th>Product Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Type</strong></td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Active Ingredient/Active Moiety</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingredient Name</strong></td>
</tr>
<tr>
<td>isosorbide (UNII: WXR179L51S)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inactive Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingredient Name</strong></td>
</tr>
</tbody>
</table>


alcohol (UNII: 3K9958V90M)
caramel (UNII: T9D99G2B1R)
crème de menthe ()
malic acid (UNII: J3TZF807X5)
potassium citrate (UNII: EE90ON6FF)
potassium sorbate (UNII: 1VPU26JZZ4)
saccharin calcium (UNII: 5101OP7P2I)
sodium citrate (UNII: 1Q73Q2JULR)
sorbitol solution ()
vanilla concentrate imitation #20 ()
potassium hydroxide (UNII: WZH3C48M4T)
water (UNII: 059QF0KO0R)

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0065-0034-08</td>
<td>220 mL in 1 BOTTLE, PLASTIC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Labeler - Alcon Laboratories, Inc.

Revised: 3/2006