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.

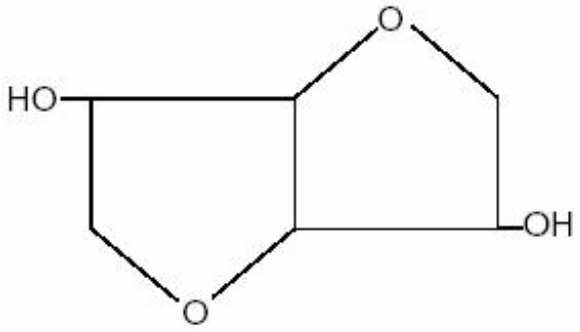
DM-00

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 $C_6H_{10}O_4$ represented by the structure:



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:

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

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

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ISMOTIC

isosorbide solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0034
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
isosorbide (UNII: WXR179L51S) (isosorbide - UNII:WXR179L51S)		450 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**

alcohol (UNII: 3K9958V90M)	
caramel (UNII: T9D99G2B1R)	
crème de menthe ()	
malic acid (UNII: J3TZF807X5)	
potassium citrate (UNII: EE90ONI6FF)	
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0034-08	220 mL in 1 BOTTLE, PLASTIC		

Labeler - Alcon Laboratories, Inc.

Revised: 3/2006 Alcon Laboratories, Inc.