

SALINE LAXATIVES

NOTE: In the case of applications for drugs which fit the criteria of this labelling standard, it is not necessary to conduct an assessment to determine if bioequivalence, pharmacodynamic/clinical studies or pharmaceutical equivalence data must be submitted.

Medicinal Ingredients

- Magnesium Citrate
- Magnesium Hydroxide
- Magnesium Sulfate
- Sodium Phosphate/Sodium Biphosphate as solution
- Sodium Phosphate
- Sodium Biphosphate

Saline Action: An agent that increases water in the intestine, thereby promoting bowel movement (osmotic effect).

Usual Claims:

- increases water in the intestine, thereby promoting bowel movement
- saline laxative
- to relieve occasional constipation

Warnings: As for all classes.

Directions:

1. Oral dosage produces bowel movement in 1/2 to 6 hours.
2. Rectal dosage produces action in 15 minutes.
3. Drink a full glass (250 ml or 8 ounces) of water or other liquid with each oral dose.

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

created:1985

revised:94-09-01

Dosage:**Children under 2 years - consult physician**

<u>Ingredients</u>	<u>Adult to 12 yrs.</u>	<u>Maximum</u>	<u>Children 6 to 12 yrs.</u>	<u>Children less than 6 yrs.</u>
Magnesium Citrate	11 to 25 g	single or divided dose	5.5 to 12.5 g	2.7 to 6.25 g
Magnesium Hydroxide	2.4 to 4.8 g	single or divided dose	1.2 to 2.4 g	0.4 to 1.2 g
Magnesium Sulfate	10 to 30 g	single or divided dose	5 to 10 g	2.5 to 5 g

RECTAL ENEMA
SOLUTION

Sodium Phosphate)	6.84 to 7.56g 18.24 to 20.16 g	single dose	3.42 to 3.78 g	3.42 to 3.78 g
Sodium Biphosphate)			9.12 to 10.02 g	9.12 to 10.02 g

ORAL SOLUTION

<u>Ingredients</u>	<u>Adult to 12 yrs.</u>	<u>Maximum</u>	<u>Children 10 to 12 yrs.</u>	<u>Children 5 to 10 yrs.</u>
Sodium Phosphate) Sodium)	3.42 to 7.56 g	single dose	1.71 to 3.78 g	0.86 to 1.89 g
Biphosphate)	9.10 to 20.2 g		4.5 to 10.1 g	2.2 to 5.05 g
Sodium Phosphate	3.42 to 7.56 g	single dose	1.71 to 3.78 g	0.86 to 1.89 g
Sodium Biphosphate	4.5 to 20 g	single dose	2.25 to 10.1 g	1.12 to 5.05 g
Disodium Phosphate (dried dibasic sodium phosphate)	1.944g-3.564g	single dose	0.950 - 1.9 g	0.475 - 0.950 g

Children under 5 years - consult physician

created:1985
revised:94-09-01