

PEDIA-LAX- magnesium hydroxide tablet, chewable
C.B. Fleet Company, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pedia-Lax Chewable Tablets 0132-0655-01

Pedia-Lax Chewable Tablets

Drug Facts

Active Ingredient

Magnesium hydroxide 400 mg

Purpose

Saline laxative

Uses

for relief of occasional constipation

this product usually produces bowel movement in 1/2 to 6 hours

Warnings

Ask a doctor before using any laxative if child has

kidney disease

a magnesium-restricted diet abdominal pain, nausea or vomiting

a sudden change in bowel habits lasting more than 2 weeks constipation

continues after 1 week of use, contact

your child's doctor already used a laxative for more than 1 week

Stop use and consult a doctor if your child has

rectal bleeding

no bowel movement within 6 hours of

using this product These symptoms may indicate a serious condition.

Keep out of reach of children to prevent accidental ingestion.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Use dosage chart for proper dosing. Doses may be taken as a single daily dose or in divided doses. Drink a full glass (8 ounces) of liquid with each dose.

Age	Starting dose	Starting Dose	Maximum dose per day (24 hours)
children 6 to under 12 years	3-6 tablets	6 tablets	
children 2 to under 6 years	1-3 tablets	3 tablets	
children under 2 years	ask a doctor		

Other information

each tablet contains : 170 mg of magnesium

CHILD RESISTANT CAP

The top of the bottle sealed for safety. Do not use if foil imprinted "SEALED for YOUR PROTECTION" is broken or missing.

Gluten Free and Sugar Free

Inactive ingredients

colloidal silicon dioxide, FD&C red #40 aluminum lake, flavor, magnesium stearate, maltodextrin, mannitol, sorbitol, stearic acid, sucralose

Questions?

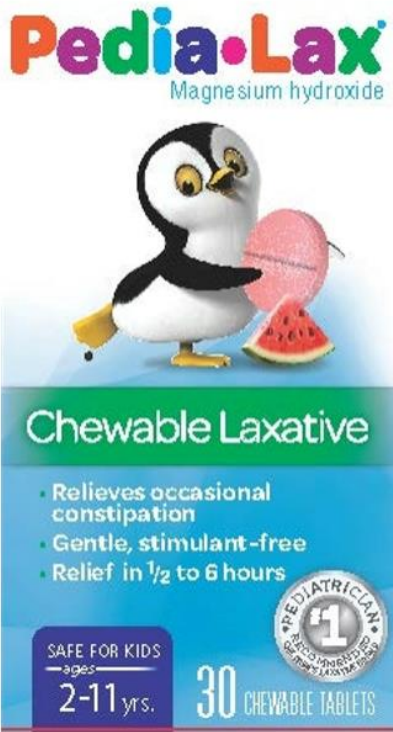
1-866-255-6960 or www.pedia-lax.com

PRINCIPAL DISPLAY PANEL

Pedia-Lax

Magnesium hydroxide

Chewable Laxative
30 chewable tablets



PEDIA-LAX

magnesium hydroxide tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0655
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	400 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OVM53L36A)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	14mm
Flavor	WATERMELON	Imprint Code	Pedia;Lax
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0655-01	1 in 1 CARTON	03/01/2008	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part334	03/01/2008	

Labeler - C.B. Fleet Company, Inc. (003119054)

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