

INTESTINOMICINA- loperamide hci, simethicone capsule
Procaps S.A. de C.V.

Intestinomicina AD+ (Deactivated)

Drug Facts

Active ingredients (in each caplet) & Purposes

Active ingredients (in each caplet)

Loperamide HCl 2 mg

Simethicone 125 mg

Purposes

Anti-diarrheal

Anti-gas

Uses

Relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas.

Warnings

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

Heart alert: Taking more than directed can cause serious heart problems or death

Do not use

- if you have bloody or black stool
- if you have difficulty swallowing

Ask a doctor before use if you have

- fever
- mucus in the stool
- a history of liver disease
- a history of abdominal heart rythm

Ask a doctor or pharmacist before use if you are

- taking a prescription drug. Loperamide interact with certain prescriptions drugs.

When using this product

tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

Stop use and ask a doctor if

- symptoms get worse
- diarrhea lasts for more than 2 days
- you get abdominal swelling or bulging. These may be signs of a serious condition.
- you have difficulty swallowing the caplet

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- take only on an empty stomach (1 hour before or 2 hours after a meal)
- take with a full (8 oz.) glass of water
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- **each caplet contains:** calcium 180 mg, sodium 3 mg
- store between 20 °-25 °C (68 °-77 °F). Protect from light.
- **do not use if printed blister unit is broken or torn**

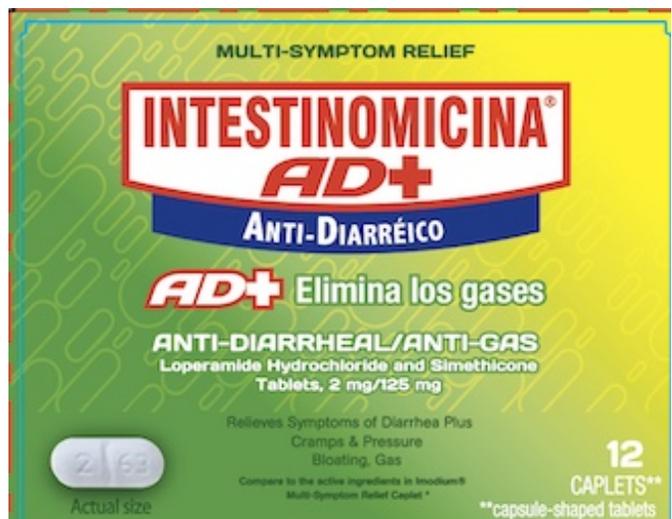
Inactive ingredients

acesulfame potassium, colloidol silicone dioxide, croscarmellose sodium, dibasic calcium phosphate, flavor, microcrystalline cellulose, stearic acid

Questions or comments?

call **1-754-260-6474** (Monday - Friday 8 am - 4 pm)

Package/Label Principal Display Panel



INTESTINOMICINA

loperamide hci, simethicone capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76864-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
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Shape	CAPSULE	Size	16mm
Flavor	CARAMEL ((Caramel Vanilla))	Imprint Code	2;63
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76864-100-12	12 in 1 CARTON	07/08/2022	11/30/2024
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214541	07/04/2018	11/30/2024

Labeler - Procaps S.A. de C.V. (851259341)

Revised: 1/2024

Procaps S.A. de C.V.