

ESTOMAROL- aluminum hydroxide, bismuth subcarbonate, calcium carbonate, magnesium carbonate, sodium bicarbonate powder

Laboratorios Imperiales, S.A. de C.V.

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.

Estomarol Antacid Powder

Drug Facts

Active Ingredients

In each pack

Aluminum Hydroxide 0.18g

Bismuth Subcarbonate 0.21g

Calcium Carbonate 0.25g

Magnesium Carbonate 0.59g

Sodium Bicarbonate 2.27g

Purpose

Antacid

Uses

- For the relief of heartburn, sour stomach, and acid indigestion

Directions

Add packet (3.5g) to a cup of water after each meal taken, maximum of 6 doses in 24 hours or as directed by a physician.

Other information

In each pack:

Calcium 95mg, Magnesium 145mg, and Sodium 605mg.

Inactive Ingredients

Colloidal silicon dioxide, glycerine anhydrous, peppermint oil

Warnings

- Ask a doctor or pharmacist before use if you are now taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product

- Do not take more than 6 doses in 24-hour period, or use more than 2 weeks, except under the advice and supervision of a physician.
- Do not use this product except under the advice and supervision of a physician if you have kidney disease or are on a sodium restricted diet.
- Do not take this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline.
- Do not use if you are pregnant or lactating.
- Use caution in patients who are taking anticoagulants or who are diabetic.

- Do not administer to adolescents who have or have recently had chicken pox
- This medication can cause constipation and in large doses can cause diarrhea, dark urine and dark bowel movements.
- Do not give to children under 6

Keep out of reach of children.

Estomarov

Antacid Powder

LIMSA

15-0.12 oz packets (3.5g) - Net Wt. 1.9 oz (52.5 g)

Drug Facts/ Información del Medicamento	
Active Ingredients/ Ingredientes Activos <i>In each pack / En cada empaque</i>	Purpose / Propósito
Aluminum Hydroxide / Hidróxido de Aluminio gel seco 0.18g.....) Bismuth Subcarbonate / Subcarbonato de Bismuto 0.21g) Calcium Carbonate / Carbonato de Calcio 0.25g.....) Magnesium Carbonate / Carbonato de Magnesio 0.59g.....) Sodium Bicarbonate / Bicarbonato de Sodio 2.27g.....)Antacid
Uses / Uso	
■ For the relief of heartburn, sour stomach, and acid indigestion / Para el alivio de reflujo, acidez estomacal, y indigestión ácida.	
Directions / Instrucciones	
Add packet (3.5g) to a cup of water after each meal taken, maximum of 6 doses in 24 hours or as directed by physician. / Mezclar un paquete (3.5g) con un vaso de agua tres veces al día después de comer. No usar mas de 6 dosis dentro de 24 horas, o como le aconseje su médico.	
Other information/Otra información	
■ In each pack/en cada empaque: Calcium/Calcio 95mg, Magnesium/Magnesio 145mg, and Sodium/Sodio 605mg.	
Inactive Ingredients/Ingredientes Inactivos Colloidal silicon dioxide, glycerine anhydrous, peppermint oil/Dióxido de silicio coloidal, glicerina anhidra, aceite esencial de menta piperita.	

Antacid Powder Antiácido en polvo
LIMSA

Estomarov®

This Unit Not labeled For Retail Sale. This label does not contain complete drug facts information. For complete information, please see outer carton. / esta unidad no es para la venta individual. Esta etiqueta no contiene toda la información sobre el producto. Para mayor información por favor referirse a la caja.

**NetWeight 0.12oz(3.5g)/
Contenido Neto 0.12 Onzas**

15 Paquetes de 0.12 onzas. Contenido Neto 1.9 Onzas(52.5 g)
15 - 0.12 oz packets (3.5g) - Net Wt. 1.9 oz (52.5 g)

Antacid Powder Antiácido en polvo
LIMSA

Estomarov®



Estomarovol®

Antacid Powder Antiácido en polvo
LIMSA

15 – 0.12 oz packets (3.5 g) – Net Wt. 1.9 oz (52.5 g)

15 Paquetes de 0.12 onzas. Contenido Neto 1.9 Onzas (52.5 g)

Drug Facts/ Información del Medicamento

Continued /Suite

interact with certain prescription drugs. / Algunos antiácidos, pueden interactuar con ciertas prescripciones medicas, o ciertos medicamentos.

■ **When using this product / Al usar este producto** ■ Do not take more than 6 doses in a 24-hour period, or use more than 2 weeks, except under the device and supervision of a physician. /No tome mas de 6 dosis en un período de 24 horas, o use por mas de 2 semanas, excepto bajo la autorización y supervisión de un médico.

■ Do not use this product except under the advice and supervision of a physician if you have kidney disease or are on a sodium restricted diet. / No use este producto sin advertencia y supervisión de un médico si tiene alguna enfermedad del riñón o esta bajo una dieta restringida en sodio. ■ Do not take this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline. /No tome este producto si esta tomando actualmente un medicamento de prescripción con antibiótico conteniendo cualquier forma de tetraciclina. ■ Do not use if you are pregnant or lactating. / No use si se encuentra embarazada o en lactancia. ■ Use caution in patients who are taking anticoagulants or who are diabetic /Cuidado en pacientes que estén tomando anticoagulantes o si es diabético. ■ Do not administer to adolescents who have or have recently had chicken pox / No administrarlo en adolescentes con o que recientemente hayan tenido varicela. ■ This medication can cause constipation and in large doses can cause diarrhea, dark urine and dark bowel movements./ Este medicamento puede provocar estreñimiento y en grandes dosis causar diarrea, puede oscurecer temporalmente la orina y evacuaciones. ■ Do not give to

Drug Facts/ Información del Medicamento

Continued /Suite

children under 6. / no se administre en niños menores de 6 años.

■ **Keep out of reach of children. /Mantener fuera del alcance de los niños**

Directions/Instrucciones

Add packet (3.5g) to a cup of water after each meal taken, maximum of 6 doses in 24 hours or as directed by a physician. / Mezclar un paquete (3,5g) con un vaso de agua tres veces al día despues de comer. No usar mas de 6 dosis dentro de 24 horas, o como le aconseje su médico.

Other information/ Otra información

■ In each pack/en cada empaque: Calcium/Calcio 95 mg, Magnesium/Magnesio 145mg, and Sodium/Sodio 605 mg.

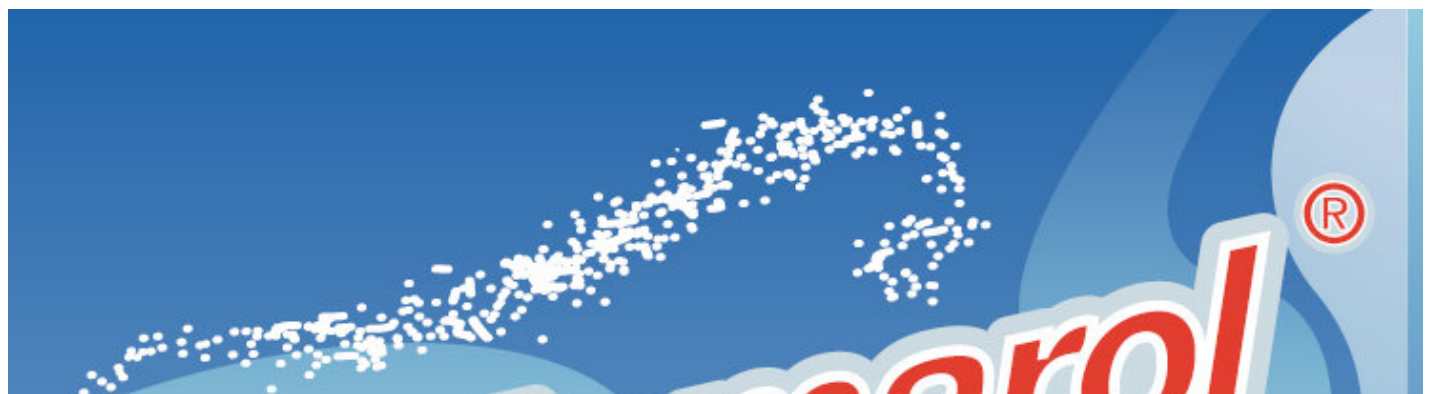
Inactive Ingredients/ Ingredientes Inactivos

Colloidal silicon dioxide, glycerine anhydrous, perppermint oil/ Dióxido de silicio coloidal, glicerina anhidra, aceite esencial de menta piperita.

Manufactured for/ Fabricado por:

Laboratorios Imperiales, S.A. de C.V. Calle 13 Este, No. 606, CIVAC, C.P. 62500 Jiutepec, Edo. de Morelos.

Made in Mexico/ Hecho en Mexico:



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Antacid Powder Antiácido en polvo
LIMSA

15 – 0.12 oz packets (3.5 g) – Net Wt. 1.9 oz (52.5 g)/
15 Paquetes de 0.12 onzas. Contenido Neto 1.9 Onzas (52.5 g)



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Lot/ Lote:

Expiration/ Caducidad:

Public Maximum Rate/ Precio máximo al público:

To report a serious adverse event/ Para reportar un grave efecto adverso:

Drug Facts/ Información del Medicamento

Active Ingredients/ Ingredientes Activos	Purpose/ Propósito
In each pack/ En cada empaque	
Aluminum Hydroxide/ Hidroxido de Aluminio gel seco 0.18g.....	}Antacid
Bismuth Subcarbonate / Subcarbonato de Bismuto 0.21g.....	
Calcium Carbonate/ Carbonato de Calcio 0.25g.....	
Magnesium Carbonate/ Carbonato de Magnesio 0.59g.....	
Sodium Bicarbonate/ Bicarbonato de Sodio 2.270g.....	

Uses/Usos

■ For the relief of heartburn, sour stomach, and acid indigestion / Para el alivio de reflujo, acidez estomacal, y indigestión ácida.

Warnings

■ Ask a doctor or pharmacist before use if you are now taking a prescription drug. Antiacids may

ESTOMAROL

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57465-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	0.18 g in 3.5 g
BISMUTH SUBCARBONATE (UNII: M41L2IN55T) (BISMUTH CATION - UNII:ZS9CD1H8YE)	BISMUTH SUBCARBONATE	0.21 g in 3.5 g
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	0.25 g in 3.5 g
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	0.59 g in 3.5 g
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	2.27 g in 3.5 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57465-100-00	15 in 1 BOX	05/11/2011	
1		3.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	05/11/2011	

Labeler - Laboratorios Imperiales, S.A. de C.V. (812643138)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Imperiales, S.A. de C.V.		812643138	manufacture(57465-100)

Revised: 12/2019

Laboratorios Imperiales, S.A. de C.V.