

BICARUVAS- antacid powder, for solution
PROSANA DISTRIBUCIONES, 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.

Bicaruvus Double Action Antacid

Bicaruvus

Double Action

BICARUVAS

.Sodium Bicarbonate

.Calcium Carbonate

Antiacid

Effervescent Powder

8 packets .17 oz (5g) ea.



Directions

.Adult and children 12 years older dissolve one packet in 1/2 glass of water every 4 hours or as directed by your doctor.

Children under 12 years, consult a doctor

Drug Facts		Drug Facts (continued)		
Active ingredients (in each packet)	Purposes	If pregnant or breast-feeding, ask a health professional before use		
Sodium Bicarbonate 2.452 g Citric Acid 1.927 g Tartaric Acid 0.220 g Calcium Carbonate 0.050 g	Antacid Antacid Antacid Antacid	Keep out of reach of children		
Uses for the relief of: • Heartburn • Sour stomach • acid indigestion • upset stomach associated with these symptoms		Ask a doctor or pharmacist before use if you are • presently taking a prescription drug (antacid may interact with certain prescription drugs) • presently on a sodium restricted diet		
Warnings • Do not exceed more than 5 packets in 24 hours period • Do not exceed more than 3 packets in 24 hours if you are 60 years and older • the maximum dosage of this product for more than 2 weeks except under the advice and supervision of a physician.		In case of overdose , get medical help or contact a Poison Control Center right away.		
Made in Mexico by PROSANA DISTRIBUCIONES, S.A. DE C.V. Oriente 225, No. 97, Col. Agrícola Oriental C.P. 08500 Del. Iztacalco, México, D.F.		Distributed in USA by: San Francisco, CA 94538 Ph (510) 868 8074 (415) 839 9581 (510) 402 4921		
		Directions • adults and children under 12 years older dissolve one packet in ½ glass of water every 4 hours or as directed by your doctor • children under 12 years: consult a doctor		
		Other information • each packet contains: 671 mg of sodium • each packet contains: 20 mg of calcium • store in a cool, dry place		
		Inactive ingredients • grape flavor • stevia • polyethylene glycol 4000		
				NOT FOR INDIVIDUAL SALE

Principal Display
 Please see box.jpg









Información del Medicamento (por sobre)		Información del Medicamento (continuación)	
Ingredientes activos	Función	Consulte a su médico o farmacéutico antes de usarlo si usted está:	
Bicarbonato de Sodio 2.452 g Ácido Cítrico 1.927 g Ácido Tartárico 0.220 g Carbonato de Calcio 0.050 g	Antiácido Antiácido Antiácido Antiácido	• tomando algún medicamento de prescripción (especialmente antibióticos) • tomando algún medicamento para el corazón • tomando algún medicamento para la diabetes • tomando algún medicamento para la hipertensión arterial • tomando algún medicamento para la epilepsia • tomando algún medicamento para la osteoporosis • tomando algún medicamento para la anemia • tomando algún medicamento para la enfermedad de Parkinson • tomando algún medicamento para la enfermedad de Alzheimer • tomando algún medicamento para la enfermedad de Huntington • tomando algún medicamento para la enfermedad de Tay-Sachs • tomando algún medicamento para la enfermedad de Gaucher • tomando algún medicamento para la enfermedad de Fabry • tomando algún medicamento para la enfermedad de Hunter • tomando algún medicamento para la enfermedad de Hurler • tomando algún medicamento para la enfermedad de Hunter • tomando algún medicamento para la enfermedad de Hunter	
Usos	• aliviar • reducir • mejorar	Instrucciones	
• aliviar la acidez • mejorar la digestión • mejorar el sabor de los alimentos		• No tome más de 5 sobres en un período de 24 horas • No tome más de 3 sobres en 24 horas si usted tiene problemas de salud • No tome más de 3 sobres si usted tiene problemas de salud • No tome más de 3 sobres si usted tiene problemas de salud • No tome más de 3 sobres si usted tiene problemas de salud	
Advertencias		Otra información	
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Ingredientes inactivos		Ingredientes inactivos	
• sabor • color • polifenólicos 4000		• sabor • color • polifenólicos 4000	

Drug Facts (in each packet)	Purposes	Drug Facts (continued)
Active ingredients Sodium Bicarbonate 2.452 g Citric Acid 1.927 g Tartaric Acid 0.220 g Calcium Carbonate 0.050 g	Antiacid Antiacid Antiacid Antiacid	If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Ask a doctor or pharmacist before use if you are • presently taking a prescription drug (antacid may interact with certain prescription drugs) • presently on a sodium restricted diet In case of overdose , get medical help or contact a Poison Control Center right away. Directions • adults and children under 12 years older dissolve one packet in 1/2 glass of water every 4 hours or as directed by your doctor • children under 12 years: consult a doctor Other information • each packet contains: 671 mg of sodium • each packet contains: 20 mg of calcium • store in a cool, dry place Inactive ingredients • grape flavor • stevia • polyethylene glycol 4000
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Made in Mexico by: PROSAR DISTRIBUCIONES, S.A. DE C.V. Oleone 202, No. 97, Caj Agrícola Oriental, CP 06500 Del. Guevarra, México, D.F.	Distributed in USA by: San Francisco, CA 94538 PO BOX 888, BOSTON MA 02111 (617) 552-9321 (617) 552-9321	NOT FOR INDIVIDUAL SALE




- Active ingredients**
- Active Ingredients (in each packet) Purpose
- Sodium Bicarbonate 2.452g antacid
- Citric Acid 1.927 g antiacid
- Tartaric Acid 0.220g antiacid
- Calcium Carbonate .05 g antiacid

Drug Facts		Drug Facts (continued)	
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PROSANA DISTRIBUCIONES, S.A. DE C.V. Oriente 225, No. 97, Col. Agrícola Oriental C.P. 08500 Del. Iztacalco, México, D.F.	Distributed in USA by:  OPMX	<ul style="list-style-type: none"> • grape flavor • stevia • polyethylene glycol 4000 	
		    	
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Uses

Uses for the relief of:

Heartburn . Sour stomach . upset stomach associated with these symptoms


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Warnings

Warnings Do not exceed more than 5 packets in a 24 hour period







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Pregnant

If pregnant or breast feeding, ask a health professional before use

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Overdose

In case of Overdose get medical help or contact a Poison Control Center right away.

Inactive



Inactive Ingredients
grape flavor. stevia. polyethylene glycol 4000

Other Information

Other Information
each packet contains 671 mg of sodium
each packet contains 20 mg of calcium
store in a dry cool place

children

Keep out of reach of children

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BICARUVAS

antacid powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69728-0001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TARTARIC ACID (UNII: W48881119H) (TARTARIC ACID - UNII:W48881119H)	TARTARIC ACID	2 g in 944 mL
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	1 g in 944 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	15 g in 944 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:L4R4M0NH37)	SODIUM BICARBONATE	19 g in 944 mL

Inactive Ingredients

Ingredient Name	Strength
GRAPE (UNII: 6X543N684K)	1 g in 944 mL
STEVIA LEAF (UNII: 6TC6NN0876)	1 g in 944 mL

POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)

1 g in 944 mL

Product Characteristics

Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69728-0001-2	8 in 1 BOX	05/18/2015	
1	NDC:69728-0001-1	944 mL 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	04/23/2013	

Labeler - PROSANA DISTRIBUCIONES, S.A. DE C.V. (816197867)**Establishment**

Name	Address	ID/FEI	Business Operations
PROSANA DISTRIBUCIONES S.A. DE C.V.		816197867	manufacture(69728-0001)

Revised: 6/2015

PROSANA DISTRIBUCIONES, S.A. DE C.V.