

**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.*

**Bicaruvás Double Action Antacid 60 pack**

**Active ingredients**



Active Ingredients (in each packet) Purpose

Sodium Bicarbonate 2.452g antacid

Citric Acid 1.927 g antacid

Tartaric Acid 0.220g antacid



Calcium Carbonate .05 g antacid

<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th><i>Active ingredients (in each packet)</i></th> <th><i>Purposes</i></th> </tr> </thead> <tbody> <tr> <td>Sodium Bicarbonate 2.452 g</td> <td>Antacid</td> </tr> <tr> <td>Citric Acid 1.927 g</td> <td>Antacid</td> </tr> <tr> <td>Tartaric Acid 0.220 g</td> <td>Antacid</td> </tr> <tr> <td>Calcium Carbonate 0.050 g</td> <td>Antacid</td> </tr> </tbody> </table> <p><b>Uses</b> for the relief of:</p> <ul style="list-style-type: none"> <li>• Heartburn • Sour stomach • acid indigestion</li> <li>• upset stomach associated with these symptoms</li> </ul> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>• Do not exceed more than 5 packets in 24 hours period</li> <li>• 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.</li> </ul> <p><b>Made in Mexico by</b>          PROSANA DISTRIBUCIONES, S.A. DE C.V.          Oriente 225, No. 97,          Col. Agrícola Oriental C.P. 08500          Del. Iztacalco, México, D.F.</p> <p><b>Distributed in USA by:</b>            San Francisco, CA 94538          Ph (510) 868 8074          (415) 839 9581          (510) 402 4921</p>	<i>Active ingredients (in each packet)</i>	<i>Purposes</i>	Sodium Bicarbonate 2.452 g	Antacid	Citric Acid 1.927 g	Antacid	Tartaric Acid 0.220 g	Antacid	Calcium Carbonate 0.050 g	Antacid	<p><b>Drug Facts (continued)</b></p> <p>If pregnant or breast-feeding, ask a health professional before use</p> <p>Keep out of reach of children</p> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>• presently taking a prescription drug (antacid may interact with certain prescription drugs)</li> <li>• presently on a sodium restricted diet</li> </ul> <p><b>In case of overdose</b>, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• each packet contains: 671 mg of sodium</li> <li>• each packet contains: 20 mg of calcium</li> <li>• store in a cool, dry place</li> </ul> <p><b>Inactive ingredients</b></p> <ul style="list-style-type: none"> <li>• grape flavor • stevia • polyethylene glycol 4000</li> </ul>	 <p><b>NOT FOR INDIVIDUAL SALE</b></p>
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**Uses**

Uses for the relief of:

Heartburn . Sour stomach . upset stomach associated with these symptoms

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## Warnings

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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

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store in a dry cool place

### children

Keep out of reach of children

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**Bicaruvás Statement of identity**  
Please see front60.jpg

**Double Action**

BICARUVAS

.Sodium Bicarbonate

.Calcium Carbonate

**Antacid**

Effervescent Powder

60 packets .17 oz (5g) ea.

Double Action

# Bicaruvras<sup>®</sup>

## Antiacid Efervescent Powder

(Polvo Antiácido Efervescente)

- **Sodium Bicarbonate**  
(Bicarbonato de Sodio)

- **Calcium Carbonate**  
(Carbonato de Calcio)

GRAPE  
FLAVOR



SABOR UVA

**Para la Acidez  
Estomacal y  
las Agruras  
Toma Bicaruvras**

**60**  
packets  
0.17 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

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
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**Principal Display**  
Please see box.jpg



**BICARUVAS**

**DOUBLE ACTION**

**Bicaruvas**

**Sodium Bicarbonate**

**Calcium Carbonate**

**Antacid**

**Efferescent powder**

**60 packets 0.17 oz (5g) ea**

**BICARUVAS**

antacid powder, for solution

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:69728-0003



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:LYR4M0NH37)	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:69728-0003-2	60 in 1 BOX	06/13/2016	
1	NDC:69728-0003-1	7080 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(69728-0003)