

**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.*

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**Bicaruvas Double Action Antacid**

**Bicaruvas**

**Double Action**

BICARUVAS

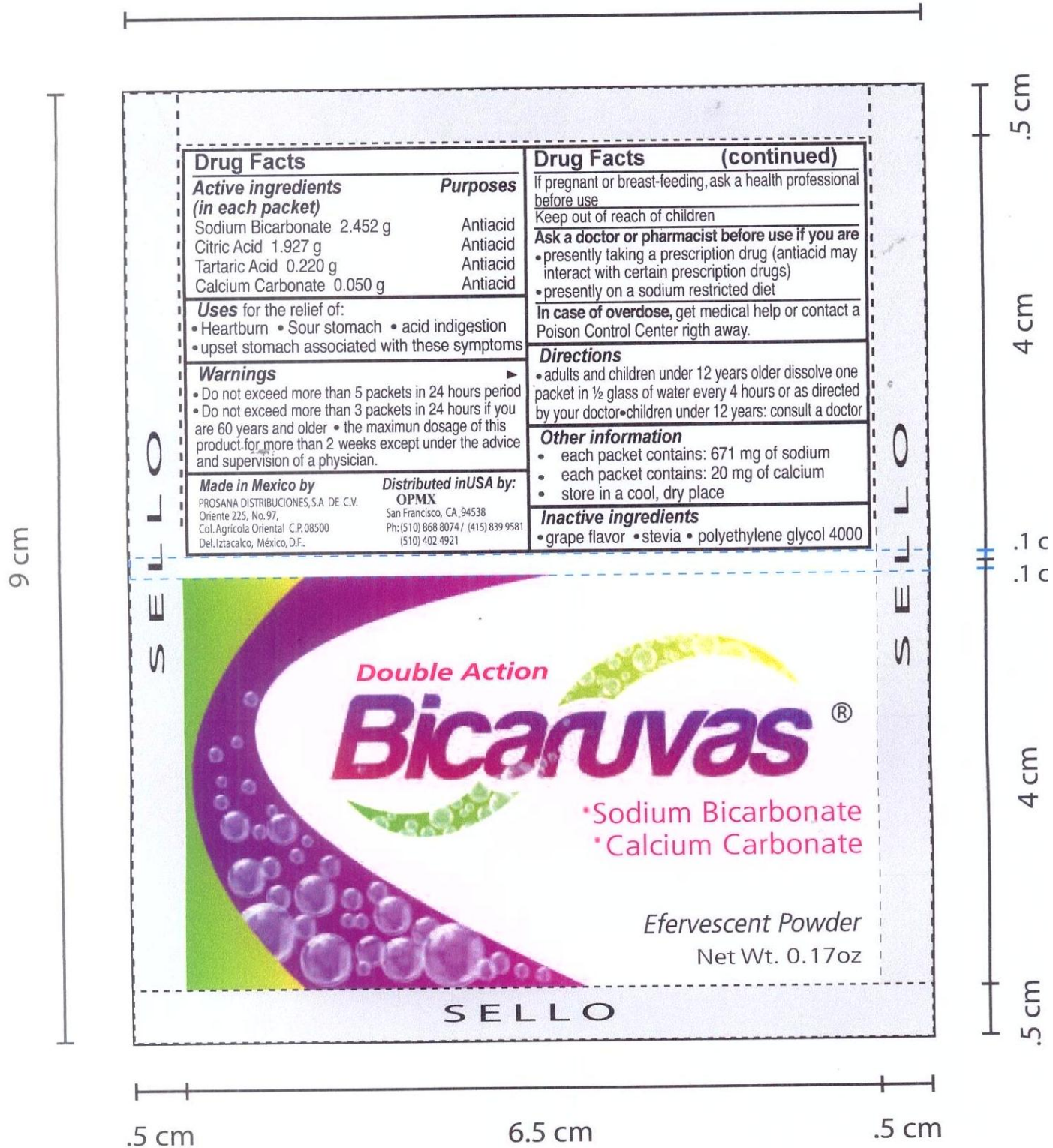
.Sodium Bicarbonate

.Calcium Carbonate

**Antacid**

Effervescent Powder

8 packets .17 oz (5g) ea.

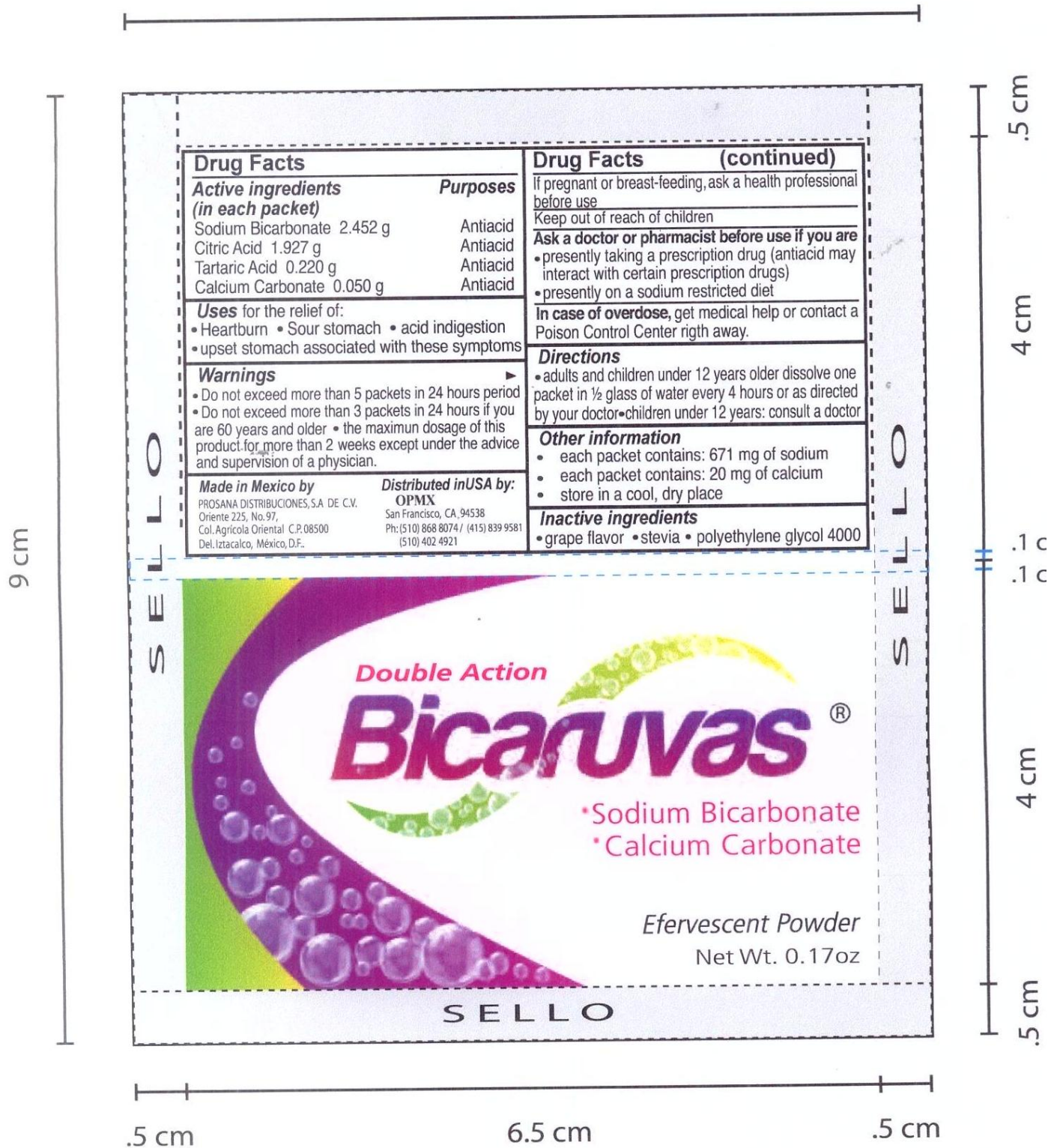


**Directions**

•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

**Principal Display**  
**Please see box.jpg**



**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

## Uses

Uses for the relief of:

Heartburn . Sour stomach . upset stomach associated with these symptoms

## Warnings

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

Do not exceed more than 3 packets in 24 hours if you are 60 years or older

the maximum dosage for more than two weeks except under the advise and supervision of a physician

## Pregnant

If pregnant or breat feeding, ask a helth professional before use

## 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

<b>BICARUVAS</b>			
antacid powder, for solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69728-0002
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	TARTARIC ACID (UNII: W48881119H) (TARTARIC ACID - UNII:W48881119H)	TARTARIC ACID	220 mg in 118 mL
	CALCIUM CARBONATE (UNII: H9C9379ECK) (CALCIUM CARBONATE - UNII:H9C9379ECK)	CALCIUM CARBONATE	50 mg

CALCIUM CARBONATE (UNII: 10G9975FGR) (CALCIUM CATION - UNII:2MB3C4R9ZB)	CALCIUM CATION	in 118 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1827 mg in 118 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	2452 mg in 118 mL

### Inactive Ingredients

Ingredient Name	Strength
GRAPE (UNII: 6X543N684K)	150 mg in 118 mL
STEVIA LEAF (UNII: 6TC6NN0876)	50 mg in 118 mL
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	150 mg in 118 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:69728-0002-1	118 mL in 1 PACKET; Type 0: Not a Combination Product	09/20/2015	

### 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(69728-0002)

Revised: 9/2015

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