

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
20-555/S-003/S-004

FINAL PRINTED LABELING

Revised Label with Changes Requested by FDA on March 31, 1998 (S-003 & S-004)
Carton

AXID AR



APPROVED

APR 1 1998

- AXID AR relieves and prevents heartburn, acid indigestion and sour stomach.
- AXID AR contains an ingredient that doctors have prescribed for years.

ACTIVE INGREDIENT:

- Nizatidine 75 mg per tablet.

USES:

- For Relief of heartburn, acid indigestion and sour stomach.
- For Prevention of these symptoms brought on by consuming food and beverages.

DIRECTIONS:

- For Relief of symptoms, take 1 tablet with a full glass of water.
- For Prevention of symptoms, take 1 tablet with a full glass of water right before eating or up to 60 minutes before consuming food and beverages that cause you heartburn.
- Can be used up to twice daily (up to 2 tablets in 24 hours).
- This product should not be given to children under 12 years old unless directed by a doctor.

WARNINGS:

- Do not take the maximum daily dosage for more than 2 weeks continuously unless directed by a doctor.
- If you have trouble swallowing, or persistent abdominal pain, see your doctor promptly. You may have a serious condition that may need different treatment.
- As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.
- Keep this and all drugs out of the reach of children.
- In case of accidental overdose, seek professional assistance or contact a poison control center immediately.



- Read the directions and warnings before use.
KEEP THE PRODUCT INFORMATION SHEET.
IT CONTAINS IMPORTANT INFORMATION.

INACTIVE INGREDIENTS: Colloidal Silicon Dioxide, Hydroxypropyl Methylcellulose, Synthetic Iron Oxides, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Propylene Glycol, Corn Starch, Titanium Dioxide.

IF YOU HAVE ANY QUESTIONS ABOUT AXID AR CALL 1-800-555-AXID

Store at 20°-25°C (68°-77°F).

Protect from light.

Replace cap tightly after opening bottle.

N2400-20/30

BEST POSSIBLE COPY

AMERICAN HOME 2+1/2 X 1+3/8 X 1+7/16 FACE # AH4

12 ct Carton

Relieves and Prevents:
Heartburn,
Acid Indigestion
& Sour Stomach.

**AXID
AR**

Nizatidine Tablets 75 mg
Acid Reducer

12 TABLETS (12 DOSES)

**AXID
AR**

Nizatidine Tablets 75 mg
Acid Reducer

12 TABLETS (12 DOSES)

LOT

EXPIRES

LEGAL TEXT DEFINED	TYPE SIZE
• DIRECTIONS	5.6 pt
• WARNINGS	5.6 pt
• INDICATIONS	5.6 pt
• ACTIVE & INACTIVE INGREDIENTS	5.6 pt
• DRUG INTERACTION PRECAUTIONS	N/A
• TAMPER RESISTANT STATEMENTS	N/A
• STATEMENT OF IDENTITY	4.5 pt



Revised Labels with Changes Requested by FDA on March 31, 1998 (S-003 & S-004)
Insert Side 1

APPROVED

PRODUCT INFORMATION SHEET
PLEASE SAVE THIS SHEET FOR FUTURE USE.

APR 1 1998

AXID[®] AR

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BEST POSSIBLE COPY

Tips for managing heartburn

- Avoid lying down flat or bending over soon after eating.
- Avoid eating late at night, or just before bedtime.
- Avoid certain foods or beverages more likely to cause heartburn such as spicy, fried foods, citrus fruits, coffee, alcohol, beer, wine, and vegetables.
- Eat slowly and drink water.
- If you are pregnant, talk to your doctor.
- If you smoke, stop smoking.
- Elevate the head of your bed.
- Avoid wearing tight fitting clothing around your stomach.

IF YOU HAVE ANY QUESTIONS ABOUT AXID AR CALL 1-800-555-AXID

STORE AT 20 -25 C (68 -77 F). PROTECT FROM LIGHT. U.S. Patent No. 4,375,547

Manufactured by: Whitehall-Robur, HealthCare, Madison, NJ 07940
Made In U.S.A. N2400-20/15

Bottles: Bottle sealed with printed foil under cap.
Do not use if foil is open or torn.

Packets: Each packet is individually sealed.
Do not use if seal is open or torn.



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BEST POSSIBLE COPY

- AXID AR is a non-prescription medicine that contains nizatidine an ingredient that doctors have prescribed for years
- AXID AR works by reducing the production of stomach acid that can cause heartburn.
- In clinical studies, AXID AR was significantly better than placebo in relieving and preventing heartburn symptoms.

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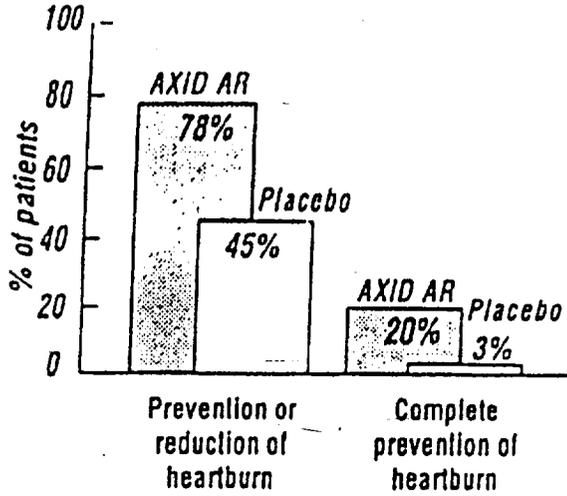
**Heartburn: a problem that can
interfere with your lifestyle.**

The stomach normally produces acid, especially following eating and drinking. Sometimes acid backing up into the esophagus can cause a burning pain and discomfort. This pain and discomfort is commonly known as heartburn.

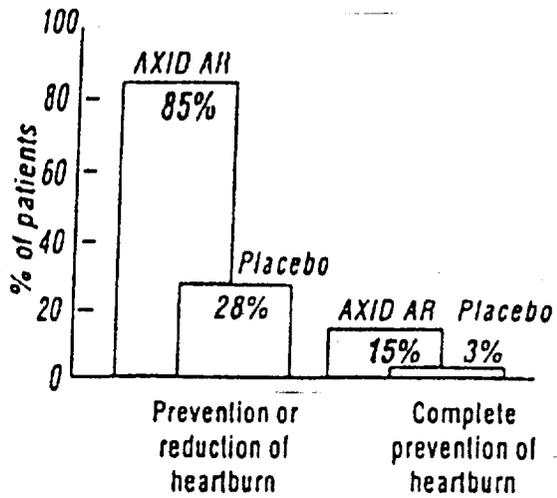
When taken as directed, AXID AR relieves and/or prevents heartburn.

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PREVENTION
Benefit of AXID AR Compared to Placebo
Study A
Pills taken 60 minutes before eating



PREVENTION
Benefit of AXID AR Compared to Placebo
Study B
Pills taken 30 minutes before eating

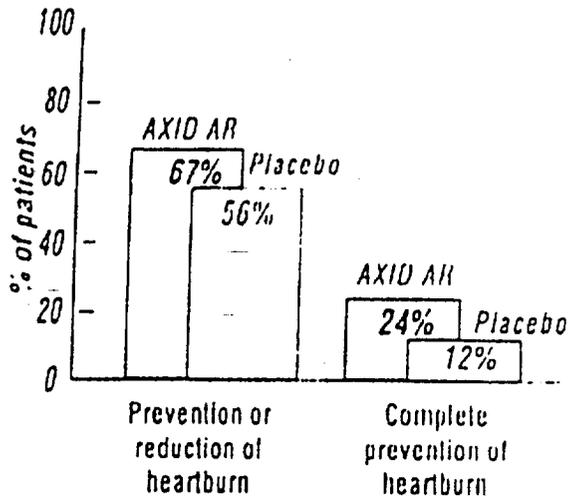


PREVENTION

Benefit of AXID AR Compared to Placebo

Study C

Pills taken immediately before eating

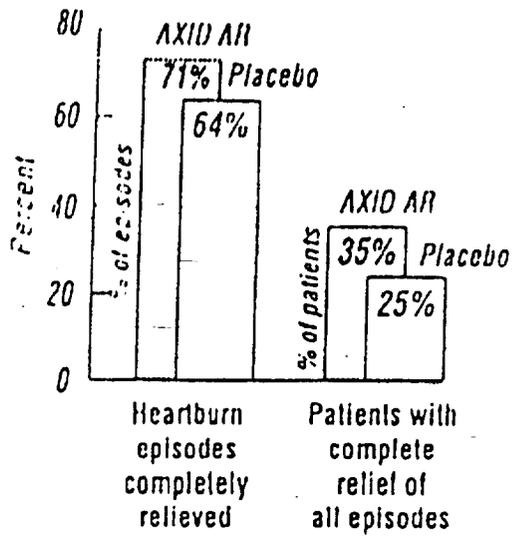


RELIEF

Benefit of AXID AR Compared to Placebo

Study D

Pills taken after symptoms occur.



APPEARS THIS WAY
ON ORIGINAL