Treats Frequent Heartburn

**Tablets**

First 2 doses of a 14-day course of treatment

May take 1 to 4 days for full effect

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Marketed by: Pfizer, Madison, NJ 07940 USA

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For most recent product information, visit www.Nexium24HR.com

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**Drug Facts**

**Active ingredient (in each tablet) Purpose**

Esomeprazole 20 mg ................................... Acid reducer

**Uses**

- Treats frequent heartburn (occurs 2 or more days a week)
- Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Warnings**

- Allergy alert:
  - Do not use if you are allergic to esomeprazole
  - Do not use if you have:
    - Trouble or pain swallowing food, vomiting with blood, or bloody or black stools
    - Heartburn with lightheadedness, sweating or dizziness
    - Chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
    - Frequent chest pain
  - These may be signs of a serious condition. See your doctor.

- Ask a doctor before use if you have
  - Had heartburn over 3 months. This may be a sign of a more serious condition.
  - Frequent wheezing, particularly with heartburn
  - Unexplained weight loss
  - Nausea or vomiting
  - Stomach pain

- Ask a doctor or pharmacist before use if you are
  - Taking warfarin, clopidogrel or cilostazol (blood-thinning medicines)
  - Prescription antifungal or anti-yeast medicines
  - Digoxin (heart medicine)
  - Diazepam (anxiety medicine)
  - Tacrolimus or mycophenolate mofetil (immune system medicines)
  - Prescription antiretrovirals (medicines for HIV infection)
  - Methotrexate (arthritis medicine)

- Stop use and ask a doctor if
  - Your heartburn continues or worsens
  - You need to take this product for more than 14 days
  - You need to take more than 1 course of treatment every 4 months
  - You get diarrhea
  - You develop a rash or joint pain
Tips for Managing Heartburn

• Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.

• Eat slowly and do not eat big meals.

• Do not eat late at night or just before bedtime.

• Do not lie flat or bend over soon after eating.

• Raise the head of your bed.

• Wear loose-fitting clothing around your stomach.

• If you are overweight, lose weight.

• If you smoke, quit smoking.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

I For adults 18 years of age and older
I This product is to be used once a day (every 24 hours), every day for 14 days
I May take 1 to 4 days for full effect
I 14-Day Course of Treatment
I Swallow 1 tablet with a glass of water before eating in the morning
I Take every day for 14 days
I Do not take more than 1 tablet a day
I Swallow whole. Do not crush or chew tablets.
I Do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)
I You may repeat a 14-day course every 4 months
I Do not take for more than 14 days or more often than every 4 months unless directed by a doctor

Other Information
I Read the directions and warnings before use
I Keep the carton. It contains important information.
I Store at 20-25°C (68-77°F)

Inactive ingredients
Corn starch, crospovidone, D&C red no. 27, D&C yellow no. 10, D&C green no. 3, D&C blue no. 1, FD&C yellow no. 5, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, paraffin, polysorbate 80, sucrose, titanium dioxide, triethyl citrate

Questions or comments? Call toll-free weekdays 9 AM to 5 PM at 1-866-226-1600

Reference ID: 4197212
Warning:

Do not use if you have:

Do not use if you are allergic to esomeprazole

Allergy alert:

Warnings

Uses

esomeprazole magnesium trihydrate) (Each delayed-release tablet corresponds to 22.3 mg Esomeprazole 20 mg......................................Acid reducer

Drug Facts

Ask a doctor or pharmacist before use if you are

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Directions

Keep out of reach of children.

In case of overdose, get

before use.

If pregnant or breast-feeding,

before use.

Managing Heartburn

Tips for

• If you smoke, quit smoking.

• If you are overweight, lose weight.

• Wear loose-fitting clothing around

• Raise the head of your bed.

• Avoid foods or drinks that are

• SPACE BETWEEN HAIRLINES AND BOX END

• BARLINES, HAIRLINES

• BULLETS

• SUBHEADINGS/BODY TEXT

• HEADINGS

• DRUG FACTS CONTINUED

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Keep the carton. It contains important information.

References: 4197212
**Warnings**

Do not use if you have:

- allergic to esomeprazole

Stop use and ask a doctor if:

- you develop a rash or joint pain
- you get diarrhea
- you need to take this product for more than 14 days
- your heartburn continues or worsens
- you are taking methotrexate (arthritis medicine)
- you are taking prescription antiretrovirals (medicines for HIV infection)
- you are taking tacrolimus or mycophenolate mofetil (immune system medicines)
- you are taking diazepam (anxiety medicine)
- you have heartburn with:
  - trouble or pain swallowing food
  - vomiting with blood
  - bloody or black stools

Other Information

- heartburn with:
  - unexplained weight loss
  - had heartburn over 3 months. This may be a sign of a more serious condition.

**Drug Facts**

- Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Uses**

(Each delayed-release tablet corresponds to 22.3 mg Esomeprazole 20 mg)

- Acid reducer

**Inactive ingredients**

triethyl citrate, polysorbate 80, sodium stearyl fumarate, sucrose, talc, titanium dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid aluuminum lake, FD&C red no. 40 aluminum lake, glyceryl monostearate, corn starch, crospovidone, D&C red no. 27 aluminum lake, FD&C blue no. 2

**Questions or comments?**

1-866-226-1600

**Managing Heartburn**

- Do not take more than 1 tablet a day
- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol
- If you smoke, quit smoking
- If you are overweight, lose weight
- Wear loose-fitting clothing around your stomach
- If possible, lie down with your head elevated for 2-3 hours after eating
- Take this medicine once a day (every 24 hours), every day for 14 days

**See new warning**

Due to concerns about heart attack, stroke, and heartburn associated with long-term use of NSAIDs, you should talk to your doctor about using other acid reducers like this one. Esomeprazole magnesium delayed-release tablets are indicated to treat frequent heartburn (occurs 2 or 3 days a week) and is a member of a class of drugs known as proton pump inhibitors.

See new warning

**Managing Heartburn**

- Do not smoke
- Avoid alcohol
- Lose weight
- Avoid spicy, rich and fried foods
- Avoid chocolate
- Lie down with head elevated for 2-3 hours after eating
- Take once a day, every day for 14 days

**Drug Facts continued**

- Esomeprazole magnesium delayed-release tablets (each tablet contains 22.3 mg esomeprazole magnesium)
- Tablet (Round)
- 42 tablets
- 8.0 pt

**Directions**

- In case of overdose, get medical help or contact a poison control center for treatment recommendations.

**Other Information**

- Keep out of reach of children.
- If pregnant or breast-feeding, ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

**Other Information**

- Keep the carton. It contains important information.

**Proper Storage**

- Store at room temperature

**Questions or comments?**

1-866-226-1600

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
12/18/2017