

ACID REDUCER- esomeprazole magnesium tablet, delayed release
CVS Pharmacy

Esomeprazole Magnesium Delayed-Release Capsules 20 mg - Actavis

Drug Facts

Active ingredient (in each tablet)

Esomeprazole 20 mg

(*Each delayed-release tablet corresponds to 22.25 mg esomeprazole magnesium, USP trihydrate)

Purpose

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.
- Esomeprazole may cause severe skin reactions. Symptoms may include:
 - skin reddening
 - blisters
 - rash

If an allergic reaction occurs, stop use and seek medical help right away.

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

- taking a prescription drug. Acid reducers may interact with certain prescription drugs.

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

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 (1-800-222-1222) right away.

Directions

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- may take 1 to 4 days for full effect

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4**

months unless directed by a doctor

- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

black iron oxide, colloidal silicon dioxide, croscopovidone, hydroxypropyl cellulose, hypromellose, low substituted hydroxypropyl cellulose, magnesium stearate, methacrylic acid - ethyl acrylate copolymer dispersion, microcrystalline cellulose, mono- and di-glycerides, polyethylene glycol, polysorbate 80, propylene glycol, red iron oxide, shellac glaze, sodium lauryl sulfate, sodium stearyl fumarate, sugar spheres (corn starch and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in Nexium® 24R†

Treats Frequent Heartburn

May take 1 to 4 days for full effect

Esomeprazole Magnesium

DELAYED-RELEASE TABLETS 20 mg*

Acid reducer

See new warning information

TABLET

One 14-day course of treatment

**This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Nexium® 24HR.

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP BROKEN OR MISSING.

KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Package label

Drug Facts

Active ingredient (in each tablet)
Esomeprazole 20 mg
*Each delayed-release tablet corresponds to 22.25 mg esomeprazole magnesium, USP (bifidate)

Purpose
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.
Esomeprazole may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash
If an allergic reaction occurs, stop use and seek medical help right away.

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 vomiting, particularly with heartburn
unexplained weight loss
nausea or vomiting
stomach pain

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

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

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 (1-800-222-1222) right away.

Directions
adults 18 years of age and older
this product is to be used once a day (every 24 hours), every day for 14 days
may take 1 to 4 days for full effect
14-Day Course of Treatment
swallow 1 tablet with a glass of water before eating in the morning
take every day for 14 days
do not take more than 1 tablet a day
swallow whole. Do not crush or chew tablets.
do not use for more than 14 days unless directed by your doctor
Repeated 14-Day Courses (if needed)
you may repeat a 14-day course every 4 months
do not take for more than 14 days or more often than every 4 months unless directed by a doctor
children under 18 years of age: ask a doctor before use.
Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information
read the directions and warnings before use
keep the carton. It contains important information.
store at 20° to 25°C (68° to 77°F)

Inactive ingredients black iron oxide, colloidal silicon dioxide, croscarmellose, hydroxypropyl cellulose, hypromellose, low substituted hydroxypropyl cellulose, magnesium stearate, methacrylic acid - ethyl acrylate copolymer dispersion, microcrystalline cellulose, mono- and di-glycerols, polyethylene glycol, polyacrylate 60, polyethylene glycol, red iron oxide, shellac, sodium lauryl sulfate, sodium stearoyl fumarate, sugar spheres (corn starch and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide

Questions or comments?
Call 1-877-753-3939 Monday-Friday 9AM-5PM EST

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP IS BROKEN OR MISSING.

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

***This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Nexium® 24HR.

Compare to the active ingredient in Nexium® 24HR™
NDC 69842-679-14

Treats Frequent Heartburn
May take 1 to 4 days for full effect

Esomeprazole Magnesium

DELAYED-RELEASE TABLETS 20 mg*

Acid reducer

See new warning information

14 TABLETS
(1 bottle inside)
One 14-day course of treatment

Actual Size

Treats Frequent Heartburn
May take 1 to 4 days for full effect

Esomeprazole Magnesium

DELAYED-RELEASE TABLETS 20 mg*

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.

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CVS HEALTH Acid Reducer

ACID REDUCER

esomeprazole magnesium tablet, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-679 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| ESOMEPRAZOLE MAGNESIUM (UNII: R6DXU4WAY9) (ESOMEPRAZOLE - UNII:N3PA6559FT) | ESOMEPRAZOLE | 20 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98R082HJ) | |
| MAGNESIUM STEARATE (UNII: 70097M6130) | |
| METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SUCROSE (UNII: C151H8M554) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TALC (UNII: 7SEV7J4R1U) | |

| | |
|--|--|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| CROSPROVIDONE (UNII: 2S7830E561) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SHELLAC (UNII: 46N107B71O) | |
| SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |

Product Characteristics

| | | | |
|-----------------|--------------|---------------------|----------|
| Color | white (pink) | Score | no score |
| Shape | CAPSULE | Size | 14mm |
| Flavor | | Imprint Code | EL |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69842-679-14 | 1 in 1 CARTON | 12/31/2021 | |
| 1 | | 14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 2 | NDC:69842-679-42 | 3 in 1 CARTON | 12/31/2021 | |
| 2 | | 14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA212088 | 12/31/2021 | |

Labeler - CVS Pharmacy (062312574)