

ABGRESS-40/80TM

Esomeprazole Gastro Resistant 40/80 mg
Capsules

Description

Esomeprazole is used to treat conditions where there is too much acid in the stomach. It is used to treat duodenal and gastric ulcers, erosive esophagitis, gastroesophageal reflux disease (GERD), and Zollinger-Ellison syndrome, a condition wherein the stomach produces too much acid. Esomeprazole is also used with antibiotics (eg, amoxicillin, clarithromycin) to treat ulcers that are caused by the H. pylori bacteria. This medicine is also used to prevent stomach ulcers and stomach irritation in patients taking NSAIDs (eg, aspirin, ibuprofen) for long periods of time.

Esomeprazole is a proton pump inhibitor (PPI). It works by decreasing the amount of acid that is produced by the stomach.

This medicine is available both over-the-counter (OTC) and with your doctor's prescription.

This product is available in the following dosage forms:

- *Capsule, Delayed Release*
- *Packet*
- *Tablet, Delayed Release*

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Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of esomeprazole for GERD in children. However, safety and efficacy have not been established for children younger than 1 month of age.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of esomeprazole in the elderly. However, elderly patients are more sensitive to the effects of this medicine than younger adults.

Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- **Rilpivirine**

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- ***Acalabrutinib***
- *Amphetamine*
- *Apalutamide*
- *Atazanavir*
- *Atezolizumab*
- *Belumosudil*
- *Belzutifan*
- *Benzphetamine*
- *Bosutinib*
- *Cannabidiol*
- *Capecitabine*
- *Carbamazepine*
- *Cefuroxime Axetil*
- *Cilostazol*
- *Citalopram*
- *Clopidogrel*
- *Dacomitinib*
- *Dasatinib*
- *Defactinib*
- *Dextroamphetamine*
- *Digoxin*
- *Erlotinib*
- *Escitalopram*
- *Eslicarbazepine Acetate*
- *Finerenone*
- *Gefitinib*

- *Haloperidol*
- *Infigratinib*
- *Ketoconazole*
- *Ledipasvir*
- *Lemborexant*
- *Levoketoconazole*
- *Lisdexamfetamine*
- *Lonafarnib*
- *Loperamide*
- *Mavacamten*
- *Methadone*
- *Methamphetamine*
- *Methotrexate*
- *Methylergonovine*

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Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- *Itraconazole*
- *Levothyroxine*
- *Risedronate*
- *Warfarin*

Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following may cause an increased risk of certain side effects but may be unavoidable in some cases. If used together, your doctor may change the dose or how often you use this medicine, or give you special instructions about the use of food, alcohol, or tobacco.

- **Cranberry**

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- **Diarrhea or**
- *Hypomagnesemia (low magnesium in the blood), history of or*
- *Osteoporosis (thinning of the bones) or*
- *Seizures, history of or*
- *Vitamin B12 deficiency—Use with caution. May make these conditions worse.*
- *Liver disease, severe—Use with caution. The effects may be increased because of slower removal of the medicine from the body.*

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Proper Use

Take this medicine exactly as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered.

This medicine comes with a Medication Guide and patient instructions. Read and follow the instructions carefully. Ask your doctor if you have any questions.

Take this medicine at least 1 hour before a meal and for the full time of treatment, even if you begin to feel better after a few days.

If you are taking this medicine to treat an ulcer caused by an *H. pylori* infection, take it together with the antibiotics (eg, amoxicillin, clarithromycin) at the same time of day.

To use the capsule:

- Swallow the capsule whole. Do not crush or chew it.

- *If the capsule cannot be swallowed, open it and sprinkle the contents on one tablespoonful of applesauce.*
- *Swallow the mixture right away. Do not chew or crush the granules.*

To use the capsule with a nasogastric (NG) tube:

- *Open the capsule and empty the granules into a 60 mL catheter-tipped syringe and mix it with 50 mL of water.*
- *Shake the syringe well for 15 seconds.*
- *Inject or pour the mixture into the nasogastric tube.*
- *Refill the syringe with a small amount of water and shake.*
- *Flush the tube to rinse all of the medicine into the stomach.*

To use the oral suspension:

- *Empty the contents of a 2.5 mg or 5 mg packet into a container with 5 mL of water.*
- *Empty the contents of a 10 mg, 20 mg, or 40 mg packet into a container with 15 mL of water.*
- *Stir and leave it for 2 to 3 minutes to thicken.*
- *Stir well and drink within 30 minutes.*
- *If any medicine remains after drinking, add more water, stir, and drink immediately.*

To use the oral suspension with a nasogastric or gastric tube:

- *Add 5 mL of water to a catheter-tipped syringe and add the contents of a 2.5 mg or 5 mg packet.*
- *Add 15 mL of water to a catheter-tipped syringe and add the contents of a 10 mg, 20 mg, or 40 mg packet.*
- *Shake the syringe right away and leave it for 2 to 3 minutes to thicken.*
- *Shake the syringe again and inject or pour the mixture into the tube within 30 minutes.*
- *Refill the syringe with 15 mL of water and shake.*
- *Flush the tube to rinse all of the medicine into the stomach.*

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- *For oral dosage forms (capsules or suspension):*
 - *To prevent NSAID-associated gastric ulcer:*
 - *Adults—20 or 40 milligrams (mg) once a day for up to 6 months. Your doctor may adjust your dose if as needed.*
 - *Children—Use and dose must be determined by your doctor.*
 - *To treat duodenal ulcers with H. pylori infection:*
 - *Adults—40 milligrams (mg) once a day for 10 days. The dose is usually taken together with amoxicillin and clarithromycin. Your doctor may adjust your dose as needed.*
 - *Children—Use and dose must be determined by your doctor.*
 - *To treat erosive esophagitis:*
 - *Adults—20 or 40 milligrams (mg) once a day for 4 to 8 weeks. Your doctor may adjust your dose as needed. To prevent erosive esophagitis from coming back, your doctor may want you to take 20 mg once a day for up to 6 months.*
 - *Children 12 to 17 years of age—20 or 40 milligrams (mg) once a day for 4 to 8 weeks. Your doctor may adjust your dose as needed.*
 - *Children 1 to 11 years of age and weighing 20 kilograms (kg) or more—10 or 20 mg once a day for 8 weeks. Your doctor may adjust your dose as needed.*
 - *Children 1 to 11 years of age and weighing less than 20 kg—10 mg once a day for 8 weeks. Your doctor may adjust your dose as needed.*
 - *Children 1 month to less than 1 year of age and weighing more than 7.5 kg to 12 kg—10 mg once a day for up to 6 weeks. Your doctor may adjust your dose as needed.*

- *Children 1 month to less than 1 year of age and weighing more than 5 kg to 7.5 kg—5 mg once a day for up to 6 weeks. Your doctor may adjust your dose as needed.*
- *Children 1 month to less than 1 year of age and weighing 3 kg to 5 kg—2.5 mg once a day for up to 6 weeks. Your doctor may adjust your dose as needed.*
- *Infants younger than 1 month of age—Use and dose must be determined by your doctor.*
- **To treat gastroesophageal reflux disease (GERD):**
 - *Adults—20 milligrams (mg) once a day for 4 weeks. Your doctor may adjust your dose as needed.*
 - *Children 12 to 17 years of age—20 milligrams (mg) once a day for 4 weeks. Your doctor may adjust your dose as needed.*
 - *Children 1 to 11 years of age—10 milligrams (mg) once a day for up to 8 weeks. Your doctor may adjust your dose as needed.*
 - *Children younger than 1 year of age—Use and dose must be determined by your doctor.*
- **To treat Zollinger-Ellison syndrome:**
 - *Adults—40 milligrams (mg) 2 times a day. Your doctor may adjust your dose as needed.*
 - *Children—Use and dose must be determined by your doctor.*
- **For oral dosage form (delayed-release 24 hour capsules):**
 - *To treat heartburn:*
 - *Adults—20 milligrams (mg) once a day for 14 days.*
 - *Children—Use and dose must be determined by your doctor.*

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

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Precautions

It is very important that your doctor check your or your child's progress at regular visits. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it. Blood, urine, and other laboratory tests may be needed to check for unwanted effects. If your condition does not improve, or if it becomes worse, check with your doctor.

Do not use esomeprazole if you are also using medicines containing rilpivirine (Edurant®, Complera®). Using these medicines together may cause unwanted side effects.

Esomeprazole may cause a serious type of allergic reaction when used in patients with conditions treated with antibiotics. Call your doctor right away if you or your child has itching, trouble breathing or swallowing, or any swelling of your hands, face, or mouth.

*This medicine is sometimes given together with amoxicillin (Amoxil®) and clarithromycin (Biaxin®) to treat ulcers caused by *H. pylori* infection. Be sure you understand the risks and proper use of any other medicines your doctor prescribes.*

Check with your doctor right away if you have a change in frequency of urination or amount of urine, blood in the urine, fever, joint pain, loss of appetite, nausea, skin rash, swelling of the body, feet, or ankles, unusual tiredness or weakness, or unusual weight gain after using this medicine. These could be symptoms of a serious kidney problem called acute tubulointerstitial nephritis.

Taking this medicine for a long time may make it harder for your body to absorb vitamin B12. Tell your doctor if you have concerns about vitamin B12 deficiency.

Serious stomach conditions may occur while taking this medicine alone or together with antibiotics. Check with your doctor immediately if you or your child has stomach cramps, bloated feeling, watery and severe diarrhea which may also be bloody sometimes, fever, nausea or vomiting, or unusual tiredness or weakness.

This medicine may increase your risk of having fractures of the hip, wrist, and spine. This is more likely if you are 50 years of age and older, use high doses, or use it for one year or more. Call your doctor right away if you have severe bone pain or are unable to walk or sit normally.

This medicine may cause serious skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, and drug reaction with eosinophilia and systemic symptoms (DRESS). Check with your doctor right away if you have black, tarry stools, blistering, peeling, or loosening of the skin, chest pain, chills, cough, diarrhea, itching, joint or muscle pain, painful or difficult urination, red irritated eyes, red skin lesions, often with a purple center, sore throat, sores, ulcers, or white spots in the mouth or on the lips, swollen glands, unusual bleeding or bruising, or unusual tiredness or weakness.

This medicine may cause hypomagnesemia (low magnesium in the blood). This is more likely to occur if you are using this medicine for more than one year, or if you are using it together with digoxin (Lanoxin®) or certain diuretics (water pills). Check with your doctor right away if you have convulsions (seizures), a fast, racing, or uneven heartbeat, muscle spasms (tetany), tremors, or unusual tiredness or weakness.

Cutaneous or systemic lupus erythematosus may occur or gets worse in lupus patients and are taking PPI. Call your doctor right away if you or your child have a joint pain or skin rash on your cheeks or arms that gets worse when exposed in the sun.

This medicine may increase your risk for fundic gland polyps (abnormal tissue growth in the upper part of your stomach). This is more likely if you are using this medicine for more than 1 year. Talk to your doctor if you have concerns.

Do not stop using this medicine without first checking with your doctor, or unless told to do so by your doctor.

Make sure any doctor or dentist who treats you knows that you or your child are using this medicine. This medicine may affect the results of certain medical tests.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription (eg, clopidogrel, atazanavir, nelfinavir, Plavix®, Reyataz®, Viracept®) or nonprescription (over-the-counter [OTC]) medicines and herbal (eg, St. John's wort) or vitamin supplements.

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Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Incidence not known

- *Black, tarry stools*
- *blistering, peeling, or loosening of the skin*
- *bloating*
- *chest pain or tightness*
- *chills*
- *confusion*
- *constipation*
- *cough*
- *darkened urine*
- *decreased urine*
- *difficulty with swallowing*
- *dizziness*
- *drowsiness*
- *dry mouth*
- *fast heartbeat*
- *fever*
- *indigestion*
- *joint or muscle pain*
- *loss of appetite*
- *mood or mental changes*
- *muscle cramps in the hands, arms, feet, legs, or face*
- *muscle spasms (tetany) or twitching*
- *nausea*

- *numbness and tingling around the mouth, fingertips, or feet*
- *painful or difficult urination*
- *pains in the stomach, side, or abdomen, possibly radiating to the back*
- *puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue*
- *red skin lesions, often with a purple center*
- *red, irritated eyes*
- *seizures*
- *skin rash, hives, itching*
- *sore throat*
- *sores, ulcers, or white spots in the mouth or on the lips*
- *stomach cramps*
- *swollen glands*
- *trouble breathing*
- *trembling*
- *unusual bleeding or bruising*
- *unusual tiredness or weakness*
- *vomiting*
- *yellow eyes or skin*

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- *Bad, unusual, or unpleasant (after) taste*
- *change in taste*

Less common

- *Sleepiness or unusual drowsiness*

Rare

- Acne
- back pain

Incidence not known

- Agitation
- decreased interest in sexual intercourse
- excess air or gas in the stomach or bowels
- full feeling
- inability to have or keep an erection
- increased sensitivity of the skin to sunlight
- loss in sexual ability, desire, drive, or performance
- loss or thinning of the hair
- muscular weakness
- passing gas
- redness or other discoloration of the skin
- seeing, hearing, or feeling things that are not there
- severe sunburn
- swelling of the breasts or breast soreness in both females and males
- swelling or inflammation of the mouth
- swollen joints

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.