

MEDICATION GUIDE
YOSPRALA™ (yo SPRA lah)
(aspirin and omeprazole)
delayed-release tablets

What is the most important information I should know about YOSPRALA?

You should take YOSPRALA exactly as prescribed, at the lowest dose possible and for the shortest time needed.

YOSPRALA may help reduce the risk of stomach ulcers from aspirin use, but you could still have bleeding and stomach or intestine ulcers, or other serious stomach or intestine problems. Talk with your doctor.

Tell your doctor if you have unexpected bleeding, if you bleed more than usual, or if your bleeding lasts longer than is normal for you, such as increased bruising or more frequent nose bleeds.

Tell your doctor if you have stomach problems while taking or after you stop taking YOSPRALA.

YOSPRALA contains aspirin. Before taking YOSPRALA, tell your doctor if you take:

- aspirin, or any prescription or over-the-counter medicines containing aspirin or other NSAIDs (non-steroidal anti-inflammatory drugs)
- clopidogrel bisulphate (PLAVIX®). You should not take clopidogrel bisulphate (PLAVIX®) if you take YOSPRALA.
- ticagrelor (BRILINTA®). If your doctor prescribes YOSPRALA for you, you should not take YOSPRALA that contains the 325/40 mg strength dose.

Do not stop taking YOSPRALA without talking with your doctor. Stopping YOSPRALA suddenly could increase your risk of having a heart attack or stroke.

YOSPRALA can cause serious side effects, including:

- **Kidney problems (acute interstitial nephritis)** may happen at any time during treatment with YOSPRALA. Call your doctor if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea** caused by an infection (*Clostridium difficile*) in your intestines. Call your doctor if you have watery stools or stomach pain that does not go away. You may or may not have a fever.
- **Bone fractures (hip, wrist, or spine)** in people who take multiple daily doses of proton pump inhibitor (PPI) medicines and for a long period of time (a year or longer).
- **Certain types of lupus erythematosus** may happen or get worse in people who already have lupus and who take PPI medicines, including YOSPRALA. Call your doctor right away if you have joint pain or a rash on your cheeks or arms that gets worse in the sun.

Talk to your doctor about your risk of these serious side effects.

YOSPRALA can have other serious side effects. See **“What are the possible side effects of YOSPRALA?”**

What is YOSPRALA?

YOSPRALA is a prescription medicine used:

- in people who have had heart problems or strokes caused by blood clots, to help reduce their risk of further heart problems or strokes, **and**
- who are at risk of developing stomach ulcers with aspirin

YOSPRALA contains the medicines aspirin and omeprazole (a proton pump inhibitor medicine).

The aspirin in YOSPRALA is used:

- to help reduce the risk of strokes and death in people who have previously had certain types of “mini strokes” (transient ischemic attacks or TIAs) or strokes
- to help reduce the risk of heart attack and death in people who have previously had a heart attack or a type of chest pain called unstable angina pectoris
- to help reduce the risk of heart attack and sudden death in people with a type of ongoing chest pain called chronic stable angina pectoris
- in people who have had surgery or a procedure to improve blood flow to their heart, such as coronary artery bypass grafting (CABG), or percutaneous transluminal coronary angioplasty (PTCA), and who already have another condition that is being treated with aspirin

The omeprazole in YOSPRALA is used:

- to help decrease the risk of developing stomach ulcers due to aspirin in people who are 55 years of age or older, or who have a history of stomach ulcers

YOSPRALA should not be used to treat sudden signs and symptoms of a heart attack or stroke. YOSPRALA should only be used as directed by your doctor to help reduce the risk of further heart problems or strokes.

It is not known if YOSPRALA is safe and effective in children.

YOSPRALA has not been shown to reduce the risk of bleeding in the stomach or intestines that is caused by aspirin.

You should not take an aspirin tablet and an omeprazole tablet together instead of taking YOSPRALA, because they will not work the same way.

Who should not take YOSPRALA?

Do not take YOSPRALA if you:

- are allergic to aspirin, omeprazole, or any of the ingredients in YOSPRALA. See the end of this Medication Guide for a complete list of ingredients in YOSPRALA.
- are allergic to any non-steroidal anti-inflammatory drug (NSAID)
- have a medical condition with severe shortness of breath, chest tightness or pain, coughing or wheezing (asthma), sneezing, runny nose or itchy nose (rhinitis), and growths inside of your nose or sinuses (nasal polyps)
- are taking a medicine that contains rilpivirine (EDURANT, COMPLERA, ODEFSEY) used to treat HIV-1 (Human Immunodeficiency Virus)

Do not give YOSPRALA to a child who **has a suspected viral infection, even if they do not have a fever**. There is a risk of Reye's syndrome with YOSPRALA because it contains aspirin.

What should I tell my doctor before taking YOSPRALA?

See **“What is the most important information I should know about YOSPRALA?”**

Before taking YOSPRALA, tell your doctor about all of your medical conditions, including if you:

- drink 3 or more drinks that contain alcohol every day
- have any bleeding problems
- have been told that you have low magnesium levels in your blood
- have liver or kidney problems
- are of Asian descent and have been told that your body's ability to break down (metabolize) omeprazole is poor or if your genotype called CYP2C19 is not known
- are pregnant or plan to become pregnant. It is not known if YOSPRALA will harm your unborn baby if taken before 30 weeks of pregnancy. YOSPRALA can harm your unborn baby if taken at 30 weeks of pregnancy or after. You should avoid taking YOSPRALA starting at 30 weeks of pregnancy. Talk to your doctor for advice.
- are breastfeeding or plan to breastfeed. The aspirin and omeprazole in YOSPRALA can pass into your breast milk and may harm your baby. Breastfeeding is not recommended during treatment with YOSPRALA. Talk to your doctor about the best way to feed your baby if you take YOSPRALA.
- are a female who can become pregnant. NSAIDs, including YOSPRALA, may be related to infertility in some women that is reversible when treatment with YOSPRALA is stopped.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, anti-cancer medicines, vitamins and herbal supplements.

YOSPRALA may affect how other medicines work, and other medicines may affect how YOSPRALA works.

See **“What is the most important information I should know before taking YOSPRALA?”**

Especially tell your doctor before you take:

- a medicine that contains rilpivirine (EDURANT, COMPLERA, ODEFSEY)
- clopidogrel bisulphate (PLAVIX®)
- ticagrelor (BRILINTA®)
- St. John's Wort (Hypericum perforatum)
- rifampin (Rimactane, RIFATER®, RIFAMATE® RIFADIN®)
- methotrexate (Otrexup, Rasuvo, Trexall)

Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take YOSPRALA?

- Take YOSPRALA exactly as prescribed by your doctor.
- Do not change your dose or stop taking YOSPRALA without talking to your doctor.
- Take YOSPRALA 1 time each day.
- Take YOSPRALA at least 1 hour before a meal.
- Swallow YOSPRALA tablets whole with liquid. Do not split, chew, crush, or dissolve YOSPRALA.
- If you miss a dose of YOSPRALA, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time unless your doctor tells you to.
- If you take too much YOSPRALA, call your doctor or your poison control center at 1-800-222-1222 right away or go to the nearest emergency room.

What should I avoid while taking YOSPRALA?

Avoid heavy alcohol use during treatment with YOSPRALA. People who drink three or more drinks that contain alcohol every day have a higher risk of bleeding during treatment with YOSPRALA, because it contains aspirin.

What are the possible side effects of YOSPRALA?

YOSPRALA can cause serious side effects, including:

- See “**What is the most important information I should know about YOSPRALA?**”
- **Stomach and intestine problems.** Stop taking YOSPRALA and call your doctor right away if you have any of the following signs or symptoms: black, bloody, or tarry stools, coughing up blood or vomit that looks like coffee grounds, or severe nausea, vomiting, or stomach pain.
- **Kidney failure.** Long-lasting (chronic) kidney failure can happen with regular use of aspirin, a medicine in YOSPRALA. This is more likely to happen in people who already have kidney problems before treatment with YOSPRALA. Tell your doctor if you have signs or symptoms of kidney failure, including: changes in urination, swelling, skin rash or itching, or your breath smells like ammonia.
- **Liver problems.** Long-term use of YOSPRALA at certain doses may cause liver problems. Tell your doctor if you have signs or symptoms of liver problems, including: yellowing of your skin or your eyes, stomach-area (abdominal) pain and swelling, itchy skin, and dark (tea-colored) urine.
- **Low vitamin B-12 levels** in your body can happen in people who have taken a PPI medicine, such as omeprazole, for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B-12 levels, including: shortness of breath, lightheadedness, irregular heartbeat, muscle weakness, pale skin, feeling tired, mood changes, and tingling or numbness.
- **Low magnesium levels** in your body can happen in people who have taken YOSPRALA for at least 3 months. Tell your doctor if you have symptoms of low magnesium levels, including: seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.

The most common side effects of YOSPRALA include: indigestion or heartburn and stomach-area pain, nausea, diarrhea, growths (polyps) in your stomach, and chest pain behind the breastbone, for example, with eating.

These are not all the possible side effects of YOSPRALA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store YOSPRALA?

- Store YOSPRALA at room temperature between 68°F to 77°F (20°C to 25°C).
- Store YOSPRALA in the original container.
- Keep the container of YOSPRALA tightly closed to protect from moisture.
- The YOSPRALA container may contain a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the container. Do not throw away the desiccant packet.

Keep YOSPRALA and all medicines out of the reach of children.

General information about the safe and effective use of YOSPRALA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use YOSPRALA for a condition for which it was not prescribed. Do not give YOSPRALA to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for information about YOSPRALA that is written for health professionals.

What are the ingredients in YOSPRALA?

Active ingredients: aspirin and omeprazole

Inactive ingredients: microcrystalline cellulose, corn starch, pre-gelatinized starch, colloidal silicon dioxide, stearic acid, methacrylic acid copolymer dispersion, triethyl citrate, glyceryl monostearate, polysorbate 80, titanium dioxide, hydroxypropyl methylcellulose, polyethylene glycol, polydextrose, triacetin, yellow iron oxide, FD&C Blue #2, talc, sodium phosphate dibasic anhydrous, carnauba wax and povidone.

Manufactured for: Aralez Pharmaceuticals US Inc. 400 Alexander Park Drive Princeton, NJ 08540-6539

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For more information, go to www.YOSPRALA.com or call 1-866-207-6592.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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