

Information for **Patients & Caregivers**



delayed-release tablets
Yosprala[™]
(aspirin and omeprazole)

WHY YOU WERE PRESCRIBED **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

Please see Important Safety Information on page 4.

Please see accompanying Medication Guide.

Yosprala[®] is a registered trademark of Genus Lifesciences, Inc. and is used under license. All other product/brand names are trademarks of their respective owners. Manufactured for: Innovida Pharmaceutique Corporation, Charleston, WV 25301 © 2019 Innovida Pharmaceutique Corporation. All rights reserved.

*Not actual patients

For more information
1-888-202-0649
yosprala@innovidarx.com

www.yosprala.com
www.innovidarx.com

INNOVIDA
PHARMACEUTIQUE CORPORATION



Why Yosprala®?



Yosprala for heart and stomach protection

Whether you're a patient or caregiver, it is certain that you want to do everything you can to help prevent another stroke or heart attack. An important part of protecting your heart health is following a daily aspirin regimen, as directed by your doctor.

But while aspirin provides excellent care for your heart, it can cause serious damage to your stomach, including ulcers.

Because you have had a heart problems or strokes caused by blood clots, and are also at risk for stomach ulcers with aspirin, your doctor has prescribed Yosprala for you. The ingredients in Yosprala and its unique design offer you the life-saving benefits of aspirin with added protection from stomach ulcers caused by aspirin.

Please see Important Safety Information on page 4.

What ingredients are in Yosprala?

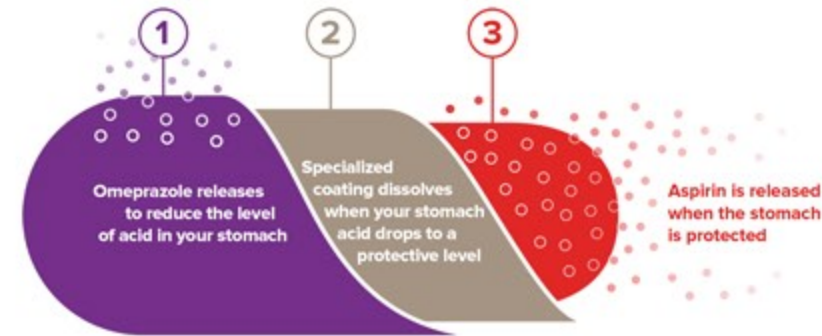
Yosprala contains 2 medicines, aspirin and prescription-strength omeprazole.

Aspirin helps to reduce your risk of further heart problems or strokes caused by blood clots.

Omeprazole is a proton pump inhibitor (also called a PPI). This medicine helps lower your risk of stomach ulcers that can happen with aspirin treatment, especially if you have a history of stomach ulcers or you are 55 years of age or older.


How does Yosprala work?

Yosprala works in a 3-step process designed to coordinate the release of the 2 ingredients:



For illustration purposes only. Not a visual representation of the tablet.

Remember: Yosprala has been shown to reduce the risk of stomach ulcers from aspirin use, but you could still develop stomach or intestine ulcers, bleeding, or other serious stomach or intestine problems. Talk with your doctor.

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

Please see accompanying Medication Guide.



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. Just 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 are not sure about the correct way to take Yosprala, call your doctor.



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.

Do not take Yosprala if you:

- Are allergic to aspirin, omeprazole, or any of the ingredients in Yosprala
 - See the end of the 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)
 - 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.



Reading this guide is not a substitute for discussing your medical condition or your treatment with your healthcare provider.

*Not an actual patient

Please see Important Safety Information on page 4.

Please see accompanying Medication Guide.

*Not an actual doctor



Important Safety Information about Yosprala®

Active Ingredients

Yosprala (aspirin and omeprazole) is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI).

Uses

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 use

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.

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

You should take Yosprala exactly as prescribed.

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 if you experience any of these problems.

Do not use Yosprala if you:

- are allergic to aspirin, omeprazole, or any of the ingredients in Yosprala
- are allergic to any non-steroidal antiinflammatory 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.

Warnings and Precautions

- 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
- Do not stop taking Yosprala without talking with your doctor. Stopping Yosprala suddenly could increase your risk of having a heart attack or stroke
- 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
- If you are pregnant, planning to become pregnant, breastfeeding (nursing) or planning to breastfeed, talk with your doctor before taking Yosprala. 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. Breastfeeding is not recommended during treatment with Yosprala

Use With Other Medicines

Yosprala contains aspirin and omeprazole. Before taking Yosprala, 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.

Especially tell your doctor if you are taking:

- 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 both ticagrelor and Yosprala for you, you should not take Yosprala that contains the 325/40 mg strength dose
- a medicine that contains rilpivirine (EDURANT®, COMPLERA®, ODEFSEY®)
- St. John's Wort (Hypericum perforatum)
- rifampin (RIMACTANE®, RIFATER®, RIFAMATE®, RIFADIN®)
- methotrexate (OTREXUP™, RASUVO®, TREXALL®)

Serious Side Effects

- Kidney problems may happen at any time during treatment with Yosprala. Call your doctor if you have a decrease in the amount that you urinate, if you have blood in your urine, swelling, skin rash or itching, or your breath smells like ammonia
- Certain stomach and intestine problems may happen during treatment with Yosprala. 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
- Medicines containing PPIs (such as omeprazole) may have an increased risk of 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) may be more likely to happen 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

- 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, stomachache (abdominal) pain and swelling, itchy skin, and dark (tea-colored) urine
- Low vitamin B12 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 B12 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

Common Side Effects

- indigestion or heartburn and stomach-area pain,
- nausea, diarrhea, growths (polyps) in your stomach,
- and chest pain behind the breastbone, for example, with eating.

The risk information provided here is not comprehensive. To learn more, talk about Yosprala with your pharmacist or other health care providers. The product information can be found at www.Yosprala.com or 1-866-207-6592.

Call your doctor for medical advice about side effects. **You are encouraged to report negative side effects of prescription drugs to Innovida Pharmaceutical Corporation at 1-888-202-0649 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Please see accompanying Medication Guide.

