

MEDICATION GUIDE
SYMBRAVO® (sim-BRAH-voh)
(meloxicam-rizatriptan)
tablets, for oral use

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

SYMBRAVO contains 2 medicines: meloxicam (a nonsteroidal anti-inflammatory drug [NSAID]) and rizatriptan (a triptan).

NSAIDs, including SYMBRAVO, can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
 - with increasing doses of NSAIDs
 - with longer use of NSAIDs

Do not take SYMBRAVO right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking SYMBRAVO after a recent heart attack unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

Stop taking SYMBRAVO and get emergency help right away if you have any of the following symptoms of a heart attack or stroke:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded
- weakness in one part or on side of your body
- slurred speech

SYMBRAVO is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. You have a higher risk for heart disease if you:

- have high blood pressure
- have high cholesterol levels
- smoke
- are overweight
- have diabetes
- have a family history of diabetes

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach, and intestines:**

- anytime during use
- without warning symptoms
- that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs” or “SNRIs” (antidepressants), or aspirin (an antiplatelet)
- increasing doses of NSAIDs
- older age
- longer use of NSAIDs
- poor health
- smoking
- advanced liver disease
- drinking alcohol
- bleeding problems

- **SYMBRAVO may cause serious allergic reactions or serious skin reactions that can be life-threatening.**

Stop taking SYMBRAVO and get emergency help right away if you develop:

- sudden wheezing
- swelling of your lips, tongue, throat or body
- rash
- fainting
- problems breathing or swallowing
- reddening of your skin with blisters or peeling
- blisters or bleeding of your lips, eye lids, mouth, nose, or genitals

- **SYMBRAVO should only be used:**

- exactly as prescribed
- for the shortest time needed

- **SYMBRAVO already contains an NSAID (meloxicam). Do not use SYMBRAVO with other medicines to lessen pain or fever or with other medicines for colds or sleeping problems without talking to your healthcare provider first, because they may contain an NSAID also.**

What is SYMBRAVO?

SYMBRAVO is a combination of meloxicam (an NSAID) and rizatriptan (a triptan).

SYMBRAVO is used to treat acute migraine headaches with or without aura in adults.

SYMBRAVO is not for the treatment of other types of migraines such as hemiplegic (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura).

SYMBRAVO is not to be used to prevent or decrease the number of migraine headaches you have.

It is not known if SYMBRAVO is safe and effective for the treatment of cluster headaches.

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

Who should not take SYMBRAVO?

Do not take SYMBRAVO if you:

- have or have had heart problems.
- right before or after heart bypass surgery.
- have or have had a stroke or a transient ischemic attack (TIA).
- have or have had blood vessel problems, including ischemic bowel disease.
- have or had hemiplegic migraines or basilar migraines.
- narrowing of blood vessels of your legs and arms (peripheral vascular disease), stomach (ischemic bowel disease), or kidneys.
- have uncontrolled high blood pressure.
- take a propranolol containing medicines.
- have taken any medicines in the last 24 hours that are called 5-HT₁ agonists (triptans) or contain ergotamine.
- take an antidepressant medicine called monoamine oxidase (MAO) inhibitor or have taken a MAO inhibitor within the last 2 weeks.
- are allergic to meloxicam, rizatriptan, NSAIDs or any of the ingredients in SYMBRAVO. See the end of this Medication Guide for a complete list of ingredients in SYMBRAVO.
- have had an asthma attack, hives, or other allergic reaction after taking with aspirin or any other NSAIDs.
- have moderate to severe kidney problems and are at risk of kidney failure or if you are on dialysis.

Talk to your healthcare provider before taking this medicine if you have any of the conditions listed above or if you are not sure if you take any of these medicines.

What should I tell my healthcare provider before taking SYMBRAVO?

Before you take SYMBRAVO, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had heart problems, high blood pressure, chest pain, or shortness of breath.
- have any risk factors for heart problems or blood vessel problems such as:
 - high blood pressure
 - high cholesterol
 - smoking
 - obesity
 - diabetes
 - family history of heart problems
 - you are post-menopausal
 - you are a male over 40
- have kidney or liver problems.
- have asthma.
- have any other medical condition.
- are pregnant or plan to become pregnant. Taking NSAIDs, including SYMBRAVO, at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should not take NSAIDs after about 30 weeks of pregnancy.**
- are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the best way to feed your baby if you take SYMBRAVO.

Tell your healthcare provider about all of the medicines you take, including prescription or over the counter medicines, vitamins, or herbal supplements.

SYMBRAVO and other medicines may affect each other causing side effects. SYMBRAVO may affect the way other medicines work, and other medicines may affect how SYMBRAVO works.

Do not start taking any new medicine without talking to your healthcare provider first.

Especially tell your healthcare provider if you take:

- propranolol containing medicines such as Inderal®, Inderal® LA, or Innopran® XL
- medicines used to help your mood, including SSRIs or SNRIs.
- Aspirin
- Any anticoagulant medicines

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

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

How should I take SYMBRAVO?

- Take SYMBRAVO exactly as your healthcare provider tells you to take it.
- It is not known if taking more than 1 dose of SYMBRAVO in 24 hours is safe and effective. Talk to your healthcare provider about what to do if your headache does not go away or comes back.
- Swallow SYMBRAVO tablets whole.
- **Do not** crush, divide, or chew SYMBRAVO tablets.
- SYMBRAVO can be taken with or without food.
- If you take too much SYMBRAVO, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking SYMBRAVO?

SYMBRAVO may cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything that needs you to be alert.

What are the possible side effects of SYMBRAVO?

SYMBRAVO can cause serious side effects, including:

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

- heartbeats that are too fast or too slow (arrhythmias)
- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- asthma attacks in people who have asthma
- **Other side effects of NSAIDs, like SYMBRAVO, include:** stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.
- **Heart attack.** Get emergency help right away if you have any of the following symptoms of a heart attack may include:
 - chest discomfort in the center of your chest that lasts for more than a few minutes or that goes away and comes back
 - chest discomfort that feels like uncomfortable pressure, squeezing, fullness or pain
 - pain or discomfort in your arms, back, neck, jaw or stomach
 - shortness of breath with or without chest discomfort
 - breaking out in a cold sweat
 - nausea or vomiting
 - feeling lightheaded
- **Stroke.** Get emergency help right away if you have any of the symptoms of a stroke may include the following sudden symptoms:
 - numbness or weakness in your face, arm or leg, especially on one side of your body
 - confusion, problems speaking or understanding
 - problems seeing in 1 or both of your eyes
 - problems walking, dizziness, loss of balance or coordination
 - severe headache with no known cause
- **Stomach and intestinal problems** (gastrointestinal and colonic ischemic events). Get emergency help right away if you have any of the following symptoms of gastrointestinal and colonic ischemic events including:
 - sudden or severe stomach pain
 - severe stomach pain after meals
 - sudden unexplained weight loss
 - severe nausea or vomiting
 - severe constipation or diarrhea
 - bloody diarrhea
- **Problems with blood circulation to your legs and feet** (peripheral vascular ischemia). Get emergency help right away if you have any of the following symptoms of peripheral vascular ischemia including:
 - cramping and pain in your legs or hips
 - feeling of heaviness or tightness in your leg muscles
 - burning or aching pain in your feet or toes while resting
 - numbness, tingling, or weakness in your legs
 - cold feeling or color changes in 1 or both legs or feet
- **Medication overuse headaches.** Some people who use too many SYMBRAVO tablets may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with SYMBRAVO.

- **Serotonin syndrome.** A condition called serotonin syndrome can happen when Triptan medicines such as SYMBRAVO are taken with certain other medicines called SSRIs or SNRIs. Stop taking SYMBRAVO and get emergency help right away if you have any of the following symptoms of serotonin syndrome:
 - mental changes such as seeing things that are not there (hallucinations); agitation, or coma
 - fast heartbeat
 - changes in your blood pressure
 - high body temperature
 - tight muscles
 - trouble walking

Stop taking SYMBRAVO and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- flu-like symptoms
- vision problems
- vomit blood
- there is blood in your bowel movement of it is black and sticky like tar
- unusual weight gain
- skin rash or blisters with fever
- swelling of the arms, legs, hands, and feet
- tenderness in your right upper side

The most common side effects of SYMBRAVO include:

- dizziness
- feeling tired

These are not all the possible side effects of SYMBRAVO. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

Other information about NSAIDs:

- Aspirin is an NSAID, but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines. **Do not** take aspirin with SYMBRAVO without talking to your healthcare provider first.
- Some NSAIDs are sold without a prescription (over the counter). Talk to your healthcare provider before using over the counter NSAIDs with SYMBRAVO.

General Information about the safe and effective use of SYMBRAVO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SYMBRAVO for a condition for which it was not prescribed. Do not give SYMBRAVO to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about SYMBRAVO. If you would like more information, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about SYMBRAVO that is written for health professionals. For more information, go to www.SYMBRAVO.com.

How should I store SYMBRAVO?

- Store SYMBRAVO at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.
- **Keep SYMBRAVO and all medicines out of the reach of children.**

What are the ingredients in SYMBRAVO?

Active ingredients in SYMBRAVO: meloxicam and rizatriptan.

Inactive ingredients in SYMBRAVO: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, partially hydrolyzed polyvinyl alcohol, polyethylene glycol, povidone, pregelatinized starch, sodium bicarbonate, sulfobutyl-ether-β-cyclodextrin sodium, talc, and titanium dioxide.

Distributed by:

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New York, NY 10007

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For more information about SYMBRAVO, visit SYMBRAVO.com or call 1-800-484-1672.