

Medication Guide
ELYXYB (ee-lix'-ib))
(celecoxib) oral solution

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

ELYXYB contains celecoxib (a non-steroidal anti-inflammatory drug or NSAID). NSAIDs, including ELYXYB, 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 ELYXYB right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAIDs, including ELYXYB, 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.

- **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”, “antiplatelet drugs”, “anticoagulants”, “SSRIs” or “SNRIs”
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

ELYXYB should only be used:

- exactly as prescribed
- for the shortest time needed

What is ELYXYB?

ELYXYB is a prescription medicine used for the acute treatment of migraine attacks with or without aura in adults.

- ELYXYB is not used as a preventive treatment of migraine.
- It is not known if ELYXYB is safe and effective in children.

Who should not take ELYXYB?

Do not take ELYXYB:

- if you are allergic to celecoxib or any of the ingredients in ELYXYB. See the end of this Medication Guide for a complete list of ingredients in ELYXYB.
- If you are allergic to sulfonamides.
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.

Before taking ELYXYB, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- have a history of stomach ulcer or bleeding in your stomach or intestines.
- have heart disease or risk factors that increase your chance of getting heart disease.
- have high blood pressure.
- have asthma.
- are pregnant or plan to become pregnant. Taking NSAIDs, including ELYXYB, 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 breast feed. ELYXYB may pass into your breast milk. Talk with your healthcare provider about the best way to feed your baby if you take ELYXYB.

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs, including ELYXYB, and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

How should I take ELYXYB?

See the detailed “Instructions for Use” on how to take ELYXYB solution.

- Take ELYXYB exactly as your healthcare provider tells you to take it.
- Take ELYXYB by mouth with or without food.
- Do not take more than one dose in a 24-hour period.
- Use ELYXYB for the fewest number of days a month, as needed.

What are the possible side effects of ELYXYB?

ELYXYB can cause serious side effects, including:

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

- liver problems including liver failure
- new or worse high blood pressure
- heart failure
- kidney problems including kidney failure
- life-threatening allergic reactions
- asthma attacks in people who have asthma
- life-threatening skin reactions
- medication overuse headaches. Some people who use too much ELYXYB may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with ELYXYB.
- low red blood cells (anemia)
- **Other side effects of NSAIDs include:** stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking ELYXYB 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
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- skin rash or blisters with fever
- swelling of the arms, legs, hands and feet

If you take too much ELYXYB, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs. 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.
- Some NSAIDs are sold in lower doses without a prescription (over-the counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

General information about the safe and effective use of ELYXYB

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

If you would like more information about ELYXYB, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ELYXYB that is written for health professionals.

Manufactured for: BioDelivery Sciences International, Inc.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: Sep 2021

Instructions For Use

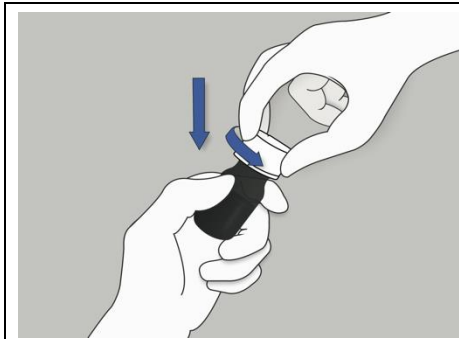
**ELYXYB (ee-lix'-ib)
(celecoxib)
oral solution
25 mg/mL**

Read this Instructions for Use before you start taking ELYXYB and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment. Take ELYXYB exactly how your healthcare provider tells you to.

If your healthcare provider has prescribed 120 mg of ELYXYB, take all of the medicine in the bottle as described below in **Instructions-1**.

If your healthcare provider has prescribed 60 mg of ELYXYB, take 2.4 mL of the medicine, as described in **Instructions-2**. You will need a dosing syringe from the pharmacy to give the right amount of medicine. **Do not** use a household teaspoon to measure ELYXYB.

Instructions-1 (Full dose of 120 mg)



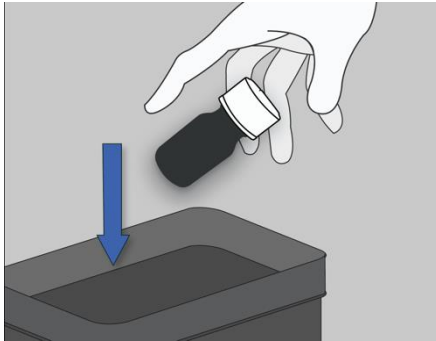
Step 1: When you need to take ELYXYB, push down the cap and turn it to the left (counterclockwise) to open it.



Step 2: When taking 120 mg of ELYXYB, drink it directly from the bottle. Hold the bottle upside down for 10 seconds to make sure the full amount of medicine is taken.



Step 3: Close the bottle by turning the cap to the right (clockwise) right away after drinking the medicine.



Step 4: Throw away (discard) the bottle.

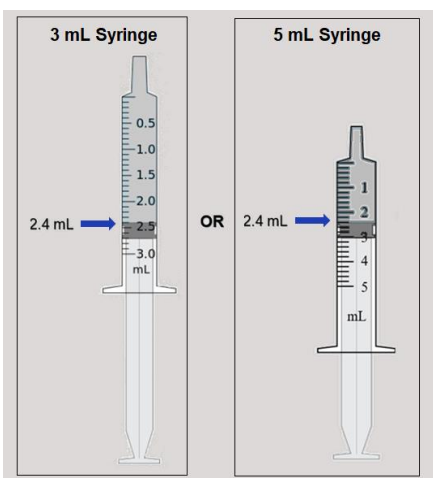


Step 5: After you take ELYXYB, you may drink up to 8 ounces (240 mL) of water.

Instructions-2 (50% reduced dose of 60 mg)



Step 1: When you need to take ELYXYB, push down the cap and turn it to the left (counterclockwise) to open it.



Step 2: Use an oral dosing syringe (3 mL or 5 mL) from your pharmacy to withdraw 2.4 mL of ELYXYB. Insert the syringe through ELYXYB bottle opening and draw up 2.4 mL of ELYXYB directly from the bottle into the syringe. This 2.4 mL will be your 60 mg dose.

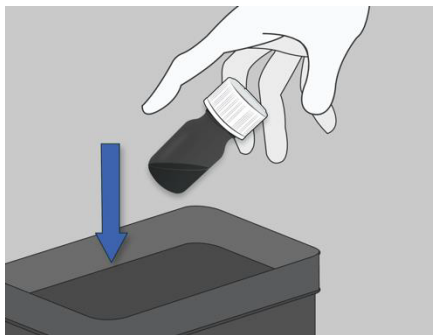
Note: Do not use a household teaspoon to measure ELYXYB.

Step 3: Place the 2.4 mL of the ELYXYB that is in the dosing syringe in your mouth and swallow it right away.

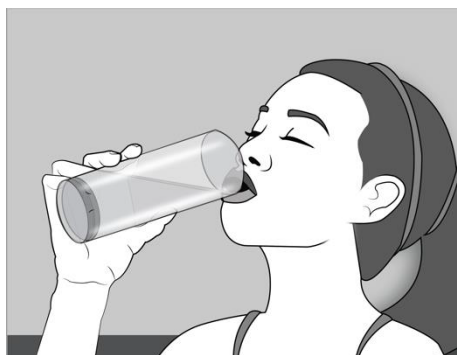


Step 4: Close the bottle tightly by turning the cap to the right (clockwise) right away after taking the correct dose of ELYXYB.

Note: Do not store the bottle to reuse the remaining medicine.



Step 5: Throw away (discard) the bottle with the unused ELYXYB.



Step 6: After you take ELYXYB, you may drink up to 8 ounces (240 mL) of water.

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Revised: Sep 2021

For more information call BioDelivery Sciences International, Inc. at 1-800-469-0261.

Manufactured for:
BioDelivery Sciences International, Inc., Raleigh, NC 27612

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ELY-001-MGIFU-Sep2021

