

MEDICATION GUIDE
SYNRIBO® (sin-RYE-bo)
(omacetaxine mepesuccinate)
for injection, for subcutaneous use

Read this Medication Guide before you start using SYNRIBO and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

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

SYNRIBO can cause serious side effects including:

Low blood counts. Low blood counts are common when using SYNRIBO, including low red blood cells, white blood cells, and platelets, and can be severe. If your white blood cell count becomes very low, you are at increased risk for infection which can lead to death. Your healthcare provider will check your blood counts regularly during treatment with SYNRIBO. Tell your healthcare provider right away if you get any of the following symptoms:

- fever
- chills
- body aches
- feeling very tired
- shortness of breath
- bleeding (see below)

Bleeding. SYNRIBO causes severe low platelet counts that may increase your risk of severe bleeding. Severe low platelet counts can cause you to have bleeding in your brain or severe stomach bleeding, that can lead to death. Your healthcare provider will check your platelet counts regularly during treatment with SYNRIBO. Tell your healthcare provider right away if you get any of the following symptoms:

- unusual bleeding
- easy bruising
- blood in urine or stool
- confusion
- slurred speech
- vision changes

See “**What are the possible side effects of SYNRIBO?**” for more information about side effects.

What is SYNRIBO?

SYNRIBO is a prescription medicine used to treat adults with a type of blood cancer (leukemia) called chronic myeloid leukemia (CML):

- that is in the chronic phase or accelerated phase, and
- who have not responded to (resistant) or cannot tolerate 2 or more medicines called tyrosine kinase inhibitors.

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

What should I tell my healthcare provider before using SYNRIBO?

Before using SYNRIBO, tell your healthcare provider if you:

- have diabetes or a family history of diabetes
- have bleeding problems
- plan to have any dental or surgical procedures
- have any other medical problems
- are pregnant or plan to become pregnant. SYNRIBO can harm your unborn baby. You should not become pregnant during treatment with SYNRIBO. Tell your healthcare provider right away if you become pregnant during treatment with SYNRIBO.
- are breastfeeding or plan to breastfeed. It is not known if SYNRIBO passes into your breast milk. You and your healthcare provider should decide if you will take SYNRIBO or breastfeed. You should not do both.

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

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 use SYNRIBO?

- **Follow the detailed Instructions for Use at the end of this Medication Guide for information about the right way to:**
 - **properly handle and inject SYNRIBO**
 - **dispose of used supplies for injecting SYNRIBO**
 - **clean up any spilled SYNRIBO**
- Your healthcare provider will tell you how much SYNRIBO to inject and the timing of when to inject it. Inject SYNRIBO exactly as prescribed.
- Do not change your dose or the timing of when you inject SYNRIBO, unless your healthcare provider tells you to.
- SYNRIBO is given as an injection under the skin (subcutaneous injection) of your thigh or stomach-area (abdomen). The injection can be given in the back of the arm if a caregiver is giving the injection.
- If your healthcare provider decides that you or a caregiver can inject SYNRIBO, your healthcare provider will show you or your caregiver how to prepare for an injection and how to inject SYNRIBO before you use it for the first time.
- SYNRIBO is injected 2 times each day, about every 12 hours.
- Your healthcare provider may tell you to stop using SYNRIBO for a period of time, or tell you to use SYNRIBO less often depending on the side effects that you get.
- Your healthcare provider will arrange for you to receive syringes filled with SYNRIBO that are ready to inject, along with the other supplies that you will need to inject SYNRIBO. Each syringe contains **1** dose of SYNRIBO as prescribed by your healthcare provider.
- Follow your healthcare provider’s instructions for how to carry (transport) SYNRIBO using ice packs or a cooler.
- Do not eat or drink while handling SYNRIBO.
- You or your caregiver should wear gloves and protective eyewear, for example protective eyeglasses (not regular eyeglasses) or face shield when handling SYNRIBO and while giving your injection.
- If you or your caregiver get SYNRIBO on your skin, wash the area with soap and water.
- If you or your caregiver get SYNRIBO in your eyes, flush your eyes with water and call your healthcare provider right away.
- If you miss a dose of SYNRIBO, just skip the missed dose. Give your next injection of SYNRIBO at your next scheduled time. Do not give 2 doses of SYNRIBO at the same time to make up for a missed dose.
- If you inject too much SYNRIBO, call your healthcare provider or go to the nearest emergency room right away. Follow your healthcare provider’s instructions for when you should inject your next dose of SYNRIBO.
- If another person accidentally injects themselves with SYNRIBO, or if anyone accidentally swallows SYNRIBO, call your doctor or get emergency help right away.

What should I avoid while using SYNRIBO?

SYNRIBO may cause tiredness. Avoid driving, or operating dangerous tools or machinery if you develop tiredness when using SYNRIBO.

What are the possible side effects of SYNRIBO?

SYNRIBO may cause serious side effects, including:

- See “**What is the most important information I should know about SYNRIBO?**”
- **High blood sugar levels (hyperglycemia).** SYNRIBO can cause high blood sugar levels. If you have diabetes or are at risk for diabetes, your healthcare provider will check your blood glucose levels often during treatment with SYNRIBO. If you have diabetes or if your blood sugar is not well controlled, your healthcare provider may decide not to start treatment with SYNRIBO until your diabetes is under control first.

The most common side effects of SYNRIBO are:

- Infections. See the information about low blood cell counts in the section “**What is the most important information I should know about SYNRIBO?**”
- diarrhea
- nausea
- tiredness
- weakness
- redness, swelling, or pain at injection site

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the side effects of SYNRIBO. 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.

How should I store SYNRIBO?

- Carry (transport) SYNRIBO as instructed by your healthcare provider. It is important to use ice packs or a cooler.
- When stored in a refrigerator 36°F to 46°F (2°C to 8°C), **use SYNRIBO within 6 days from when it was mixed.**
- When stored at room temperature, 68°F to 77°F (20°C to 25°C), **use SYNRIBO within 12 hours from when it was mixed.**
- When stored in a refrigerator, keep SYNRIBO from coming into contact with food or drink

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

General information about the safe and effective use of SYNRIBO.

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

For more information, go to www.synribo.com or call Teva at 1-800-896-5855.

What are the ingredients in SYNRIBO?

Active ingredient: omacetaxine mepesuccinate

Inactive ingredients: mannitol

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

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Instructions for Use SYNRIBO® (sin-RYE-bo) (omacetaxine mepesuccinate) for injection, for subcutaneous use

Read this Instructions for Use before you inject SYNRIBO for the first time and each time you get a refill. Also read the Medication Guide for SYNRIBO.

Before you or your caregiver injects SYNRIBO, your healthcare provider will show you how to properly:

- handle syringes and inject SYNRIBO
- dispose of used supplies for injecting SYNRIBO
- clean up any spilled SYNRIBO

Important:

- Be sure that you store SYNRIBO exactly as your healthcare provider tells you to. See the section “**How should I store SYNRIBO?**” in the Medication Guide.
- **Never try to re-cap the needle.** This could cause a needle-stick injury.
- If SYNRIBO comes into contact with your skin, wash the area well with soap and water.

Your healthcare provider will arrange for you to receive all of the supplies that you will need for each injection of SYNRIBO:

- syringe with attached needle, containing SYNRIBO for injection
- protective eyewear, such as protective eyeglasses (not regular eyeglasses) or face shield
- gloves
- disposal biohazard container
- absorbent pads for use to clean up an accidental spill of SYNRIBO
- alcohol swabs
- gauze pads

You may also need an adhesive bandage.

Never mix SYNRIBO yourself. If you don't receive syringes already filled with SYNRIBO, contact your doctor or pharmacy.

Step 1. Preparing to give an injection of SYNRIBO.

- Find a clean flat work surface.
- Wash your hands well with soap and water.
- Put on a pair of gloves and your protective eyewear before you handle the syringe containing SYNRIBO. Wearing gloves and protective eyewear protects you from splashes or spills. See Figure A.
- Look at the date printed on the syringe label to make sure that the expiration date has not passed. Do not use if the expiration date has passed and contact your doctor or pharmacy immediately.
- Gather the rest of your supplies and place them on your work surface.

Figure A



Step 2. Choose an injection site.

- You may inject SYNRIBO into your thigh or stomach-area (abdomen). See Figure B. The injection can be given in the back of your arm if a caregiver is giving the injection. See Figure C.
- Use a different site for each injection to help decrease tenderness at the injection site. Each injection site should be at least 1 inch away from any recently used injection site.
- Do not inject SYNRIBO into areas of your skin that are tender, red, bruised, hard, or that have scars or stretch marks.

Figure B

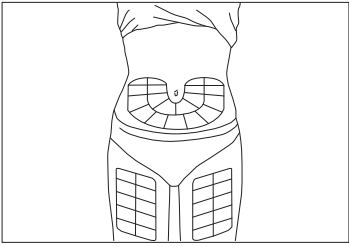
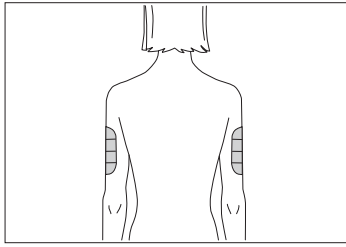
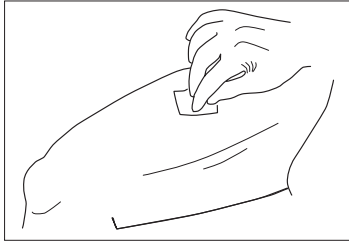


Figure C

**Step 3.** Prepare the injection site.

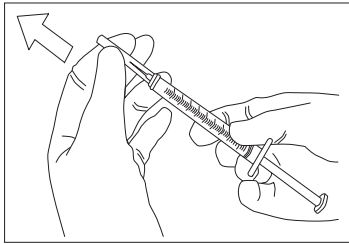
- Clean the injection site well with an alcohol wipe and allow it to air dry. See Figure D.

Figure D

**Step 4.** Inject SYNRIBO.

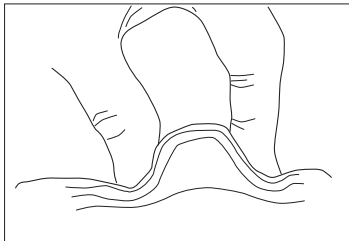
- Carefully remove the needle cap by pulling, taking care not to stick yourself. See Figure E.
- Do not press down on the plunger.

Figure E



- With one hand, pinch skin of injection site between your thumb and forefinger. See Figure F.

Figure F



- With your other hand, hold the syringe at a 45 degree or 90 degree angle to your skin. Use a quick dart-like motion to insert the needle through the skin at the injection site. See Figures G and H. The needle should go through the skin but not into your muscle.

Figure G

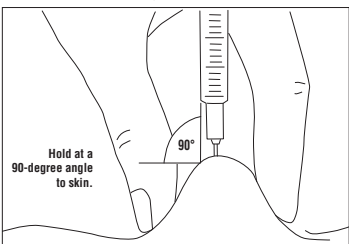
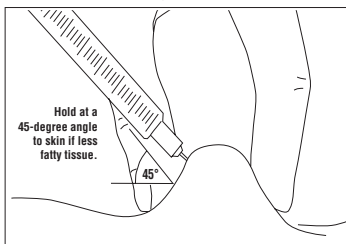
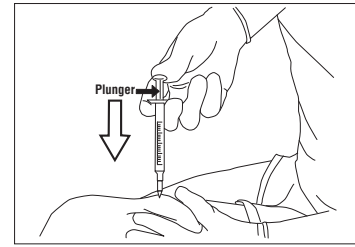


Figure H



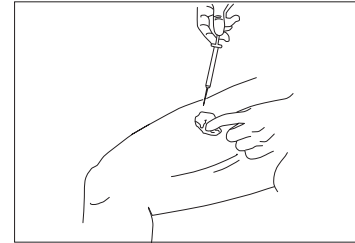
- Slowly push down on the plunger with your thumb until syringe is empty. See Figure I.

Figure I



- Stop pinching your skin. Quickly remove needle and then apply pressure on injection site with a dry gauze pad. You can put a small adhesive bandage over the injection site if there is bleeding. See Figure J.

Figure J



- Follow the instructions below for how to dispose of the syringe, needle, and other supplies used to give your injection. Never try to re-cap the needle. This could cause a needle-stick injury.
- Remove your gloves. Wash your hands right away with soap and water, and then remove your protective eyewear.

How should I throw away (dispose of) used SYNRIBO syringes, needles, and other supplies?

- Throw away (dispose of) used SYNRIBO syringes, needles, and other used supplies in an appropriate biohazard container.
- Return the biohazard container to your healthcare provider for disposal.
- Do not place used syringes, needles, or other supplies in a household trash or recycle container. Do not re-cap or clip the used needle. This could cause a needle-stick injury.
- Do not throw away the protective eyewear. You will need them for each dose of SYNRIBO.

What should I do in case of an accidental SYNRIBO spill?

- Your healthcare provider will arrange for you to receive supplies to use in case you spill SYNRIBO.
- Follow your healthcare provider's instructions about how to clean up a SYNRIBO spill.
- Do not touch a spill unless you are wearing gloves and protective eyewear.
- Use an absorbent pad to wipe up the spill. Wash the area with soap and water. Use an extra absorbent pad or paper towel to dry the area.
- Place the pad, gloves, and other supplies that were used to clean the spill in the biohazard container.
- Call your healthcare provider right away to report the spill.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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