

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. SYNRIPO can harm your unborn baby. You should not become pregnant during treatment with SYNRIPO. Tell your healthcare provider right away if you become pregnant during treatment with SYNRIPO.
- are breastfeeding or plan to breastfeed. It is not known if SYNRIPO passes into your breast milk. You and your healthcare provider should decide if you will take SYNRIPO 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 SYNRIPO?

- **Follow the detailed Instructions for Use at the end of this Medication Guide for information about the right way to:**
 - **properly handle and inject SYNRIPO**
 - **dispose of used supplies for injecting SYNRIPO**
 - **clean up any spilled SYNRIPO**
- Your healthcare provider will tell you how much SYNRIPO to inject and the timing of when to inject it. Inject SYNRIPO exactly as prescribed.
- Do not change your dose or the timing of when you inject SYNRIPO, unless your healthcare provider tells you to.
- SYNRIPO 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 SYNRIPO, your healthcare provider will show you or your caregiver how to prepare for an injection and how to inject SYNRIPO before you use it for the first time.
- SYNRIPO is injected 2 times each day, about every 12 hours.
- Your healthcare provider may tell you to stop using SYNRIPO for a period of time, or tell you to use SYNRIPO less often depending on the side effects that you get.
- Your healthcare provider will arrange for you to receive syringes filled with SYNRIPO that are ready to inject, along with the other supplies that you will need to inject SYNRIPO. Each syringe contains **1** dose of SYNRIPO as prescribed by your healthcare provider.
- Follow your healthcare provider's instructions for how to carry (transport) SYNRIPO using ice packs or a cooler.
- Do not eat or drink while handling SYNRIPO.

- You or your caregiver should wear gloves and protective eyewear, for example protective eyeglasses (not regular eyeglasses) or face shield when handling SYNRIPO and while giving your injection.
- If you or your caregiver get SYNRIPO on your skin, wash the area with soap and water.
- If you or your caregiver get SYNRIPO in your eyes, flush your eyes with water and call your healthcare provider right away.
- If you miss a dose of SYNRIPO, just skip the missed dose. Give your next injection of SYNRIPO at your next scheduled time. Do not give 2 doses of SYNRIPO at the same time to make up for a missed dose.
- If you inject too much SYNRIPO, 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 SYNRIPO.
- If another person accidentally injects themselves with SYNRIPO, or if anyone accidentally swallows SYNRIPO, call your doctor or get emergency help right away.

What should I avoid while using SYNRIPO?

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

What are the possible side effects of SYNRIPO?

SYNRIPO may cause serious side effects, including:

- See **"What is the most important information I should know about SYNRIPO?"**
- **High blood sugar levels (hyperglycemia).** SYNRIPO 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 SYNRIPO. If you have diabetes or if your blood sugar is not well controlled, your healthcare provider may decide not to start treatment with SYNRIPO until your diabetes is under control first.

The most common side effects of SYNRIPO are:

- Infections. See the information about low blood cell counts in the section **"What is the most important information I should know about SYNRIPO?"**
- 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 SYNRIPO. 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.

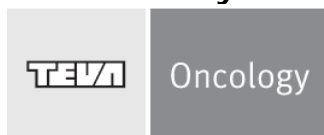
What are the ingredients in SYNRIBO?

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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