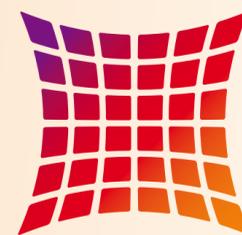




SYNRIBO (omacetaxine mepesuccinate) for Injection



FOR SUBCUTANEOUS USE

Indication

SYNRIBO[®] is a prescription medicine used to treat adults with chronic or accelerated phase chronic myeloid leukemia (CML) who are no longer responding to, or who could not tolerate, two or more tyrosine kinase inhibitors (TKI).

PLEASE READ THE FULL PRESCRIBING INFORMATION INCLUDING THE MEDICATION GUIDE AND COMPLETE INSTRUCTIONS FOR USE BEFORE YOU START USING SYNRIBO AND EACH TIME YOU GET A REFILL.

Instructions for Use

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

HOW SHOULD I USE SYNRIBO?

- Follow the detailed **Instructions for Use** for information about the right way to properly handle and inject SYNRIBO, dispose of used supplies for injecting SYNRIBO, and 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

GATHER SYNRIBO INJECTION SUPPLIES

To complete each injection, you will need the following items: (contents may vary)

- A** SYRINGE WITH ATTACHED NEEDLE CONTAINING SYNRIBO
- B** PROTECTIVE EYEWEAR
- C** GLOVES
- D** DISPOSAL BIOHAZARD CONTAINER
- E** ABSORBENT PADS
- F** ALCOHOL SWABS
- G** GAUZE PADS
- H** ADHESIVE BANDAGES



ONCE YOU HAVE READ THE MEDICATION GUIDE, TALKED TO YOUR DOCTOR, AND COLLECTED THE ITEMS ABOVE, CONTINUE TO STEP 1 ON THE REVERSE SIDE.

Important Safety Information

Warnings and Precautions

Low Blood Counts: SYNRIBO is associated with low blood counts (myelosuppression) that can lead to tiredness, bleeding, or increased risk of infection. Your doctor will regularly check (weekly or every 2 weeks) your blood counts throughout treatment. Low blood counts were usually managed in clinical trials by delaying the next cycle and/or reducing days of treatment. Complications from low blood counts can be severe and/or fatal. Call your doctor immediately if you experience fever, aches, chills, nausea, vomiting, significant tiredness, shortness of breath, or bleeding.

Bleeding: Serious bleeding can occur. Low platelet counts (thrombocytopenia) can lead to bleeding in the brain or severe stomach bleeding, which can sometimes

be fatal. Your doctor will regularly check (weekly or every 2 weeks) your blood counts, including platelets, throughout treatment. Call your doctor immediately if you see signs of internal bleeding (unusual bleeding, easy bruising, or blood in urine or stool; confusion, slurred speech, or altered vision).

High Blood Sugar Levels: SYNRIBO can cause high blood sugar levels (hyperglycemia). If you have diabetes or are at risk for diabetes, your doctor will check your blood sugar levels often during treatment.

Harm to an Unborn Baby: Fetal harm can occur in pregnant women. If you are pregnant or plan to become pregnant, please speak with your doctor before starting treatment.

Related Side Effects

Serious side effects (occurring in 5% or more of studied patients) in chronic and accelerated phase CML:

- Inability to produce certain types of blood cells (bone marrow failure)
- Low platelet count (thrombocytopenia)
- Low white blood cell count with a fever (febrile neutropenia)
- Low red blood cell count (anemia) which can leave you easily tired*
- Diarrhea*
- Infections

*Affected 5% or more of accelerated phase patients; affected less than 5% of chronic phase patients.

The most common side effects (occurring in 20% or more of studied patients) in chronic and accelerated phase CML:

- Decreased blood counts (thrombocytopenia, anemia, neutropenia, or lymphopenia)
- Diarrhea
- Nausea
- Tiredness
- Weakness
- Redness, swelling, or pain at injection site
- Fever
- Infections

Please see accompanying Full Prescribing Information beginning on page 3.

For more information, visit SYNRIBO.com

You can receive more resources and support for home administration by contacting SYNCareTM at 1-844-SYNCare

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, call 1-800-FDA-1088, or fax to 1-800-FDA-0178.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Instructions for Use of SYNRIBO®

(omacetaxine mepesuccinate) for Injection, for subcutaneous use

STEP 1: PREPARING TO GIVE AN INJECTION OF SYNRIBO

A

FIND A CLEAN, FLAT WORK SURFACE AND GATHER ALL SUPPLIES BEFORE INJECTING SYNRIBO

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.



B

WASH YOUR HANDS WELL WITH SOAP AND WATER



C

ALWAYS WEAR PROTECTIVE EQUIPMENT

PUT ON PROTECTIVE EQUIPMENT

Put on a pair of gloves and your protective eyewear before you handle the syringe containing SYNRIBO. Wearing gloves and protective eyewear (even if you wear glasses) protects you from splashes or spills. Gather the rest of your supplies and place them on your work surface.



STEP 2: CHOOSE AN INJECTION SITE

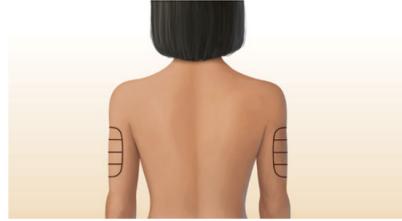
D

SELECT AN APPROPRIATE INJECTION SITE

You may inject SYNRIBO into your thigh or stomach-area (abdomen). The injection can be given in the back of your arm if a caregiver is giving the injection.



Use a different site for each injection to help reduce tenderness at the injection site. Each injection site should be at least 1 inch 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.



STEP 3: PREPARE THE INJECTION SITE

E

CLEAN THE INJECTION SITE

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



STEP 4: INJECT SYNRIBO

F

REMOVE CAP FROM NEEDLE

Carefully remove the needle cap by pulling, taking care not to stick yourself. Do not press down on the plunger. **NEVER recap a needle.**



G

PINCH SKIN AT INJECTION SITE

With one hand, pinch skin of injection site between your thumb and forefinger.



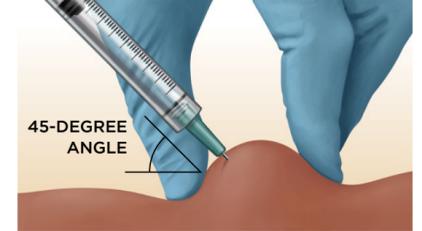
H

INSERT NEEDLE INTO SKIN

With your other hand, hold the syringe at a 45-degree or 90-degree angle to your skin (hold at a 45-degree angle to the skin if there is less fatty tissue).



Use a quick dart-like motion to insert the needle through the skin at the injection site. The needle should go through the skin but not into your muscle.



I

PUSH DOWN ON PLUNGER

Slowly push down on the plunger with your thumb until syringe is empty.



J

REMOVE NEEDLE FROM SKIN

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.



NEVER TRY TO RECAP THE NEEDLE. This could cause a needle stick injury.

DISPOSE OF YOUR MATERIALS

Throw away (dispose of) used SYNRIBO syringes, needles, gloves, and other used supplies in an appropriate biohazard container. Do not place used syringes, needles, or other supplies in a household trash or recycle container.

REMEMBER DO NOT RECAP OR CLIP THE USED NEEDLE.

Do not throw away the protective eyewear. You will need them for each dose of SYNRIBO.



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.

NEVER recap a needle. This could cause a needle stick injury.

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SYNRIBO
(omacetaxine mepesuccinate)
for Injection
FOR SUBCUTANEOUS USE



SYNCare[™]
SUPPORT, ACCESS AND RESOURCES IN SYNC

Figure B

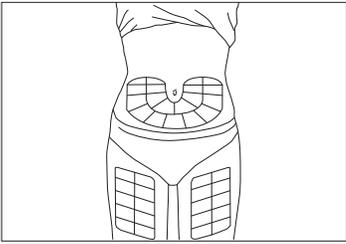
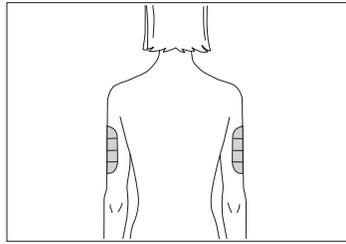
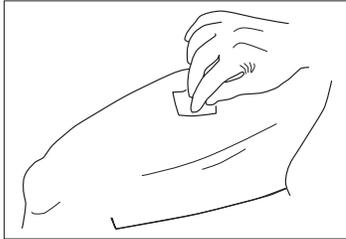


Figure C

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

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

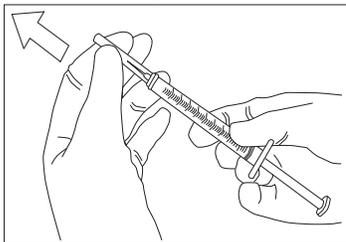
Figure D

**Step 4. Inject SYNRIBO.**

Carefully remove the needle cap by pulling, taking care not to stick yourself. See Figure E.

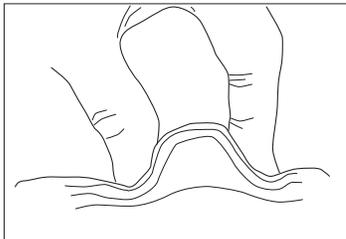
Do not press down on the plunger.

Figure E



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

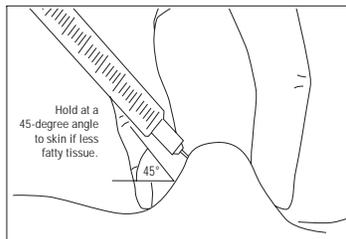
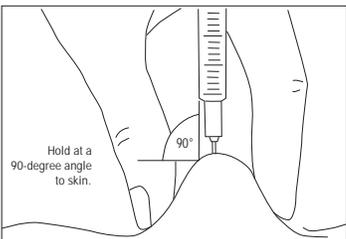
Figure F



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.

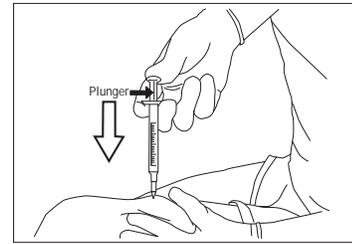
Figure G

Figure H



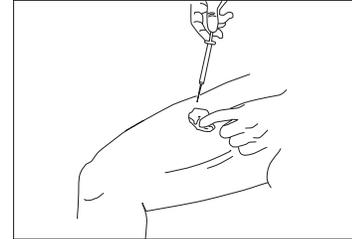
Slowly push down on the plunger with your thumb until syringe is empty. See Figure I.

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, gloves, 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.

Distributed by:

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