

## Teva Pharmaceuticals Safe Needle Collection and Disposal Plan for SYNRIBO<sup>®</sup>

Teva Pharmaceutical Industries Ltd. and Cephalon, Inc., (collectively “Teva Pharmaceuticals” or “Teva”) respectively the manufacturer and marketer of SYNRIBO, a therapy indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI), are committed to ensuring that CML patients have access to the information they need to keep themselves and their households safe and in compliance with local and state sharps disposal laws.

Teva educates healthcare practitioners and patients and their caregivers about the importance of proper needle and syringe disposal through the dissemination of print and digital patient communication materials, as well as through **SYNCare**<sup>™</sup>, the patient support program for SYNRIBO home administration.

**SYNCare** provides 24-hour call center support with access to trained pharmacists and nurses. Patients and their caregiver can call anytime with questions about their SYNRIBO therapy, injection training support, as well as product disposal and cleanup. SYNCare also provides services throughout the treatment process, including:

- Arranging for delivery of prepared syringes of SYNRIBO directly to the home
- Supplying ancillary materials for injection, cleanup, and disposal of injection waste
- Providing self-injection educational materials and resources for patients and their doctors
- Providing to all **SYNCare** patients a biohazard container at no cost to the patient AND providing for prepaid return of used biohazard containers AND subsequent replacement of returned biohazard containers at no cost to patients for those patients continuing SYNRIBO home administration therapy.

Information about proper sharps disposal is available through a number of key SYNRIBO communications, including:

- SYNRIBO Prescribing Information
- SYNRIBO Stylized Instructions for Administration Poster
- SYNRIBO Injection Training Video
- SYNRIBO.com

### **INDICATION**

SYNRIBO is indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI).

### **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 studies 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.

**Please see Important Safety Information continued on next page and accompanying full Prescribing Information.**

# Teva Pharmaceuticals Safe Needle Collection and Disposal Plan for SYNRIPO® (continued)

In these SYNRIPO® (omacetaxine mepesuccinate) for injection, for subcutaneous use, communications, patients are cautioned against the reuse of needles or syringes, advised not to cut or clip needles as a part of the disposal process, and educated about safe disposal and cleanup procedures. Patients are instructed to:

- Put on protective equipment (goggles and gloves that are provided by **SYNCare**) before handling the syringe containing SYNRIPO
- Throw away (dispose of) used SYNRIPO syringes, needles, and other used supplies in an appropriate biohazard container.
- Not to recap or clip the used needle.
- How to handle a spill, including placing all materials that were used for cleaning in the biohazard container and contacting the patient's healthcare provider right away
- Get emergency help if patients inject too much SYNRIPO, or if another person accidentally injects themselves with SYNRIPO, or if anyone accidentally swallows SYNRIPO

Patients interested in learning more about proper needle and syringe disposal may contact **SYNCare** toll-free, day or night, at **1-844-SYNCARE**.

## **IMPORTANT SAFETY INFORMATION (Continued)**

**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:** SYNRIPO 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

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

**Please see accompanying full Prescribing Information.**



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SYN-40379 October 2015. Printed in USA.

**SYNRIBO**  
(omacetaxine mepesuccinate)  
for Injection  
FOR SUBCUTANEOUS USE



**SYNCare**  
SUPPORT, ACCESS AND RESOURCES IN SYNC









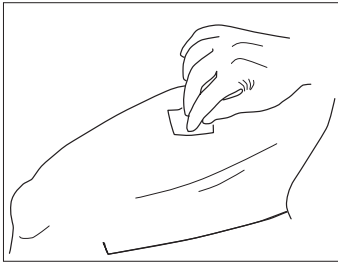






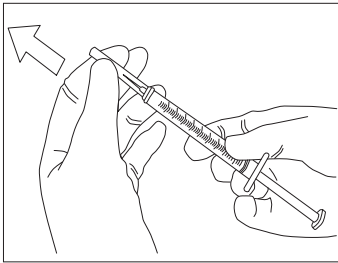


Figure C

**Step 4. Inject SYNRIBO.**

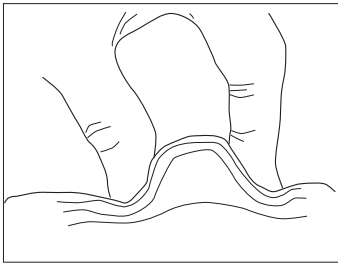
- Carefully remove the needle cap by pulling, taking care not to stick yourself. See Figure D.
- Do not press down on the plunger.

Figure D



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

Figure E



- 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 F and G. The needle should go through the skin but not into your muscle.

Figure F

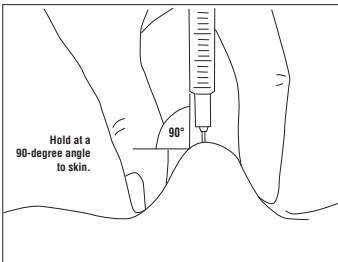
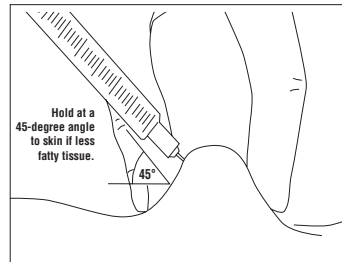
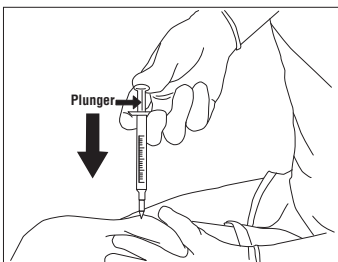


Figure G



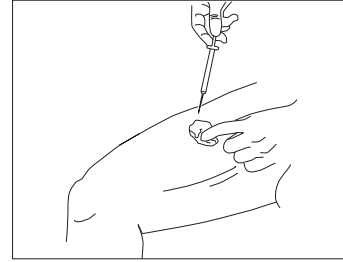
- Slowly push down on the plunger with your thumb until syringe is empty. See Figure H.

Figure H



- 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 I.

Figure I



- Follow the instructions below for how to dispose of the syringe, needle, and other supplies used to give your injection.
- 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 recap or clip the used needle.
- 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:**

Teva Pharmaceuticals USA, Inc.  
North Wales, PA 19454

SYNIFU-001

Issued: April 2014

SYN-40191