

Teva Pharmaceuticals Safe Needle Collection and Disposal Plan for SYNRIBO® (omacetaxine mepesuccinate)

Teva Pharmaceutical Industries Ltd. and Cephalon, Inc., (collectively “Teva Pharmaceuticals” or “Teva”) respectively the manufacturer and marketer of SYNRIBO® (omacetaxine mepesuccinate) for injection, for subcutaneous use, 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™**, 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

In these SYNRIBO 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 SYNRIBO
- Throw away (dispose of) used SYNRIBO 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-SYN-CARE**.

SYNRIPO® (omacetaxine mepesuccinate) for Injection, for subcutaneous use, 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).

Important Safety Information

Warnings and Precautions

Low Blood Counts: SYNRIPO 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.

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

Important Safety Information (continued)

- 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, call 1-800-FDA-1088, or fax to 1-800-FDA-0178.

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