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Teva Pharmaceuticals Needle Collection and Disposal Plan for COPAXONE[®] (glatiramer acetate injection)

Teva Pharmaceutical Industries Ltd. and Teva Neuroscience, Inc. (collectively "Teva Pharmaceuticals" or "Teva"), respectively the manufacturer and marketer of COPAXONE[®], a therapy indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), are committed to ensuring that MS 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.

Information about proper FDA-cleared sharps disposal is available through a number of key COPAXONE[®] communications, including:

- COPAXONE[®] Prescribing Information
- Injection Guide
- COPAXONE.com

In Teva's COPAXONE[®] communications, patients are cautioned against the reuse of needles or syringes and educated about safe disposal procedures. Patients are instructed to:

- Check with their local health department, doctor's office, or pharmacist for guidance and follow local regulations for disposal
- Dispose of used syringes into a hard-walled plastic container or disposable, biohazard, FDA-cleared sharps container immediately after injection
- Use each COPAXONE[®] prefilled syringe for only 1 injection
- Always keep the waste container in an area of the home that is out of the reach of children and pets
- Consider using a needle clip device, which snaps the used needle off the syringe and houses it within a protective compartment
 - Follow local regulations for needle disposal

Patients interested in learning more about proper needle and syringe disposal should speak to their doctor.

What is COPAXONE?

COPAXONE is a prescription medicine that is used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

It is not known if COPAXONE is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

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

• Serious allergic reactions (anaphylactic reactions). Serious allergic reactions that may be life-threatening or lead to death may happen any time after you start using COPAXONE. These reactions may happen right after your first dose up to years after starting treatment with COPAXONE, even if you never had an allergic reaction before. Many reactions have happened within 1 hour of using COPAXONE. Some signs and symptoms may be the same as those of an immediate post-injection reaction. See What are the possible side effects of COPAXONE?

Stop using COPAXONE and get emergency help right away if you have:

- o widespread rash
- o swelling of the face, eyelids, lips, mouth, throat, or tongue
- o sudden shortness of breath, difficulty breathing, or wheezing
- o uncontrolled shaking (convulsions)
- o trouble swallowing or speaking
- o fainting, feeling dizzy or faint

Do not take COPAXONE:

• if you are allergic to glatiramer acetate or mannitol. Serious allergic reactions including lifethreatening or anaphylactic reactions that can lead to death have happened.

What should I tell my healthcare provider before taking COPAXONE? Before you use COPAXONE, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. Talk to your healthcare provider who will advise if you should take COPAXONE during your pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if COPAXONE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using COPAXONE.

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

COPAXONE may affect the way other medicines work, and other medicines may affect how COPAXONE works.



IMPORTANT SAFETY INFORMATION (CONTINUED)

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of COPAXONE?

COPAXONE may cause serious side effects, including:

Immediate Post-Injection Reactions. Serious side effects may happen right after or within minutes after you inject COPAXONE at any time during your course of treatment. Some signs and symptoms may be the same as those of a serious allergic reaction (anaphylaxis).
See What is the most important information I should know about COPAXONE? Call a healthcare provider right away if you have any of these immediate post-injection reaction symptoms including:

o redness to your cheeks or other	o anxiety
parts of the body (flushing)	o breathing problems or
o chest pain	tightness in your throat
o fast heartbeat	o swelling, rash, hives, or itching

If you have symptoms of an immediate post-injection reaction, do not give yourself more injections until a healthcare provider tells you to.

- **Chest Pain.** You can have chest pain as part of an immediate post-injection reaction or by itself. This type of chest pain usually lasts a few minutes and can begin around 1 month after you start using COPAXONE. Call your healthcare provider right away if you have chest pain while using COPAXONE.
- **Damage to your skin.** Damage to the fatty tissue just under your skin's surface (lipoatrophy) and, rarely, death of your skin tissue (necrosis) can happen when you use COPAXONE. Damage to the fatty tissue under your skin can cause a "dent" at the injection site that may not go away. You can reduce your chance of developing these problems by:

o following your healthcare provider's instructions for how to use COPAXONE

o choosing a different injection area each time you use COPAXONE.

- Liver problems. Liver problems, including liver failure, can occur with COPAXONE. Call your healthcare provider right away if you have symptoms, such as:
 - o nausea o loss of appetite o tiredness
- o yellowing of your skin or the
- white part of your eye
 - o bleeding more easily than normal
- o dark colored urine and pale stools
- o confusion o sleepiness





IMPORTANT SAFETY INFORMATION (CONTINUED)

What are the possible side effects of COPAXONE? (continued)

The most common side effects of COPAXONE are:

- Skin problems at your injection site, including:
 - o redness
 - o lumps
 - o pain
 - o itching
 - o swelling
- rash
- shortness of breath
- flushing (vasodilation)
- chest pain

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

These are not all the possible side effects of COPAXONE. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call 1-800-FDA-1088.

Please click <u>here</u> to read/print the Medication Guide or visit <u>www.COPAXONE.com</u>.



