

Medication Guide
COPAXONE (co-PAX-own)
(glatiramer acetate injection)
for subcutaneous use

Read this Medication Guide before you start using COPAXONE and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

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:

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

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.

Do not take COPAXONE:

- if you are allergic to glatiramer acetate or mannitol. Serious allergic reactions including life-threatening or anaphylactic reactions that can lead to death have happened. See the end of this leaflet for a complete list of the ingredients in 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.

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.

How should I use COPAXONE?

- For detailed instructions, see the **Instructions for Use** at the end of this leaflet for complete information on how to use COPAXONE.
- Your healthcare provider will tell you how much COPAXONE to use and when to use it.
- COPAXONE is given by injection under your skin (subcutaneously).
- Use COPAXONE exactly as your healthcare provider tells you to use it.
- Since every body type is different, talk with your healthcare provider about the injection areas that are best for you.
- You should receive your first dose of COPAXONE with a healthcare provider or nurse present. This might be at your healthcare provider's office or with a visiting home health nurse who will teach you how to give your COPAXONE injections.
- Some glatiramer acetate products can be used with an optional compatible autoinjector. Compatible autoinjectors are supplied separately if available, but the availability of compatible autoinjectors may change with time.
 - Check with your healthcare provider when you fill or refill your medicine to make sure the autoinjector you have is meant to be used with your glatiramer acetate product. Not all optional autoinjectors are meant to be used with all glatiramer acetate products. If you use the wrong autoinjector, you might not get the correct dose of your medicine. Contact the manufacturer of your glatiramer acetate product to find out if there is an autoinjector that is meant to be used with your glatiramer acetate product.
- Read your Instructions for Use and talk to your healthcare provider about the best way for you to use COPAXONE.

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:

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| ○ redness to your cheeks or other parts of the body (flushing) | ○ anxiety |
| ○ chest pain | ○ breathing problems or tightness in your throat |
| ○ fast heartbeat | ○ 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:
 - following your healthcare provider's instructions for how to use COPAXONE
 - choosing a different injection area each time you use COPAXONE. See Step 4 in the Instructions for Use, "Choose your injection area".

COPAXONE® (glatiramer acetate injection)

- **Liver problems.** Liver problems, including liver failure, can occur with COPAXONE. Call your healthcare provider right away if you have symptoms, such as:

- nausea
- loss of appetite
- tiredness
- dark colored urine and pale stools
- yellowing of your skin or the white part of your eye
- bleeding more easily than normal
- confusion
- sleepiness

The most common side effects of COPAXONE are:

- skin problems at your injection site, including:
 - redness
 - pain
 - swelling
 - lumps
 - itching
- 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 may report side effects to FDA at 1-800-FDA-1088.

How should I store COPAXONE?

- Store COPAXONE in the refrigerator between 36°F to 46°F (2°C to 8°C).
- When you are not able to refrigerate COPAXONE, you may store it for up to 1 month at room temperature between 59°F to 86°F (15°C to 30°C).
- Protect COPAXONE from light or high temperature.
- Do not freeze COPAXONE syringes. If a syringe freezes, throw it away in a sharps disposal container. **See Step 13 in the Instructions for Use, "Dispose of your needles and syringes".**

Keep COPAXONE and all medicines out of the reach of children.

General information about the safe and effective use of COPAXONE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use COPAXONE for a condition for which it was not prescribed. Do not give COPAXONE to other people, even if they have the same symptoms as you have. It may harm them. You can ask your pharmacist or healthcare provider for information about COPAXONE that is written for health professionals.

What are the ingredients in COPAXONE?

Active ingredient: glatiramer acetate

Inactive ingredients: mannitol

Manufactured for: Teva Neuroscience, Inc., Parsippany, NJ 07054

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COPMG-001



For more information, go to www.copaxone.com or call 1-800-887-8100

This Medication Guide has been approved by the U.S. Food and Drug Administration
Revised: January 2025

COP-46907