

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

**COPAXONE® 40 MG/ML  
Solution for injection in pre-filled pen  
For subcutaneous injection only**

**Composition**

Each Copaxone 40 mg/ml pen (1 ml) contains: glatiramer acetate 40 mg

For information on inactive ingredients see section 6 "Additional information".

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

**This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.**

**This medicine is intended for subcutaneous injection only.**

**This medicine is not intended for use in children or adolescents below 18 years of age.**

**1. What is this medicine intended for?**

Copaxone 40 mg/ml modifies the way in which your body's immune system works. The symptoms of multiple sclerosis are thought to be caused by a defect in the body's immune system. This produces areas of inflammation in the brain and spinal cord.

Copaxone 40 mg/ml is indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis.

**Therapeutic group:**

Immune system stimulant.

**2. Before using this medicine**

**Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredient (glatiramer acetate) or to any of the additional ingredients contained in the medicine (see section 6 – "Additional information" in this leaflet).

**Special warnings about using this medicine**

Before starting treatment, inform the doctor or pharmacist if:

- you suffer from kidney or heart problems, since regular testing and monitoring may be necessary.
- you suffer from or have ever suffered from liver problems (including those due to alcohol consumption).

**Use in children**

This medicine is not intended for use in children under 18 years of age.

**Use in the elderly**

Copaxone has not been specifically studied in the elderly. Please consult your doctor if you belong to this population group.

**Interactions with other medicines**

**If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.**

**Pregnancy and breastfeeding**

Consult a doctor regarding the use of Copaxone during pregnancy. Contact your doctor if you are pregnant, think you are pregnant or if you are planning a pregnancy.

Limited data from use in humans showed no negative effects of Copaxone on breastfed newborns/infants. Copaxone can be used during breastfeeding.

**Driving and using machines**

As far as is known, Copaxone 40 mg/ml has no effect on the ability to drive or operate machines.

**3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

**Only your doctor will determine your dose and how you should take this medicine. The recommended dose is usually:**

The dosage in adults is one pre-filled pen (40 mg glatiramer acetate), administered subcutaneously 3 times a week at intervals of at least 48 hours (for example Sundays, Tuesdays and Thursdays). It is recommended to inject the medicine on the same days every week.

**Carefully read the instructions for use at the end of this leaflet before using the pre-filled pen**

It is very important to inject Copaxone 40 mg/ml correctly:

- Inject into the tissue under the skin (subcutaneous tissue) only (see section "Instructions for use").
- Use the dose that has been determined by your doctor. Use only the dosage that your doctor has prescribed for you.
- Never use a pen more than once. Discard any waste or unused remainder of the product.
- Do not mix or use the contents of the Copaxone 40 mg/ml pen together with any other medicine.
- Check the solution appearance through the viewing window on the side of the pen. Do not use a solution in which particles have been discovered. In such case, use a new pen.

**Do not exceed the recommended dose.**

The first time you use Copaxone 40 mg/ml, you will be supervised by a doctor or nurse, from whom you will receive full instructions. The doctor or nurse will be with you when you inject the medicine to yourself and for half an hour afterwards, just to make sure that you do not encounter any problems.

Inform the doctor if you have the impression that the effect of Copaxone 40 mg/ml is too strong or too weak.

**If you accidentally use a higher dose**

If you used more than one pen of Copaxone in a day, or if a child has accidentally used the medicine, immediately contact a doctor or proceed to a hospital emergency room, and bring the medicine package with you.

**If you forgot to use Copaxone 40 mg/ml**

If you forgot to use Copaxone 40 mg/ml at the scheduled time, inject a dose as soon as you remember; then skip the next day. Do not under any circumstances use two doses together to make up for the forgotten dose. If possible, you should return to the usual dosage regimen the following week.

**Follow the treatment as recommended by the doctor.**

Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor.

**If you stop using Copaxone 40 mg/ml**

Do not stop using Copaxone 40 mg/ml without consulting the doctor.

**Do not use medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them.**

**If you have further questions about using this medicine, consult your doctor or pharmacist.**

**4. Side effects**

As with any medicine, using Copaxone may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**Allergic reactions (hypersensitivity)**

Occasionally a serious allergic reaction to this medicine may develop, but it is not common.

**If you experience any of the following side effects, stop using the medicine and tell the doctor immediately, or proceed to the nearest hospital:**

- Swelling of the eyelids, face or lips
- Rash (red spots or nettle rash)
- Convulsions (fits)
- Sudden shortness of breath
- Fainting

**Additional side effects following injection (immediate post-injection reaction)**

Some patients may experience one or more of the following symptoms within minutes after injecting Copaxone 40 mg/ml. These symptoms do not cause any problems and usually disappear within half an hour. However, if the following

symptoms last more than 30 minutes, tell your doctor immediately or proceed to the emergency room of the nearest hospital:

- Flushing (redness) of the face and/or chest (dilation of blood vessels)
- Shortness of breath
- Chest pain
- Rapid and strong heartbeat (palpitations, tachycardia)

**Liver problems**

Liver problems or worsening of liver problems, including liver failure (some cases resulting in liver transplantation), can occur rarely with Copaxone use. Contact your doctor right away if you have symptoms such as:

- Nausea
- Loss of appetite
- Dark colored urine and pale stools
- Yellowing of your skin or the white part of your eye
- Bleeding more easily than normal

**In general, side effects reported by patients using Copaxone 40 mg/ml three times a week were also reported in patients who used Copaxone 20 mg/ml (see the list below)**

**Very common side effects (affecting more than 1 in 10 patients):**

- Nausea
- Feeling weak, skin reactions at the injection site, including reddening of the skin, pain, formation of swelling (local skin edema, light pink in color, usually accompanied by itchiness), itching, tissue swelling, inflammation and hypersensitivity (these reactions at the injection site are not unusual and usually decrease with time), non-specific pain
- Infections, flu
- Pain in the joints or back
- Headache
- Anxiety, depression
- Skin rash

**Common side effects (affecting up to 1 in 10 patients):**

- Swollen lymph nodes
- Ear problems
- Eye problems, double vision
- Problem at the anus or rectum, constipation, caries, indigestion, difficulty swallowing, bowel incontinence, vomiting
- Chills, local reaction, peripheral swelling due to accumulation of fluids, swollen face, fever, loss of subcutaneous tissue at the injection site
- Allergic reactions
- Inflammation of the respiratory tract, inflammation of the stomach and intestine (gastroenteritis), ear inflammation, runny nose, cold sores, dental abscess, vaginal thrush
- Abnormal liver function test results
- Weight gain, loss of appetite
- Neck pain
- Non-malignant tumors in the skin and tissue
- Altered taste, increased muscle tension (tone), migraine, problems with speech, fainting, tremor
- Irritability
- A feeling of urinary urgency, high frequency of passing urine, inability to properly empty the urinary bladder
- Cough, hay fever
- Bruising, excessive sweating, itching, nettle rash, skin problems

**Uncommon side effects (affecting up to 1 in 100 patients):**

- Changes in the number or form of white blood cells, low number of platelets, enlarged spleen
- Extra heartbeats, slow heartbeats, episodic fast heartbeats (irregularity of the heart rhythm)
- Enlarged or overactive thyroid gland
- Cataract, lesion on the eye's cornea, dry eye, bleeding inside the eye, drooping eyelids, widening of the pupil, damage to the optic nerve leading to visual problems
- Burping, enlarged salivary glands, esophageal ulcer, inflammation of the gums, intestinal inflammation, polyps in the large intestine, rectal bleeding
- Cyst, hangover, hypothermia, non-specific inflammation, destruction of tissue at the injection site, problems with mucous tissues
- Abscesses, inflammation of the skin and of the soft tissue under the skin, purulent wounds, kidney inflammation, herpes (shingles)
- Disturbances after receiving a vaccination
- Gallstones, enlarged liver
- Low alcohol tolerance, gout, increase in blood fat levels, changes in the blood (high sodium, low ferritin)
- Swelling, inflammation and pain of the joints (arthritis or osteoarthritis), inflammation and pain in the fluid sac lining the joint (exists in some of the joints), pain in the upper abdomen or back and on the sides of the body, decrease in muscle mass
- Skin cancer
- Hand numbness and pain (carpal tunnel syndrome), mental illness, convulsions, writing and reading problems, muscle problems, muscle spasm, problems with movement, nerve inflammation, abnormal nerve-muscle connection leading to abnormal muscle function, paralysis, rapid involuntary movement of the eyeball, difficulty lifting the front part of the foot (neural paralysis), condition of lack of consciousness (stupor), blind spots in the visual field
- Unusual dreams, confusion, abnormal mood elevation (euphoric mood), hallucinations (seeing, hearing, smelling, tasting or feeling things that do not exist in reality), aggressiveness, personality disorder, suicide attempt
- Blood in the urine or other urinary system problem, kidney stones, abnormal urine
- Swollen breasts, vaginal problems, vaginal bleeding, abnormal cervical smear test, persistent erection, erection difficulties, problems in the prostate gland or testes, pelvic organ prolapse
- Temporary stops in breathing, problems in the lungs, sensation of pressure in the throat, inability to breath due to pressure in the throat (choking sensation), abnormally fast or deep breathing (hyperventilation), nosebleed
- Swelling of the skin and of the soft tissues, skin contact rash, skin lumps, painful red skin lumps
- Varicose veins

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

**Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.

**Storage conditions:** Store in the refrigerator (2°C-8°C). The pens can be stored outside the refrigerator, at a temperature between 15°C and 25°C, for a period of up to one month. This can be done only once.

After a month outside the refrigerator, if Copaxone 40 mg/ml pens have not yet been used and are in their original package, they should be returned to the refrigerator.

Do not freeze the Copaxone 40 mg/ml pre-filled pens.

Keep the pre-filled pens in their original carton in order to protect from light.

Do not use the pre-filled pen and it should be discarded if particles are visible in the solution it contains.

Do not dispose of any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

**6. Additional information**

**In addition to the active ingredient, this medicine also contains:**

Mannitol, water for injection

**What the medicine looks like and contents of the package**

The pre-filled pen is a white plastic body with a viewing window and a light blue needle safety shield with a transparent protective cap on it.

The pen contains clear fluid.

Each package contains 3, 12 or 36 pre-filled pens. Not all pack sizes may be marketed.

**Name and address of the manufacturer and license holder**

Teva Israel Ltd.,  
124 Devora HaNevi'a St., Tel Aviv 6944020

**This leaflet was revised in June 2023 according to Ministry of Health guidelines.**

Registration number of the medicine in the Ministry of Health's National Drug Registry:  
Copaxone 40 mg/ml 151.75.34057

**Instructions for use**

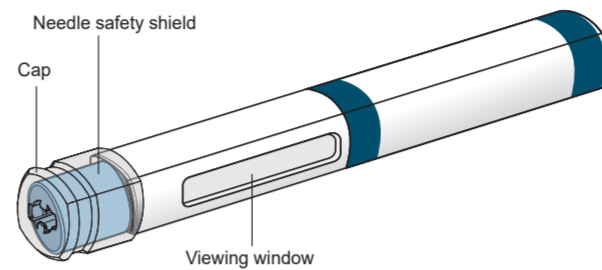
Carefully read these instructions before using Copaxone 40 mg/ml solution in a pre-filled pen. Keep the instructions for use until you use all the pre-filled pens in the package. The pre-filled pen is intended for single use only and should be discarded after use. The needle will be automatically covered immediately after the medicine is injected.

**Warnings**

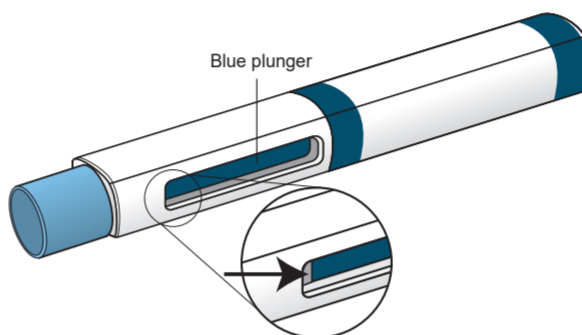
Do not touch the needle after removing the cap in order not to contaminate it. Do not try to use the pre-filled pen more than once due to the concern of injury or infection.

Do not refill the pen with other medical substances or change any of the pen components.

**What the pre-filled pen looks like before use**



**What the pre-filled pen looks like after use**



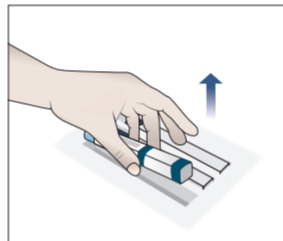
The blue plunger gradually slides down the viewing window during the injection. When the viewing window is filled, the injection is complete.

Hold the pen so that your hand does not hide the viewing window during the injection.

Attention: When the blue plunger fills the viewing window, you will still be able to see the grey stopper, as shown in the above figure.

**1. Take the pre-filled pen out of the pack**

Take one pre-filled pen out of the external package



**2. Collecting the required equipment**

Collect the following equipment and place it on a flat clean surface

- one pre-filled pen
- one alcohol wipe (not included in the pack)
- one gauze pad or cotton ball (not included in the pack)
- a sharps container or a puncture-proof container (not included in the pack)

If you do not have a sharps container, talk to the pharmacist or healthcare professional.

**3. Check the pre-filled pen**

Check that the pre-filled pen is not damaged (e.g. not cracked or leaking).

Check that the pre-filled pen is labeled with "Solution in a pre-filled pen".

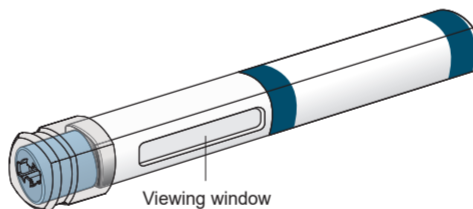
Check the expiry date.

Do not use the pre-filled pen if it is expired, damaged or if you have received a wrong medicine.

Do not use the pre-filled pen if the cap is missing or damaged.

Check that the solution in the viewing window is clear.

Attention: Small air bubbles may appear in the liquid; they are harmless and can be injected with the solution. Do not try to remove them before the injection.



Do not use the pen if the solution contains any particles. Do not use the pen if the medicine has been frozen.

**4. Wait 20 minutes**

Place the pre-filled pen on a clean flat surface.

If the pen has been stored in the refrigerator, wait 20 minutes to allow the medicine to reach room temperature.



Attention: Injecting cold medicine will not cause any damage but may be unpleasant.

Do not expose the pre-filled pen to direct sunlight since this may damage the medicine.

Do not warm the pre-filled pen in any way other than described above since this may damage the medicine.

**5. Wash your hands**

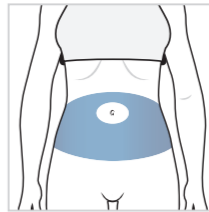
Wash your hands with soap and water and dry them thoroughly with a clean towel.

**6. Choose and prepare the injection site**

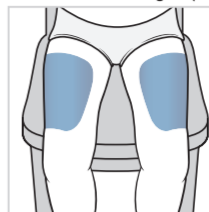
Choose an injection site in the injection area, use the diagrams.

There are 7 possible injection areas on your body.

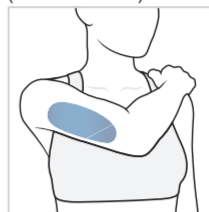
Area 1: Abdominal area around the belly button. Avoid injecting 5 cm around the belly button.



Areas 2 and 3: Thighs (above the knees).



Areas 4, 5, 6 and 7: Back of the upper arms and back of the upper hips (below the waist).



Within each injection area, there are several injection sites. Choose a different site for each injection; this will reduce the chance of irritation or pain at the injection site.

Rotate the injection areas and the injection sites within an injection area. **Do not use the same injection site each time.**

**Attention:** Do not inject in any area that is painful or discolored or where you feel firm lumps.

It is advisable to prepare a scheduled plan for injection site rotation and to record the injection sites in a diary. Some sites on your body may be difficult for self-injection (like the back of the arm). If you want to use them, you may need help.

Clean the chosen injection area with an alcohol wipe.

Wait 10 seconds to allow the skin to dry before the injection.

Do not inject Copaxone 40 mg/ml in areas that are painful or discolored or where you feel lumps.

Do not inject through clothing.

Do not inject with the pre-filled pen at the same site more than once a week.

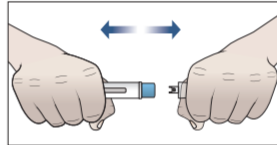
**7. Remove the cap**

Hold the pre-filled pen in one hand.

With the other hand, grasp the cap as shown in the diagram and pull it straight off the pen.

Do not remove the cap with your mouth or teeth.

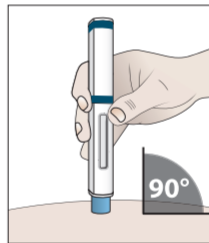
Discard the cap immediately.



Do not try to cover the needle again at any stage to prevent contamination. Do not touch the needle after removing the cap to prevent contamination. Do not cover the needle again even if it has not been used.

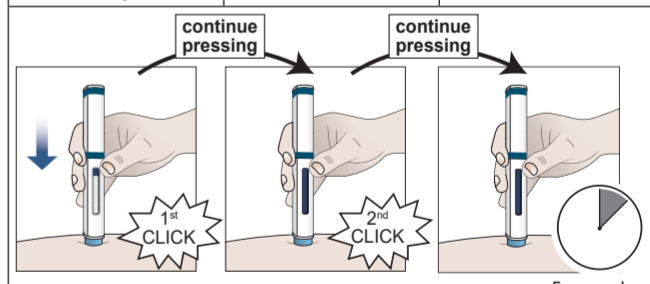
**8. Inject**

a. Place the pre-filled pen on your skin at the injection site at a 90° angle.



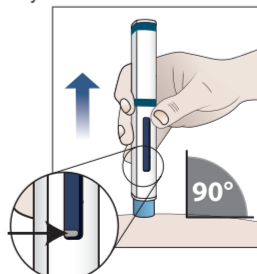
**b. Press the pen down and keep pressing it down for about 15 seconds, do not stop pressing until all the following steps are completed.**

- |   |   |   |
|---|---|---|
| - You will hear a first "click" (the injection has begun; the blue plunger starts moving downwards) | - You hear a second "click" (about 5 to 10 seconds after the first click) | - Wait 5 additional seconds (to ensure that all the medicine has been injected) |
|---|---|---|



Attention: When the needle safety shield is pushed back fully, the needle will penetrate your skin.

c. Check that the blue plunger fills the viewing window and remove the pen from your skin.



Attention: When the blue plunger fills the viewing window, the grey stopper can still be seen.

**9. Disposal**

Immediately discard the used pre-filled pen into a sharps container or a puncture-proof container.

• Discard the pen into a sharps container or a puncture-proof container. Do not discard used pens into household waste but discard them carefully into a sharps container or a puncture-proof container as recommended by the doctor or nurse.

**10. Care of the injection site**

Examine the injection site.

If you see a blood drop, you can place a clean cotton ball or gauze pad on the injection site.

You can place a bandage/plaster on the injection site, if you wish.

Do not rub the injection site since this may cause discomfort.

**The injection has been completed.**

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