322K55388-03
PE2830-04

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986
This medicine is dispensed with a doctor's prescription only

COPAXONE® 20 mg/ml
Solution in pre-filled syringe

For subcutaneous injection only

Composition
Each Copaxone 20 mg/ml syringe (1 ml) contains:
glatiramer acetate 20 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 20 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 20 mg/ml is indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis.
Copaxone 20 mg/ml is indicated for the treatment of patients after a first clinical episode that indicates a high risk of developing 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 20 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 daily dosage in adults over the age of 18 is one pre-filled syringe (20 mg glatiramer acetate), administered subcutaneously.

It is very important to inject Copaxone 20 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 syringe more than once. Discard any waste or unused remainder of the product.
- Do not mix or use the contents of the Copaxone 20 mg/ml syringe together with any other medicine.
- Do not use a solution in which particles have been discovered. In such case, use a new syringe.

Do not exceed the recommended dose.
The first time you use Copaxone 20 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.

Instructions for use
Carefully read these instructions before using Copaxone 20 mg/ml.

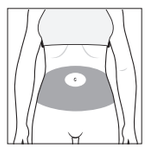
Before the injection, make sure you have everything you need:
- One blister (one tray) with a Copaxone 20 mg/ml pre-filled syringe
- Container for disposal of used needles and syringes
- For each injection, take only one blister (one tray) with a pre-filled syringe out of the package. Keep the remaining syringes in the box.
- If the syringe was stored in the refrigerator, remove the blister (tray) containing the syringe from the refrigerator at least 20 minutes before you inject the medicine, in order to enable it to reach room temperature.

Wash your hands thoroughly with soap and water.

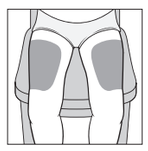
Choose the injection site in the injection area, use the following figures.

There are seven possible injection areas on your body:

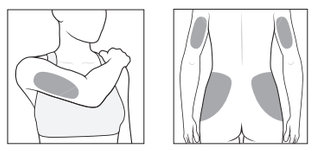
Area 1: Abdominal area around the belly button. Avoid injecting 5 cm around the belly button.



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

Note: 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. There are some sites on your body that may be difficult for self-injection (like the back of your arm). If you want to use them, you may need help.

How to inject:
- Remove the syringe from the blister (tray) by pulling back the blister tab.
- Remove the needle shield, do not remove the shield using your mouth or teeth.
- Gently pinch skin with the thumb and forefinger of the free hand (see Figure 1).
- Insert the needle into the skin as shown in Figure 2.
- Inject the medicine by steadily pushing the plunger rod all the way down until the syringe is empty.
- Pull the syringe and needle straight out.
- Discard the syringe in the container for disposal of used needles and syringes. Do not discard used syringes into household waste, but rather carefully discard them in the container that is intended for this as recommended to you by the doctor or nurse.

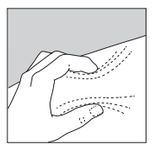


Figure 1

Figure 2

Inform the doctor if you have the impression that the effect of Copaxone 20 mg/ml is too strong or too weak.

If you accidentally use a higher dose
If you used more than one syringe of Copaxone 20 mg/ml 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 20 mg/ml
If you forgot to use Copaxone 20 mg/ml at the scheduled time, inject a dose as soon as you remember; however, under no circumstances should you use two doses together to make up for the forgotten dose. Inject the next dose 24 hours later.

Follow the treatment as recommended to you 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 20 mg/ml
Do not stop using Copaxone 20 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)
In rare cases, a serious allergic reaction to this medicine may develop.
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 20 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

The following side effects were reported during use of Copaxone:

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) 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 syringes 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 20 mg/ml syringes have not yet been used and are in their original package, they should be returned to the refrigerator.
Do not freeze the Copaxone 20 mg/ml pre-filled syringes.
Keep the pre-filled syringes in their original carton package in order to protect from light.
Do not use the pre-filled syringe 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 pack
A glass syringe containing a transparent, colorless fluid.
Each package contains 28 pre-filled syringes.

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 20 mg/ml: 128 06 30681

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