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COPAXONE®

This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved
PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

COPAXONE® 20 mg/ml
Pre-filled syringe
For subcutaneous injection only

COPAXONE® 40 mg/ml
Pre-filled syringe
For subcutaneous injection only

Composition
Each Copaxone® 20 mg/ml syringe (1 ml) contains:
Glatiramer Acetate 20 mg
Each Copaxone® 40 mg/ml syringe (1 ml) contains:
Glatiramer Acetate 40 mg

For the list of inactive ingredients in the preparation, see section 6 - "Further Information".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for subcutaneous injection only.

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

1. WHAT IS THIS MEDICINE INTENDED FOR?

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 who have experienced a first clinical episode indicating a high risk for developing multiple sclerosis.

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

Multiple sclerosis (MS) is manifested by symptoms arising from an impaired immune system in the body. This condition leads to formation of inflammatory regions in the brain and spinal cord. The mechanism of action of Copaxone® in treating MS is not known with certainty, but the working hypothesis is that Copaxone® acts by changing the immune processes which are considered responsible for development of the ailment.

Please ask the doctor or pharmacist if you want to further inquire about why this product was prescribed for you.

Therapeutic group:

Immune system stimulant.

2. BEFORE USING THE MEDICINE

❗ Do not use the preparation:

- If there is a known sensitivity to any of the ingredients of the medicine (see section 6 – "Further Information" in this leaflet).
- If you are pregnant.

When using Copaxone® be sure to:

Consult a doctor if you are suffering from kidney or heart problems, as there may be a need to have regular tests and check-ups.

Copaxone® has not been specifically studied in the elderly population. Consult your doctor in this regard.

Special warnings regarding use of the medicine

❗ Before starting treatment, inform the doctor in detail regarding your medical condition, including in the following cases:

- If you are sensitive to any food or medicine, inform the doctor before starting treatment.
- If you are suffering, or have suffered in the past, from any medical problems, especially asthma, or a history of severe allergic reactions.
- If you are due to undergo surgery under general anesthesia.

❗ Tell the doctor or pharmacist if you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements.

❗ Pregnancy and breastfeeding

Do not use this medicine during pregnancy.

Consult a doctor or pharmacist before taking this medicine if you are breastfeeding, if you became pregnant while using this medicine, if you are planning to become pregnant. You should use an effective contraceptive method during the course of treatment with Copaxone®.

❗ Use in children

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

❗ Driving or operating machinery

Copaxone® is not known to have an effect on the ability to drive or operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure about how to use.

- Use this medicine at a specified time, as determined by the attending doctor.
- Do not use the syringe more than once. Discard all waste or remainder of the product.
- Do not mix the contents of Copaxone® syringe with any other product.
- Do not use solution in which particles have been observed. Use a new syringe.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

Copaxone® 20 mg/ml:

The recommended dosage is one Copaxone® 20 mg/ml syringe administered subcutaneously, once a day.

Copaxone® 40 mg/ml:

The recommended dosage is one Copaxone® 40 mg/ml syringe administered subcutaneously, 3 times a week. It is recommended to inject the medicine on the same days of the week (at intervals of at least 48 hours, for example: Monday, Wednesday and Friday).

Do not exceed the recommended dose.

Do not change the dosage or dosage regimen and do not discontinue treatment with Copaxone® without consulting the doctor.

Instructions for use of the medicine

Please see instructions at the end of the leaflet.

If you accidentally took an overdose of the medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine.

If you forgot to inject the medicine

If you forgot to use Copaxone® at the specified time, inject a dose as soon as you remember, but never use two doses together. Inject the next dose at the regular time.

Adhere to the treatment instruction as provided to you by the doctor, even if there is an improvement in your health condition. Do not discontinue treatment without consulting the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, Copaxone® may cause side effects in some patients. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Some patients may feel, after a few minutes, a side effect known as an immediate post-injection reaction. This reaction is manifested by the following symptoms:

- Flushing (redness) in the face and/or neck
- Chest pain or tightness
- Sensation of rapid and strong heartbeat
- Anxiety and difficulty breathing

These side effects of the medicine are mild, last for a short time only and usually pass within about half an hour. If they last for more than 30 minutes, tell the doctor immediately or proceed to the nearest hospital emergency room.

Some of the patients will experience only one round of these side effects during the course of treatment.

If you feel one of the following side effects, discontinue use of the medicine and tell the doctor immediately, or proceed to the nearest hospital:

- Swelling in the face, lips, mouth or throat, which may cause swallowing or breathing difficulties
- Rash
- Convulsions
- Urticaria (an allergic reaction of the skin)
- Chest pain
- Difficulty breathing
- Fainting
- Strong pain, redness or swelling that does not disappear at the injection site

These side effects are very severe. If you felt them, you may have already developed an allergic reaction to Copaxone®. You may need emergency medical care or to be hospitalized.

These side effects are very rare.

The following side effects have been reported during the use of Copaxone® 20 mg/ml administered once a day:

These side effects have been reported, at a similar frequency, in patients using Copaxone® 40 mg/ml administered 3 times a week.

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

- Reactions at the injection site which included: reddening of skin, pain, formation of pus, itching, tissue swelling, inflammation and hypersensitivity at the injection site. These local reactions are not unusual and usually pass over time.
- Nausea
- Feeling weak, chest pain, 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
- Rapid and strong heartbeats
- Ear problems
- Blurred vision, double vision
- Constipation, caries (teeth problems), indigestion, difficulty swallowing, bowel incontinence, vomiting
- Chills, local reactions, accumulation of fluids (edema), swollen ankles, swollen face, high fever, loss of the fat tissue under the skin at the injection site
- Allergic reactions
- Infection of the respiratory tract, stomach, ears, runny nose, cold sores (herpes), gum abscess, vaginal thrush
- Abnormal liver function test results
- Weight gain, loss of appetite
- Pain in the neck
- Lumps in the skin and tissue
- Altered taste, abnormal tension of arteries or muscles, migraine, problems with speech
- Fainting, tremor
- Nervousness
- Inability to pass urine, feeling the urge to pass urine more often, high frequency in passing urine
- Cough, hay fever
- Bruising, excessive sweating, itching, urticaria and other skin problems

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

- Change in number or form of white blood cells, decreased number of platelets, enlarged spleen
- Fast or slow heartbeats
- Enlarged or overactive thyroid
- Cataract, scratches on the eyeball, dry eye, bleeding in the eye, droopy eyelids, widening of the pupil, abnormal vision or loss of vision
- Burping, enlarged salivary glands, sores in the gullet, inflammation of the gums, intestinal inflammation, polyps in the large intestine, rectal bleeding
- Cyst, hangover, hypothermia, non-specific inflammation, destruction of tissues at the injection site, problems with mucous membranes
- Abscess, boils, infection of skin or kidney, herpes (shingles)
- Post vaccination syndrome (like tiredness after vaccination)
- Gallstones, enlarged liver
- Alcohol intolerance, gout, an excess of fats in the blood, changes in the blood (high sodium, low ferritin)
- Swollen joints (arthritis or osteoarthritis), decrease in muscle mass
- Skin cancer
- Hand numbness and pain, mental disease, convulsions, writing and reading problems, muscle spasm, loss of muscle tone, nerve inflammation, muscle weakness, paralysis, eye blinking, footdrop, stupor, partial blindness
- Miscarriage
- Strange dreams, confusion, abnormal activity or happiness, hallucinations (seeing or hearing things that do not exist in reality), aggressiveness, personality change, suicidal tendencies
- Blood in the urine or other problem in the urinary system, kidney stones
- Swollen breasts, problems with the vagina, vaginal bleeding, abnormal cervical smear test, persistent erection, erection difficulties, prolapse of the uterus, problems in the prostate or testes
- Problems with the lungs, tightness in the throat, breathing difficulties, abnormally fast breathing or deep breathing (hyperventilation), nose bleed
- Swelling of the capillaries, skin contact rash, skin lumps, painful red skin lumps
- Varicose veins

Rare side effects (affecting up to 1 in 1,000 patients), and very rare side effects (affecting up to 1 in 10,000 patients):

- Severe allergic reactions.

If a side effect occurred, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

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

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

Store the pre-filled Copaxone® syringes in the refrigerator (2°C-8°C).

If the Copaxone® package cannot be stored in the refrigerator, the package can be stored at room temperature (15°C-25°C) for up to one month. Do not store the Copaxone® syringes outside of the refrigerator for a period longer than one month.

The Copaxone® syringes can be stored outside of the refrigerator for a period of up to one month only once. After a month outside of the refrigerator, if the syringes still haven't been used and are in their original package, return them to the refrigerator.

Keep the pre-filled Copaxone® syringes in a shaded place; do not expose the syringes to light. Take one syringe out of its package only before injecting – the rest of the syringes should be kept in their original package.

Do not freeze the pre-filled Copaxone® syringes. If the syringe was frozen, discard it in a proper waste bin.

Even if kept in their original package and stored as recommended, medicines may be kept for a limited period only.

Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medicines in the same package.

6. FURTHER INFORMATION

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

Mannitol, water for injection

What the medicine looks like and the contents of the package

The syringe is composed of a colorless glass barrel, with a plastic plunger and gray rubber seal. The syringe contains a clear, colorless liquid.

License holder

Teva Pharmaceutical Industries Ltd.,
P.O.B. 3190 Petach-Tikva.

Manufacturer and address

Teva Pharmaceutical Industries Ltd.,
P.O.B. 3190 Petach-Tikva.

This leaflet was checked and approved by the Ministry of Health in April 2014.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Copaxone® 20 mg per syringe (of 1 ml)

128.06.30681.00

128.06.30681.01

Copaxone® 40 mg per syringe (of 1 ml)

151.75.34057.00

READ THE INSTRUCTIONS FOR USE CAREFULLY BEFORE INJECTING WITH THE PRE-FILLED SYRINGES.

Important comments

- Be sure to perform the first injection in the presence of a professional. Afterwards, inject in the presence of someone else who will be there for you while you inject and for 30 minutes afterwards.
- Discard the syringe after use. Do not use it again.
- In order to reduce local irritation or pain, inject each day in a different point in the injection areas.
- In order to prevent inflammation, wash and dry your hands. Do not touch your hair or skin afterwards.

Instructions for use

1. Gathering the materials and injecting

First gather the following materials onto a clean and flat surface in a well-lit place:

- A single syringe package - separate a single syringe package from the package of Copaxone® pre-filled syringes. Keep the rest of the unused syringes in the carton package and return the carton package to the refrigerator.
- If the syringe was stored in the refrigerator, take it out and leave it in its package to stand and warm up at room temperature for about 20 minutes before use.
- There may be small air bubbles in the syringe. In order to avoid loss of the medicine when using the Copaxone® pre-filled syringe, avoid removing air bubbles from the syringe.

2. Choosing the injection site

- There are 7 injection areas on your body: arms, thighs, hips, lower abdominal area (see Figure 1), with a few different injection points within each injection area.
- Inject in a different injection point each day. It is recommended to keep note of the injection points and areas to avoid injecting in the same point each time, in order to reduce the chance of irritation or pain in the injection point.
- There are areas in your body which may be difficult for self injection, in which you will need assistance. Do not inject in areas where dimples in the skin have formed, the skin has changed color or if you feel lumps or pain, as an additional injection in this area will worsen the effects.

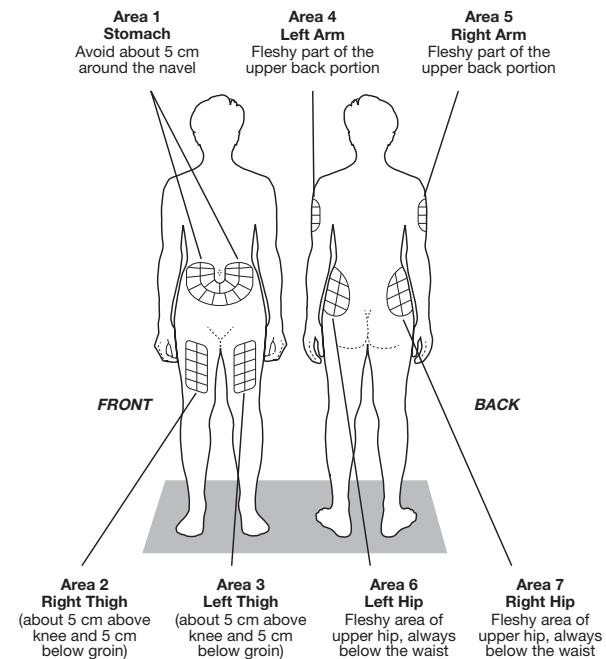


Figure 1

3. Injection

- If you use Autoject injection, please refer to the leaflet provided in the package of the Autoject device. If you inject manually, please continue reading this leaflet.
- Remove the syringe from its package by peeling back the paper tab at the tip of the syringe package.
- Before the injection, check the solution in the syringe; do not use the syringe if there are any particles or if the solution is not clear.
- Choose the injection area.
- Hold the syringe in your strong hand and the needle shield in your other hand. Be careful not to bend or twist the needle shield.
- Remove the needle shield by pulling straight out – not by twisting the needle shield. Throw the needle shield into an authorized sharps container.
- With your other hand (the weak one), fold about 5 cm of your skin with your thumb and forefinger (see Figure 2).

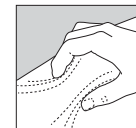


Figure 2

- Insert the needle at a 90° angle (see Figure 3).

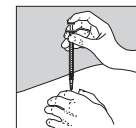


Figure 3

- In order to inject the medicine, hold the syringe steady and press the plunger down until the syringe is empty. When the contents of the syringe are fully injected, release the skin fold.
- At the end of injection, throw the syringe into an authorized sharps container.
- Press with a cotton ball on the injection area for a few seconds. Do not rub the injection area.

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