Package leaflet: Information for the user

Copaxone 40 mg/ml solution for injection in pre-filled syringe
glatiramer acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist.
• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet?
1. What Copaxone is and what it is used for
Copaxone is a medicine used for the treatment of relapsing forms of multiple sclerosis (MS). It modifies the way in which your body's immune system works and it is classified as an immunomodulating agent. The symptoms of MS are thought to be caused by a defect in the body's immune system. This produces patches of inflammation in the brain and spinal cord.

Copaxone is used to reduce the number of times you suffer attacks of MS (relapses). It has not been demonstrated to help if you have any form of MS which does not have relapses, or hardly any relapses. Copaxone may not have any effect on the length of time an MS attack lasts, or how badly you suffer during an attack.

2. What you need to know before you use Copaxone
Do not use Copaxone
• if you are allergic to glatiramer acetate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Copaxone, if you have any kidney or heart problems as you may have to regular tests and check-ups.

Children
Copaxone is not to be used in children below the age of 10 years.

Elderly
Copaxone has not been specifically studied in the elderly. Please ask your doctor for advice.

Other medicines and Copaxone
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice and consideration regarding Copaxone treatment during pregnancy and/or lactation.

Driving and using machines
Copaxone is not known to influence the ability to drive or operate machinery.

3. How to use Copaxone
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose in adults is one pre-filled syringe (40 mg of glatiramer acetate) administered subcutaneously (under the skin) three times a week, injected at least 48 hours apart, for example Monday, Wednesday and Friday. It is recommended to administer the drug on the same days every week.

It is very important to inject Copaxone properly:
• Into the tissue under the skin (subcutaneous use) only (see "Instructions for use")
• At the dose instructed by your doctor. Use only the dose prescribed by your doctor.
• Never use the same syringes more than once. Any unused product or waste must be discarded.
• Do not mix or co-administer the content of Copaxone pre-filled syringes with any product.
• If the solution contains particles, do not use it. Use a new syringe.

The first time you use Copaxone you will be given full instructions and will be supervised by a doctor or nurse. They will be with you while you give yourself the injection and for half an hour afterwards. Just to make sure you do not have any problems.

Instructions for use
Read these instructions carefully before using Copaxone.

Before the injection, make sure you have everything you need:
• One blister with one Copaxone pre-filled syringe
• Disposable unit for used needles and syringes.
• For each injection, take only one blister with one pre-filled syringe from the package. Keep all remaining syringes in the box.
• If your syringes have been stored in the refrigerator, take the blister containing the syringe out at least 20 minutes before you will inject the medicine so that it warms up to room temperature.

Wash your hands thoroughly with soap and water.
If you wish to use an injection device to make your injection, the CSYNC device can be used with Copaxone. The CSYNC device is only approved to be used with Copaxone and has not been tested with other products. Please refer to the instructions for use provided together with the CSYNC injection device.

Choose the injection site within the areas, using the diagrams.
There are seven possible areas on your body for injection:

Area 1: Stomach area (abdomen) around the belly button. Avoid 5 cm around the belly button.

Area 2 and 3: Thighs (above your knee).

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

Within each injection area there are several injection sites. Choose a different site for each injection. This will reduce the likelihood of any irritation or pain at the site of the injection. Rotate injection areas and also rotate the injection sites within an area. Do not use the same site each time.

Please note: do not inject in any area that is painful or discoloured or where you feel firm knots or lumps.
You should consider having a planned schedule for rotating injection sites and making a note of it 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 these, you may require assistance.

How to inject:
• Remove the syringe from its protective blister by peeling back the blister lid.
• Remove the shield from the needle, do not remove the shield with your mouth or teeth.
• Gently pinch up the skin with the thumb and forefinger of the free hand (Figure 1).
• Push the needle into the skin as shown in Figure 2.
• Inject the medicine by steadily pushing the plunger all the way down until the syringe is empty.
• Pull the syringes and needle straight out.
• Discard the syringe in a safe disposal container. Do not put used syringes into the household waste but dispose of them carefully in a puncture-proof container as recommended by your doctor or nurse.

Figure 1

Figure 2
4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Allergic Reactions (hypersensitivity)**
- You may develop an allergic reaction to this medicine but it is uncommon.
- **Step using Copaxone and contact your doctor immediately or go to the casualty department at your nearest hospital, if you notice any sign of these side effects:**
  - rash (red spots or nettle rash)
  - swelling of the eyelids, face or lips
  - sudden shortness of breath
  - convulsions (fits)
  - fainting

**Other reactions following injection (immediate post-injection reaction)**

Some people may get one or more of the following symptoms within minutes after injecting Copaxone. They normally do not cause any problems and usually disappear within half an hour.

However, if the following symptoms last longer than 30 minutes, contact your doctor immediately or go to the casualty department at your nearest hospital.

- flushing (reddening) of the chest or face
- shortness of breath (difficulty in breathing)
- chest pain
- pounding and rapid heartbeat (palpitations, tachycardia)

In general, the 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 following list).

**Very common:** may affect more than 1 in 10 people

- injection, flu
- anxiety, depression
- headaches
- feeling sick
- skin rash
- pain in the joints or back
- feeling weak
- skin reactions at the injection site including reddening of skin, pain, formation of wheals, itching, tissue swelling, inflammation and hyper sensitivity (sensitization reactions are not unusual and normally decrease over time), non-specific pain

**Common:** may affect up to 1 in 10 people

- infection of the respiratory tract, genitourinary tract, cold sore, inflammation of the ear, runny nose, throat, nose, oesophagus, anal, throat, chest
- non-malignant skin growth (non-malignant neoplasm of skin), tissue growth (neoplasm)
- lymph node swelling
- allergic reactions
- loss of appetite, weight gain
- nervousness
- altered taste, increased tightness of muscle tone, migraine, speech disorder, fainting, tremor
- double vision, eye disorder
- ear disorder
- cough, hoarse voice
- disorder of sense of smell, constipation, tooth decay, indigestion, difficulty in swallowing, bowel incontinence, vomiting
- abnormal liver function test
- bruising, excessive sweating, itching, skin disorder, nettle rash
- neck pain
- urge to empty your bladder, frequent urination, inability to empty your bladder appropriately
- chill, feeling unwell, sweating of tissue under the skin at injection site, local reaction, peripheral swelling due to build-up of fluid, fever

**Uncommon:** may affect up to 1 in 100 people

- oedema, inflammation of skin and the soft tissue underneath, boils, shingles, inflammation of kidney
- skin cancer
- increased white blood cell count, reduced white blood cell count, spleen enlargement, low blood platelet count, change in form of white blood cells
- enlarged thyroid, overactive thyroid
- low blood sugar, increased blood sugar, decrease in insulin secretion
- abnormal dreams, confusion, euphoric mood, seeing, hearing, swelling, tasting or feeling something that is not there (hallucinations), aggression, abnormal elevated mood, personality disorder, suicide attempt
- headache, dizziness, and perioral numbness or tingling disorder, fits (convulsion), problems with handwriting and reading, muscle disorders, problems with movement, muscle spasm, nerve inflammation, abnormal nerve–muscle link leading to abnormal muscle function, involuntary rapid movement of the eyeballs, paralysis, foot drop (peroneal nerve palsy), unconscious state (epilepsy), visual blinding spots
- cataract, eye lesion in the cornea, dry eye, eye bleeding, droopy upper eyelid, papillary widening, wasting of the optic nerve leading to visual problems
- extra heart beats, slow heart beats, episodic fast heart beats