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 in 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 classed 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
Copaxone can cause severe allergic reactions, some of which may be life-threatening.
These reactions may occur shortly after administration, even months up to years after starting treatment and even if previous administrations were without allergic reactions.

The signs and symptoms of allergic reactions may overlap with post-injection reactions. Your doctor will inform you on the signs of an allergic reaction.

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

Talk to your doctor or pharmacist before using Copaxone, if you have or have had any liver problems (including those due to alcohol consumption).

Children
Copaxone is not to be used in children below the age of 18 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, think you may be pregnant or are planning to have a baby, ask your doctor for advice and consideration regarding Copaxone treatment during pregnancy.
Copaxone may be used during pregnancy upon advice from your doctor.

Limited data in humans showed no negative effects of Copaxone on breastfed newborns/infants.
Copaxone can be used during breast-feeding.

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 under the skin (subcutaneously) 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 syringe 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
- Disposal unit for used needles and syringes.

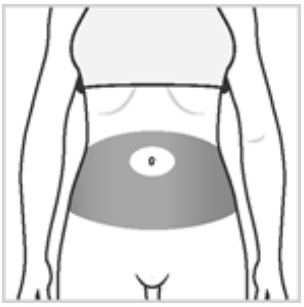
- For each injection, take only one blister with one pre-filled syringe from the package. Keep all remaining syringes in the box.
- If your syringe has been stored in the refrigerator, take the blister containing the syringe out at least 20 minutes before you will inject the medicine so that it warms 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.

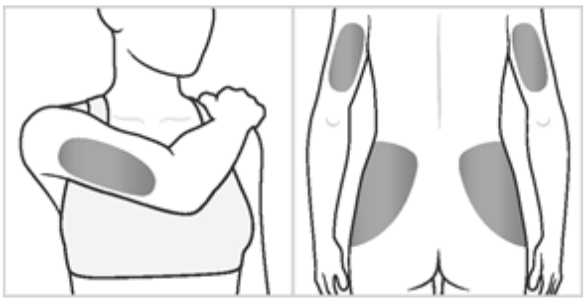
Choose the injection site within the areas, using the diagrams.
There are seven possible areas on your body for injection:

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



Area 2 and 3: Thighs (above your knees),

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 likeliness 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 syringe 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

If you have the impression that the effect of Copaxone is too strong or too weak, talk to your doctor.

If you use more Copaxone than you should
Talk to your doctor immediately.

If you forget to use Copaxone
Use it as soon as you remember or are able to use it, then skip the following day. Do not use a double dose to make up for forgotten individual doses. If possible you should return to your regular administration schedule the following week.

If you stop using Copaxone
Do not stop using Copaxone without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Allergic Reactions (hypersensitivity, anaphylactic reaction)
You may develop a serious allergic reaction to this medicine shortly after administration. This is an uncommon side effect. These reactions may occur months up to years after starting treatment with Copaxone, even if previous administrations were without allergic reactions.

Stop using Copaxone and contact your doctor immediately or go to the emergency department at your nearest hospital, if you notice any sudden sign of these side effects:

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

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 (vasodilatation)
- shortness of breath (dyspnoea)
- chest pain
- pounding and rapid 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. 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 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

- infection, flu
- anxiety, depression
- headache
- 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 hypersensitivity (these injection site reactions are not unusual and normally decrease over time), non-specific pain

Common: may affect up to 1 in 10 people

- inflammation of the respiratory tract, gastric flu, cold sore, inflammation of the ears, runny nose, tooth abscess, vaginal thrush
- 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, hay fever
- disorder of anus or rectum, 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, face swelling, wasting 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
- abscess, 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 alcohol tolerance, gout, increase in blood fat levels, increase in blood sodium, decrease in serum ferritin
- abnormal dreams, confusion, euphoric mood, seeing, hearing, smelling, tasting or feeling something that is not there (hallucinations), aggression, abnormal elevated mood, personality disorder, suicide attempt
- hand numbness and pain (carpal tunnel syndrome), mental 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 (stupor), visual blind spots
- cataract, eye lesion in the cornea, dry eye, eye bleeding, droopy upper eyelid, pupil widening, wasting of the optic nerve leading to visual problems
- extra heart beats, slow heart beats, episodic fast heart beats
- varicose vein
- periodic stops in breathing, nose bleeding, abnormally fast or deep breathing (hyperventilation), tight feeling in the throat, lung disorder, inability to breathe due to throat tightness (choking sensation)
- bowel inflammation, polyps in the colon, intestine inflammation, burping, ulcer in the gullet, inflammation of the gums, rectal bleeding, enlarged salivary glands
- gallstones, liver enlargement
- swelling of the skin and soft tissues, skin contact rash, painful red skin lumps, skin lumps
- swelling, inflammation and pain of joints (arthritis or osteoarthritis), inflammation and pain of fluid-sacs lining the joint (exist in some of the joints), flank pain, decrease in the mass of muscles
- blood in the urine, kidney stones, urinary tract disorder, urine abnormality
- breast swelling, difficulties getting an erection, fall down or slip out of the place of pelvic organs (pelvic prolapse), sustained erections, disorders of prostate, abnormal PAP smear test (Smear Cervix Abnormal), testes disorder, vaginal bleeding, vaginal disorder
- cyst, hangover, low body temperature (hypothermia), non-specific inflammation, destruction of tissue at the injection site, problems with mucous membranes
- disorders after vaccination

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Copaxone

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton (EXP). The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Copaxone pre-filled syringes can be kept for up to one month outside the refrigerator between 15°C and 25°C. You can do this only once. After one month any Copaxone pre-filled syringes that have not been used and are still in their original packaging must be returned to the refrigerator.

Do not freeze.

Keep the pre-filled syringes in the outer carton in order to protect from light.

Dispose of any syringes that contain particles.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Copaxone contains
- The active substance is glatiramer acetate. 1 ml solution for injection (the contents of one pre-filled syringe) contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.
- The other ingredients are mannitol and water for injections.

What Copaxone looks like and contents of the pack
Copaxone solution for injection in pre-filled syringe is a clear solution, free of visible particles.

Each pre-filled syringe is packed separately in a PVC blister pack.

Copaxone is available in packs containing 3, 12 or 36 pre-filled syringes of 1 ml solution for injection or in a multipack of 36 pre-filled syringes comprising 3 cartons, each containing 12 pre-filled syringes of 1 ml of solution for injection.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Teva Pharmaceuticals Ltd.
Ridings Point, Whistler Drive
Castleford, West Yorkshire
WF10 5HX
UK

Manufacturer:
Norton Healthcare Limited T/A IVAX Pharmaceuticals UK (Teva Runcorn)
Aston Lane North, Whitehouse Vale Industrial Estate
Runcorn, Cheshire, WA7 3FA
United Kingdom

or

Actavis Group PTC ehf.
Dalshraun 1
220, Hafnarfjörður
Iceland

or

Merckle GmbH
Graf-Arco-Str. 3
89079 Ulm
Germany

This medicinal product is authorised in the Member States of the EEA under the name COPAXONE 40 mg/ml in:
Austria, Belgium, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Iceland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Spain, Sweden, Slovakia, Slovenia, The Netherlands, United Kingdom (Northern Ireland).

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