

COPAXONE® 40 mg/mL

glatiramer acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Copaxone 40 mg/mL. It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Copaxone 40 mg/mL is used for

Copaxone 40 mg/mL is used for the management of relapsing forms of Multiple Sclerosis (MS).

Copaxone may also be used in patients who, for the first time, have experienced symptoms and have MRI changes that indicate a high risk for development of MS. Your doctor will rule out any other reasons which could explain these symptoms before you are treated.

The cause of MS is not yet known. MS affects the brain and spinal cord. In MS, the body's immune system reacts against its own myelin (the 'insulation' surrounding nerve fibres). In relapsing forms of MS, people can have 'exacerbations' from time to time (e.g. blurred vision, weakness in the legs or arms, or loss

of control of bowel or bladder function). These are followed by periods of recovery.

Although the exact mechanism of how Copaxone works in MS is unknown, it is thought that Copaxone works by changing the immune processes that are believed to be responsible for the disease.

Copaxone has been shown to be effective in reducing the number of relapses in patients with relapsing remitting MS. Although it is not a cure, patients treated with Copaxone 40mg/mL generally find that they will experience fewer relapses.

Your doctor, however, may prescribe Copaxone for another purpose.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you use it

When you must not use it

Do not use Copaxone if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Copaxone to children.

There is no experience with its use in children under 12 years of age.

Do not use it after the expiry date (EXP) printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is damaged or shows signs of tampering.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using it if you are pregnant.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is not known whether Copaxone passes into breast milk. Your doctor will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

Tell your doctor if you have or have ever had any medical conditions, especially the following:

- asthma
- a history of severe allergic reactions

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you use Copaxone.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may interfere with the absorption of Copaxone.

These medicines may be affected by Copaxone, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Copaxone 40 mg/mL.

How to use it

Follow all directions given to you by your doctor, MS education nurse or pharmacist.

They may differ from the information contained in this leaflet.

How much to use

The recommended dose of this medicine is one Copaxone 40 mg/mL pre-filled syringe (1mL) injected three times a week and at least 48 hours apart.

Copaxone 40 mg/mL should be given, if possible, at the same time and on the same three days each week (for example, Monday, Wednesday and Friday) at least 48 hours apart.

Do not change the dose or dosing schedule or stop using Copaxone without talking to your doctor.

How to use it

Copaxone 40 mg/mL is given by an injection into the fatty layer under the skin (subcutaneous injection).

Many people with MS learn to give themselves the injection or have it given by a carer.

Self-injection needs to be taught and practised. It is important that a

qualified healthcare professional supervises your first injection.

Your doctor may teach you to self-inject or arrange for an MS education nurse to do so.

You may have a friend attend the injection training session as your assistant. Especially when you first start giving yourself injections, your assistant should be with you.

Talk to your doctor or the MS Society or telephone 1800 502 802 in Australia or 0800 502 802 in New Zealand for more information.

Patient support kits that include a self-injection device are available by telephoning 1800 502 802 in Australia (0800 502 802 in New Zealand).

After being taught to self-inject, you can refer to this leaflet for step-by-step instructions about how to prepare and inject Copaxone 40 mg/mL.

The following instructions explain how to inject Copaxone 40 mg/mL yourself.

Do not attempt self-injection until you are confident that you understand how to inject yourself.

Please read these instructions carefully.

Before you inject

Copaxone 40 mg/mL pre-filled injection is pre-mixed and ready for you to use.

Make sure that the blister with the syringe inside is taken out of the refrigerator for 20 minutes before you use it.

It is important that the solution is at room temperature when you inject it. If you need to delay your injection, return the blister to its package in the refrigerator.

Always inspect Copaxone solution in the pre-filled syringe before you use it. Do not inject the solution if it is cloudy or has particles in it.

Gathering the Materials

Gather the following items on a towel in a well-lit area:

- **One blister with Copaxone 40 mg/mL pre-filled syringe (at room temperature - as described above)**
- **A dry cotton ball**
- **Disposal unit for used syringes**

Wash and dry your hands. Do not touch your hair or skin afterwards.

This will help prevent infection.

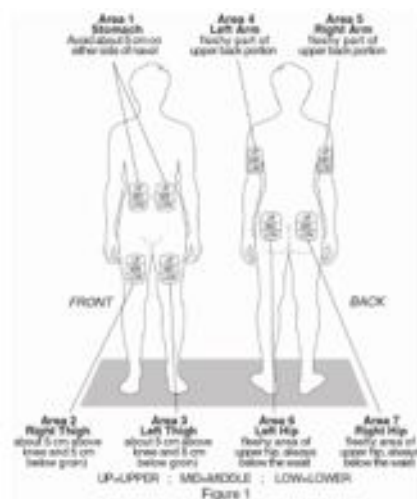
Deciding where to Inject

There are seven injection areas on your body; arms, thighs, back of the hips and stomach (belly). Within each injection area there are multiple injection sites (Figure 1).

Rotate the injection sites within an area.

You should not use any site more than one time a week. Choose a different site for each injection. This will reduce the likelihood of irritation, pain or loss of fatty tissue (lipoatrophy) at the site of injection.

Marking a calendar will help you keep track of the sites you have used each week.



Giving Yourself the Injection

1. **Remove the syringe from its protective blister by peeling back the blister foil.**

- Pick up the syringe as you would a pencil, using the hand you write with. Remove the plastic cover from the needle.
- Pinch about a 5 cm fold of skin between thumb and index finger.

When you inject in the upper back portions of your arms, it is not possible to pinch 5 cm of skin with one hand and inject yourself with the other hand. Ask your doctor / nurse for instruction on how to use these areas.



Figure 2

- Insert the needle into the 5 cm fold of skin. It may help to steady your hand by resting the heel of your hand against your body.

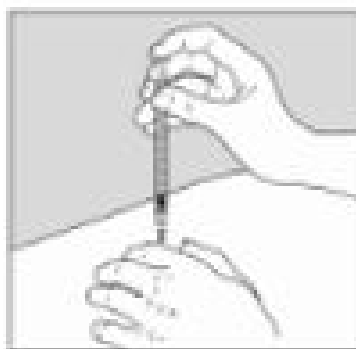


Figure 3

- When the needle is all the way in, release the fold of skin.
- Inject the medication by holding the syringe steady while pushing down on the plunger until the syringe is empty. The injection should take just a few seconds.
- Pull the needle straight out

- Press a dry cotton ball on the injection site for a few seconds, but do not massage it.
- Dispose of the pre-filled syringe in a safe hard-walled container, according to your doctor's instructions and the laws of your state (if any). Ask your doctor or pharmacist for advice if you are in doubt.

Some patients may experience a side-effect known as the Immediate Post Injection Reaction (see the information under the heading 'Side effects' below).

Proper use of needles and syringes

Do not reuse the pre-filled syringe. Each pre-filled syringe should be used only for one injection.

Ask your doctor or nurse about obtaining a "sharps container".

After use, place all used syringes and needles in a hard-walled plastic container, such as a liquid laundry detergent container.

It is very important that you keep the cover of the container tightly shut and that you store it out of the reach of children. When the container is full, check with your doctor or nurse about proper disposal.

When to use it

Give yourself the injection at the same time on the same three days of the week (for example, Monday, Wednesday and Friday) at least 48 hours apart.

Choose a time when you feel strongest

How long to use it

Do not stop using Copaxone without checking with your doctor first.

The positive effects of Copaxone are not seen immediately. They occur with long-term treatment.

If you forget to use it

If you miss a dose of Copaxone 40 mg/mL, you should take your next dose as soon as you remember or are able to take it, then skip the following day. If possible, you should return to your regular administration schedule the following week.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side-effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist or MS education nurse for some hints.

It is important not to miss injections as this can affect the success of your treatment.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26 or 0800 POISON or 0800 764 766 in New Zealand), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Copaxone 40 mg/mL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are using Copaxone.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Copaxone 40 mg/mL.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine.

If you become pregnant while you are using this medicine, talk to your doctor to discuss whether ongoing Copaxone treatment is appropriate for you.

Things you must not do

Do not use more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Copaxone 40 mg/mL.

It helps most people with MS, but it may have unwanted side effects in a few people.

Tell your doctor if you notice any of the following and they worry you:

- **pain, redness, itching, hardening of the skin or an infection at the site where you have injected yourself**
- **nausea (feeling sick)**
- **pain in the joints**
- **sore muscles**
- **feeling of weakness**
- **dizziness**
- **constipation**

- **yellowing of the skin or eyes**
- **dark urine**
- **abdominal pain**
- **vomiting**
- **loss of appetite**
- **weight loss**
- **unusual tiredness**

These side effects were reported by patients who used Copaxone 20 mg/mL every day and by patients who use Copaxone 40 mg/mL three times a week.

Some patients may experience a side-effect known as the Immediate Post Injection Reaction. This reaction consists of the following symptoms:

- reddening of the face and/or neck,
- chest pain or tightness,
- feeling your heart beat quickly (heart palpitations),
- anxiety and difficulty in breathing.

These are mild side effects of this medicine and usually are short-lived.

Some patients may experience only one episode during the treatment period.

Stop administering Copaxone and contact your doctor immediately if the above symptoms are severe.

If any of the following happen, stop using this medicine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- **swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing**
- **hives**
- **chest pain**
- **trouble breathing**
- **severe pain, redness or swelling at the injection site that does not go away.**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Copaxone. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After using it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep Copaxone 40 mg/mL in the pack until it is time to use it. Protect from direct light.

The medicine will not keep as well if taken out of the packaging.

Keep Copaxone 40 mg/mL pre-filled syringes in the refrigerator at 2°C to 8°C. In the event of refrigeration being unavailable, Copaxone 40 mg/mL may be stored below 25°C on one occasion for up to one month.

Copaxone 40 mg/mL must not be frozen. Do not place in the freezer or freezing compartment of a refrigerator.

Do not store it or any other medicine in the bathroom, near a sink or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

Disposal

Please read the package insert carefully for full details, including self disposal of needles and syringes after use.

If your doctor tells you to stop using Copaxone 40 mg/mL, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Remuera
Auckland 1541

Australian Register Number:

AUST R 218615

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Ltd.

Product description

What it looks like

Copaxone 40 mg/mL is a clear colourless solution supplied in 1mL glass single use pre-filled syringes fitted with a staked ½ inch needle.

Copaxone 40 mg/mL is supplied in a box of 12 blister packed pre-filled syringes.

Ingredients

Active Ingredient:

Each Copaxone 40 mg/mL pre-filled syringe contains 40 mg glatiramer acetate.

Inactive Ingredients:

Each injection also contains:

- mannitol
- water for injections

Distributor

Copaxone 40 mg/mL is distributed in Australia by:

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park 2113

NSW, Australia

Copaxone 40 mg/mL is distributed in New Zealand by:

Teva Pharma (New Zealand) Ltd

PO Box 128 244