

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: COPAXONE 20 mg/ml Dosage form & strength: Glatiramer acetate 20 mg/ml, Solution for injection (pre-filled syringe)
Date of Registration: 1 December 2006	Reg No: A40/34/0258

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

COPAXONE® 20 mg/ml (Solution for Injection, Pre-filled syringe)

Glatiramer acetate

Contains sugar (mannitol 40 mg/ml) per solution for injection, pre-filled syringe

Read all of this leaflet carefully before you start using COPAXONE 20 mg/ml.

- Keep this leaflet, you may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- COPAXONE 20 mg/ml has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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WHAT IS IN THIS LEAFLET:

1. What COPAXONE 20 mg/ml is and what it is used for
2. What you need to know before you use COPAXONE 20 mg/ml
3. How to use COPAXONE 20 mg/ml
4. Possible side effects
5. How to store COPAXONE 20 mg/ml
6. Contents of the pack and other information

1. WHAT COPAXONE 20 mg/ml IS AND WHAT IT IS USED FOR:

- To reduce the number of times you suffer attacks (relapses) of multiple sclerosis (MS). It has not been demonstrated to help if you have any form of MS which does not have relapses, or hardly any relapses.
- In patients who have experienced symptoms for the first time, and where the patient is at a high risk of developing multiple sclerosis. (This will be determined by your doctor). Your doctor will also rule out any other reasons which could explain these symptoms before you are treated.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE COPAXONE 20 mg/ml:

COPAXONE 20 mg/ml should not be administered to you:

- If you are hypersensitive (allergic) to glatiramer acetate or any of the other ingredients of COPAXONE 20 mg/ml (listed in **section 6**).

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Warnings and precautions:

Take special care with COPAXONE 20 mg/ml and tell your doctor if any of the following apply to you:

- if you have any kidney or heart problems as you may need to have regular tests and check-ups.
- if you have or have had any liver problems (including those due to alcohol consumption).

Elderly:

COPAXONE 20 mg/ml has not been studied in the elderly. Please ask your doctor or healthcare professional for advice.

Children and adolescents:

The use of COPAXONE 20 mg/ml is not recommended in children and adolescents under 18 years of age.

Other medicines and COPAXONE 20 mg/ml:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

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Driving and using machines:

It is not always possible to predict to what extent COPAXONE 20 mg/ml may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which COPAXONE 20 mg/ml affects you.

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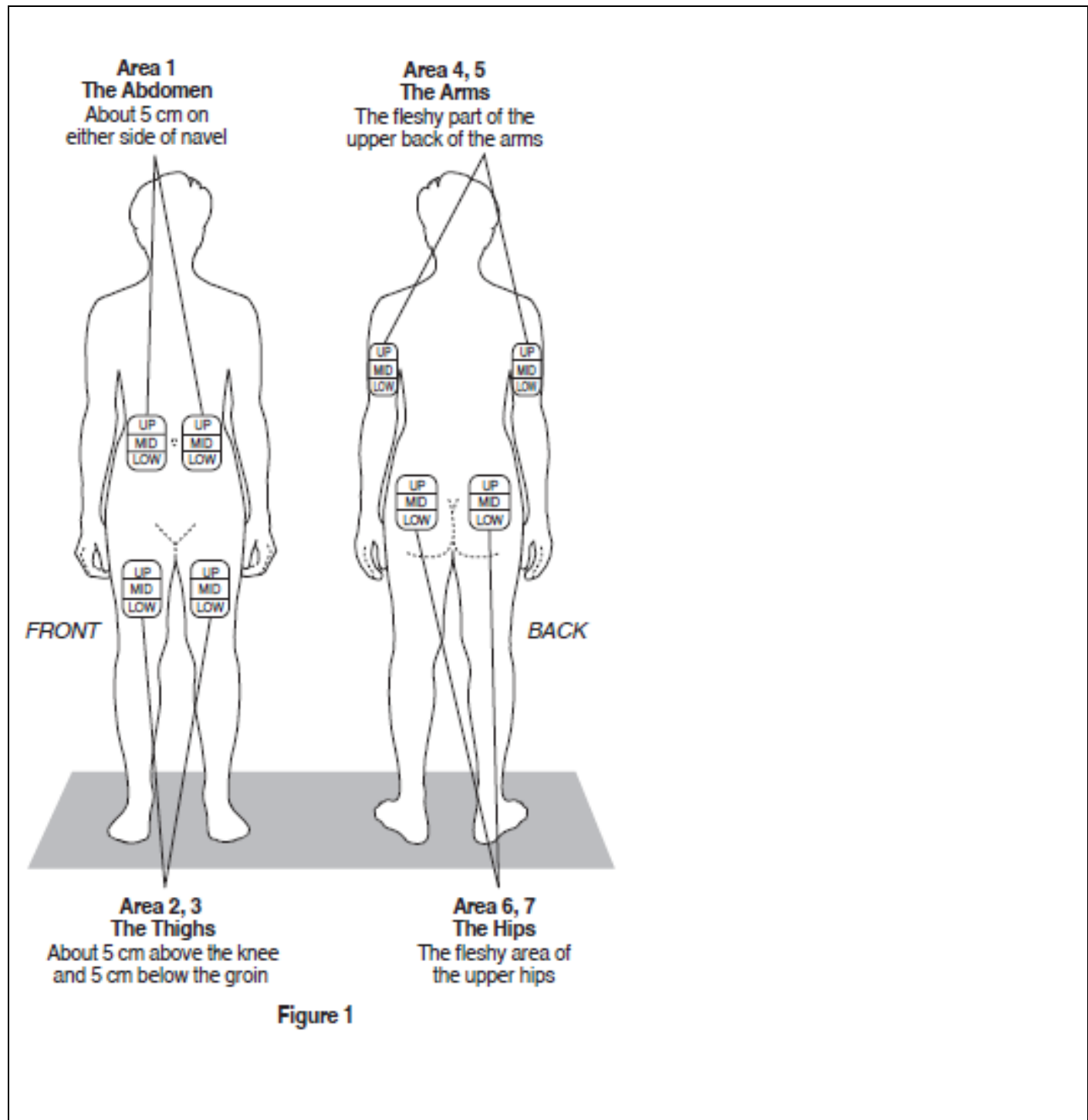
3. HOW TO USE COPAXONE 20 mg/ml:

Do not share medicines prescribed for you with any other person.

Always use COPAXONE 20 mg/ml exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The recommended daily dose in adults and adolescents aged 18 years and over is one pre-filled syringe (20 mg glatiramer acetate), injected subcutaneously (under the skin).
- Never use the same syringe more than once. Any unused medicine must be discarded.
- Do not mix the contents of the COPAXONE 20 mg/ml pre-filled syringe with any other product.
- If the solution in the pre-filled syringe contains particles or is cloudy, do not use it. Use a new syringe.
- The first time you use COPAXONE 20 mg/ml, you will be given full instructions and will be supervised by a doctor or healthcare professional. They will be with you while you give yourself the injection, and for 30 minutes afterwards to make sure you do not have any problems.
- Before using COPAXONE 20 mg/ml, you should decide where to inject yourself. Choose the injection site within the areas on your body by using the diagrams below (see Figure 1). There are seven possible areas on your body for injection.
- If you have the impression that COPAXONE 20 mg/ml is too strong or too weak for you, talk to your doctor or healthcare professional.
- Do not change the dose or dosing routine without speaking to your doctor.
- A different site of injection should be chosen every day, to reduce the chance of any irritation or pain at the injection site. Please refer to Figure 1 below.

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You should not use any site more than once each week. (Marking a calendar will help you keep track of the sites you have used each day).

If you need to delay your injection, return the blister (with the pre-filled syringe), to its package in the refrigerator.

Be consistent. Give yourself the injection at the same time each day. Choose a time when you feel strongest.

1. Remove the syringe from its protective blister by peeling back the paper label.
2. Pick-up the pre-filled syringe as you would pick up a pencil, using the hand you write with. Remove the plastic cover from the needle.
3. Pinch about a 5 cm fold of skin between thumb and index finger (see Figure 2).

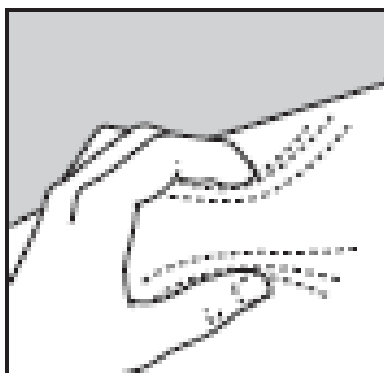


Figure 2

4. 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 (see Figure 3).

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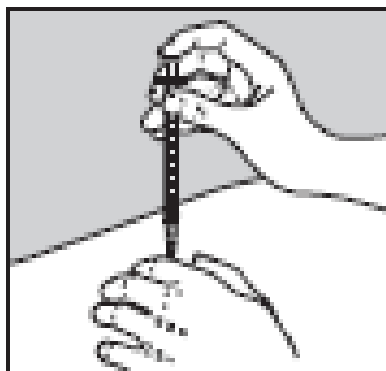


Figure 3

5. When the needle is all the way in, release the fold of skin.
6. 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.

Discard the syringe in a safe container.

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If you use more COPAXONE 20 mg/ml than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use COPAXONE 20 mg/ml:

Do not use a double dose to make up for forgotten individual doses.

If you stop using COPAXONE 20 mg/ml:

Do not stop using COPAXONE 20 mg/ml without consulting your doctor.

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4. POSSIBLE SIDE EFFECTS:

COPAXONE 20 mg/ml can have side effects.

Not all side effects reported for COPAXONE 20 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving COPAXONE 20 mg/ml, please consult your healthcare provider for advice.

If any of the following happens, stop using COPAXONE 20 mg/ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, eyelids and mouth or throat, which may cause difficulty in swallowing or breathing
- rash (red spots or nettle rash) or itching
- sudden wheeziness
- convulsions (fits)
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to COPAXONE 20 mg/ml. You may need urgent medical attention or hospitalisation.

Also tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following symptoms that last longer than 30 minutes:

- flushing (reddening) of the chest or face (vasodilatation)
- a feeling of tightness in the chest
- shortness of breath
- rapid heart beat (palpitations).

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

Frequent side effects:

- infection, flu
- inflammation of the respiratory tract, gastric flu, cold sore, inflammation of the ears, runny nose, tooth abscess, vaginal thrush
- any skin growth or other tissue growth
- lymph node swelling
- loss of appetite, weight gain
- anxiety, depression, nervousness, headache
- altered taste, increased tightness of muscle tone, migraine, speech disorder, fainting, tremor
- double vision or any other eye disorder
- ear disorder
- cough
- hay fever
- feeling sick
- 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
- pain in the joints or back, neck pain
- urge to empty your bladder, frequent urination, inability to empty your bladder appropriately
- 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
- chills, face swelling, wasting of tissue under the skin at injection site, local reaction, peripheral swelling due to build-up of fluid, fever.

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Less frequent side effects:

- 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
- abortion

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- breast swelling, difficulties getting an erection, fall down or slip out of place of the 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the '6.04 Adverse Drug Reaction Reporting Form', found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COPAXONE 20 mg/ml.

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5. HOW TO STORE COPAXONE 20 mg/ml:

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Store at 2 °C - 8 °C (in a refrigerator).

DO NOT FREEZE COPAXONE 20 mg/ml.

Store in the original outer carton until required for use, in order to protect from light. If you cannot store COPAXONE 20 mg/ml in a refrigerator you can store the pre-filled syringes at room temperature for up to one month.

Do not use COPAXONE 20 mg/ml after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What COPAXONE 20 mg/ml contains:

The active substance is glatiramer acetate.

Each pre-filled syringe contains 20 mg glatiramer acetate equivalent to 18 mg glatiramer base.

The other ingredients are mannitol and water for injection.

What COPAXONE 20 mg/ml looks like and contents of the pack:

A clear colourless solution free of visible particles supplied in a 1 ml glass single use pre-filled syringe.

A single-dose 1 ml pre-filled syringe consisting of a colourless glass barrel, a plastic plunger rod and a grey rubber stopper.

Pack size: 28 x 1 ml pre-filled syringe.

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Holder of Certificate of Registration:

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