Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name: COPAXONE 40 mg/ml** **Solution for injection in pre-filled syringe or pen**
Registration number: 48/34/0823	One pre-filled syringe or pen (1 ml) of solution for injection contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.

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PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

COPAXONE 40 mg/ml solution for injection

in a pre-filled syringe or in a pre-filled pen.

Glatiramer acetate.

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

Read all of this leaflet carefully before you start using COPAXONE 40 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 40 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.

What is in this leaflet:

1. WHAT COPAXONE 40 mg/ml IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU USE COPAXONE 40 mg/ml

3. HOW TO USE COPAXONE 40 mg/ml

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE COPAXONE 40 mg/ml

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT COPAXONE 40 mg/ml IS AND WHAT IT IS USED FOR:

COPAXONE 40 mg/ml 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 40 mg/ml 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 40 mg/ml 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 40 mg/ml:

COPAXONE 40 mg/ml should not be administered to you:

- If you are hypersensitive (allergic) to glatiramer acetate or any of the other ingredients of COPAXONE 40 mg/ml (listed in **section 6**).

Warnings and precautions:

Take special care with COPAXONE 40 mg/ml:

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 40 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 40 mg/ml is not recommended in children and adolescents under 18 years of age.

Other medicines and COPAXONE 40 mg/ml:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving COPAXONE 40 mg/ml.

Driving and using machines:

It is not always possible to predict to what extent COPAXONE 40 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 40 mg/ml affects you.

3. HOW TO USE COPAXONE 40 mg/ml:

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

Always use COPAXONE 40 mg/ml exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

COPAXONE 40 mg/ml should only be prescribed for you by a doctor with experience in the treatment of multiple sclerosis.

The recommended dose in adults is one pre-filled syringe (40 mg of glatiramer acetate), or pre-filled pen (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 medicine on the same days every week.

Elderly:

Glatiramer acetate has not been specifically studied in the elderly. Please ask your doctor for advice.

It is very important to inject COPAXONE 40 mg/ml 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 or pen more than once. Any unused product or waste must be discarded.
- Do not mix or co-administer the content of COPAXONE 40 mg/ml pre-filled syringes or pre-filled pen with any product.
- If the solution contains particles, do not use it. Use a new syringe or pen.

The first time you use COPAXONE 40 mg/ml PFS or PFP 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.

If you have the impression that the effect of COPAXONE 40 mg/ml PFS or PFP is too strong or

too weak for you, talk to your doctor. Do not change the dose or dosing routine without speaking to your doctor.

If you use more COPAXONE 40 mg/ml than you should:

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

If you forget to use COPAXONE 40 mg/ml:

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

If you stop using COPAXONE 40 mg/ml:

Do not stop using COPAXONE 40 mg/ml PFS or PFP without consulting your doctor.

4. POSSIBLE SIDE EFFECTS:

COPAXONE 40 mg/ml can have side effects.

Not all side effects reported for COPAXONE 40 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving COPAXONE 40 mg/ml, please consult your healthcare provider for advice.

If any of the following happens, stop receiving COPAXONE 40 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 and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to COPAXONE 40 mg/ml. You may need urgent medical attention or hospitalisation.

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

- flushing (reddening) of the chest or face (vasodilatation)
- a feeling of tightness in the chest
- shortness of breath (dyspnoea)
- chest pain
- pounding and rapid heartbeat (palpitations, tachycardia).

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

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 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 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.

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
- 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

- liver problems or worsening of liver problems, including liver failure (some cases resulting in liver transplantation).

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 40 mg/ml.

5. HOW TO STORE COPAXONE 40 mg/ml:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store in a refrigerator (2°C – 8°C).

DO NOT FREEZE.

If the pre-filled syringes/pre-filled pens cannot be stored in a refrigerator, they can be stored between 15 °C and 25 °C, once for up to one month.

After this one month period, if the COPAXONE 40 mg/ml pre-filled syringes/ pre-filled pens have not been used and are still in their original packaging, they must be returned to storage in a refrigerator (2 °C to 8 °C).

Do not use after the expiry date stated on the blisters.

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 40 mg/ml contains:

The active substance is glatiramer acetate.

1 ml solution for injection (the contents of one pre-filled pen or prefilled syringe) contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.

The other ingredients are mannitol and water for injections.

What COPAXONE 40 mg/ml looks like and contents of the pack:

The solution for injection in pre-filled syringe or pen is clear, colourless, and essentially free of visible particles.

COPAXONE 40 mg/ml pre-filled syringe:

A pre-filled syringe containing COPAXONE 40 mg/ml solution for injection consists of a 1 ml colourless type I glass syringe barrel with staked needle, a blue polypropylene (optional polystyrene) plunger rod, a grey rubber plunger stopper and a needle shield.

The pre-filled syringe is packed in a PVC blister closed with either a printed paper lid form or a transparent lid film, one syringe per blister, packed in carton boxes. COPAXONE 40 mg/ml pre-filled syringe is available in packs containing 12 pre-filled syringes of 1 ml solution for injection.

COPAXONE 40 mg/ml pre-filled pen:

Pre-filled pen consisting of a single use, disposable, spring-powered injector with needle safety shield integrating a pre-filled syringe which contains 1 ml solution for injection. The syringe inside the pen consists of a colourless type I glass syringe barrel, a stainless steel 29 gauge needle and a bromobutyl rubber plunger stopper.

COPAXONE 40 mg/ml pre-filled pen is available in packs containing 3 or 12 pre-filled pens of 1 ml solution for injection or in a multipack containing 36 (3 packs of 12) pre-filled pens of 1 ml solution for injection.

The assembled pens are packed directly into plastic trays holding three pens each. Four trays are then stacked on top of each other for packages holding 12 pens.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

2090

Tel: (011) 055 0200

This leaflet was last revised in:

14 June 2022

Registration number:

48/34/0823

INSTRUCTIONS FOR USE FOR THE COPAXONE 40 mg/ml SOLUTION FOR INJECTION IN PREFILLED SYRINGE:

Read these instructions carefully before using COPAXONE 40 mg/ml pre-filled syringe.

Before the injection, make sure you have everything you need:

- One blister with one COPAXONE pre-filled syringe.

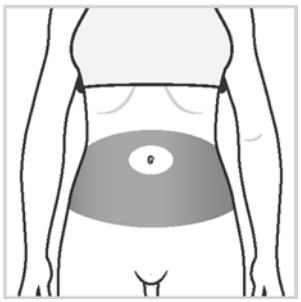
- Disposal unit for used needles and syringes.
- For each injection, take only one blister with one pre-filled syringe from the package. Keep all remaining syringes in the box.
- If your syringe has been stored in the refrigerator, take the blister containing the syringe out at least 20 minutes before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

Wash your hands thoroughly with soap and water

Choose the injection site within the areas, using the diagrams.

There are seven possible areas on your body for injection:

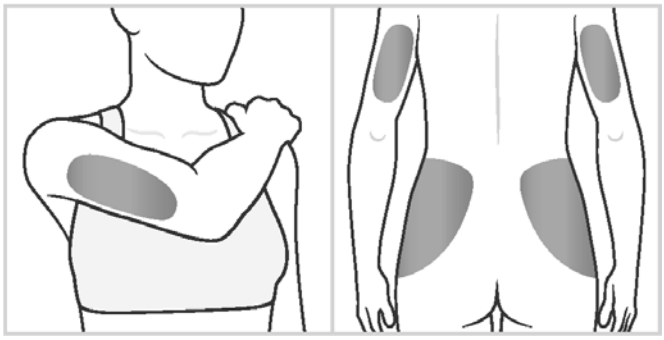
Area 1: Stomach area (abdomen) around the belly button. Avoid 5 cm around the belly button,



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

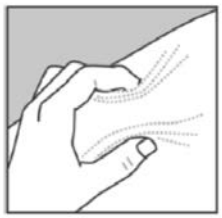


Figure 2



INSTRUCTIONS FOR USE FOR THE COPAXONE 40 mg/ml SOLUTION FOR INJECTION IN PRE-FILLED PEN:

Read these instructions for use before injecting COPAXONE 40 mg/ml prefilled pen:

Keep these instructions for use until you have used all the pre-filled pens in the packaging.

The pre-filled pen is disposable and for single-use only.

After injecting the medicine, the needle will be covered automatically.

WARNINGS AND CAUTIONS:

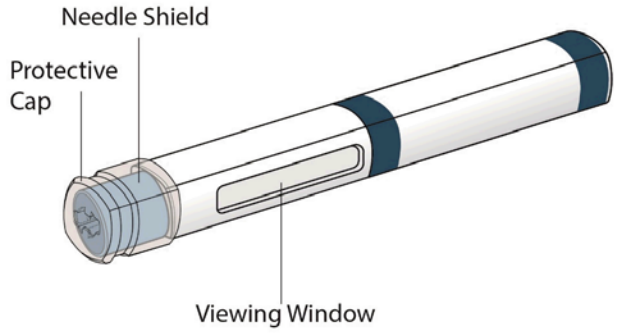
Once uncapped DO NOT touch the needle to avoid contamination.

DO NOT try to reuse the pre-filled pen as this could lead to injury or contamination.

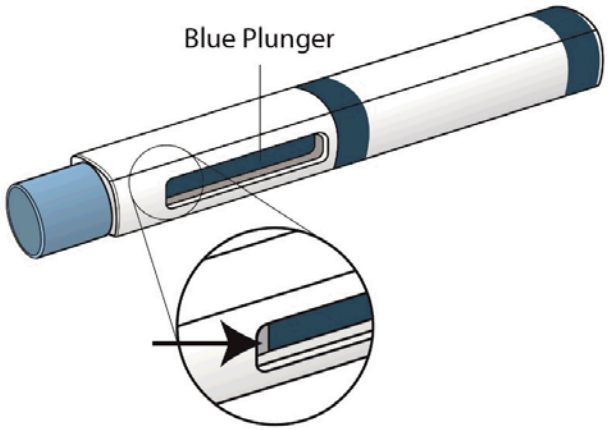
DO NOT refill the device with other medicinal products or replace any component of this

medicine or sub assembly.

HOW THE PRE-FILLED PEN LOOKS BEFORE USE:



HOW THE PRE-FILLED PEN LOOKS AFTER USE:



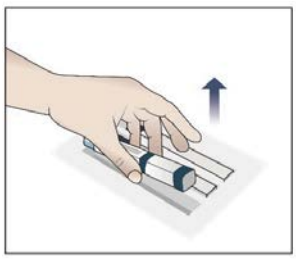
The blue plunger moves down the viewing window during the injection, and the window is full when the injection is complete.

When injecting, hold the pen so that your hand doesn't obscure the viewing window.

Note: When the blue plunger has filled the viewing window you will still be able to see the grey stopper, as shown.

1. REMOVE THE PRE-FILLED PEN:

REMOVE one pre-filled pen from the carton.



2. GATHER SUPPLIES:

GATHER AND PLACE the following supplies on a clean flat surface:

1 pre-filled pen

1 alcohol swab (not supplied)

1 gauze pad or cotton ball (not supplied)

1 sharps container or puncture-resistant container (not supplied)

Speak to your pharmacist or healthcare provider if you do not already have a sharps container.

3. CHECK THE PRE-FILLED PEN:

CHECK that the pre-filled pen is not damaged (such as cracked or leaking).

CHECK that 'Copaxone pen' appears on the pre-filled pen.

CHECK the expiry date.

DO NOT USE if the expiration date has passed, the pre-filled pen is damaged, or you have been given the incorrect product.

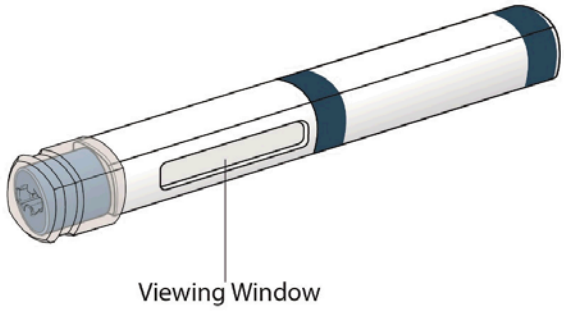
DO NOT USE if the cap has been removed or damaged.

This is important as the pre-filled pen and medicine might not be safe to use.

CHECK that the solution in the viewing window is clear,

Note: Small air bubbles may be present in the liquid, which are harmless and can be injected.

Do not attempt to remove air bubbles before injecting.



DO NOT USE if the medicine has any particles. DO NOT USE if the medicine is frozen.

This is important as the medicine might not be safe to use.

4. WAIT FOR 20 MINUTES:

PLACE the pre-filled pen on a clean, flat surface.

If your pen has been stored in the refrigerator, WAIT for 20 minutes to allow the medicine to reach room temperature.



Note: Injecting cold medicine will not cause any harm but could result in an unpleasant injection.

DO NOT leave the pre-filled pen in direct sunlight as this could adversely affect the medicine.

DO NOT warm up the pre-filled pen in any other way than instructed as this could adversely affect the medicine.

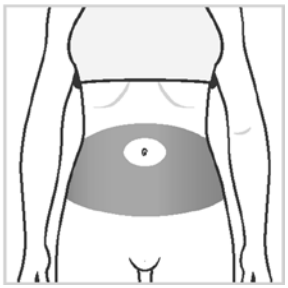
5. WASH YOUR HANDS:

WASH your hands with soap and water AND DRY THOROUGHLY with a clean towel.

6. CHOOSE AND PREPARE AN INJECTION SITE:

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

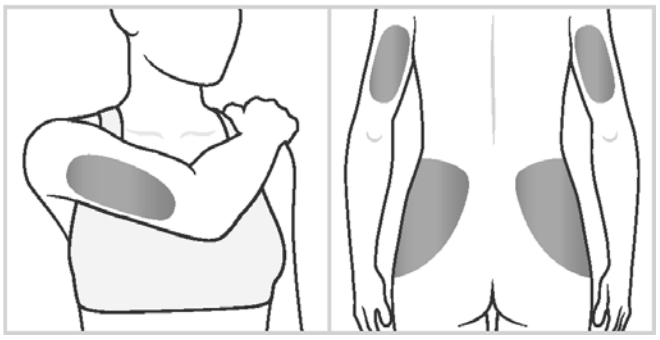
Area 1: Stomach area (abdomen) around the belly button. Avoid 5 cm around the belly button,



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.

CLEAN the chosen injection site using a new alcohol swab.

WAIT 10 seconds to allow the skin to dry before injecting.

DO NOT inject Copaxone pen into an area that is painful or discoloured or where you feel firm knots or lumps.

DO NOT inject through clothing.

DO NOT inject the pre-filled pen in the same place (site) more than 1 time each week.

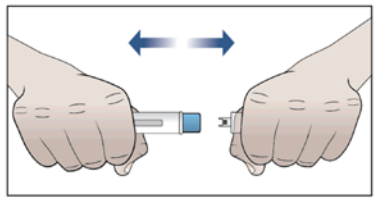
7. REMOVE PROTECTIVE CAP:

HOLD the pre-filled pen in one hand.

GRIP as shown AND PULL the protective cap STRAIGHT OFF.

DO NOT open the cap with your mouth or teeth.

IMMEDIATELY THROW AWAY the protective cap.



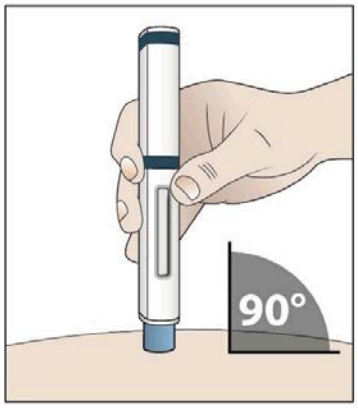
DO NOT attempt to recap the needle at any time to avoid contamination.

Once uncapped DO NOT touch the needle to avoid contamination.

DO NOT re-cap the pen even if it is unused.

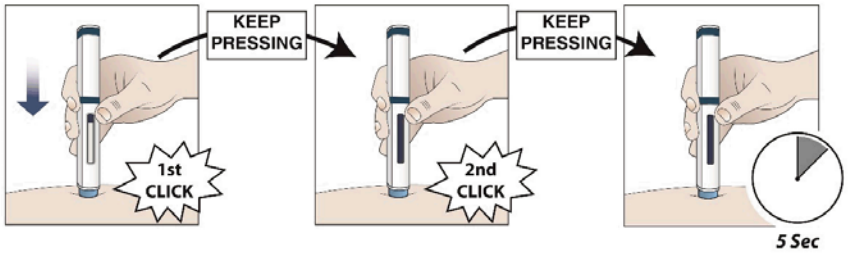
8. GIVE THE INJECTION:

A) PLACE the pre-filled pen at a 90° angle against your skin at the injection site.



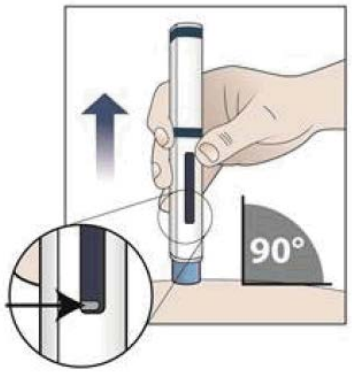
B) PRESS DOWN AND KEEP PRESSED DOWN for about **15 SECONDS**, **AND DO NOT REMOVE PRESSURE** UNTIL ALL OF THE FOLLOWING ARE COMPLETE:

You hear the 1st "CLICK" (the injection has started, the blue plunger starts to move)	You hear the 2nd "CLICK" (about 5-10 SECONDS after the 1st click)	You WAIT ANOTHER 5 SECONDS (to ensure all the medicinal product is injected)



Note: When the needle safety shield is fully pushed back, the needle is inserted into your skin.

C) CHECK that the blue plunger has filled the viewing window AND REMOVE the pre-filled pen from the skin.



Note: When the blue plunger is fully extended you will still be able to see the grey stopper.

9. DISPOSAL:

IMMEDIATELY DISPOSE of the used pre-filled pen into a sharps container or puncture-resistant container.

Discard the pen in a sharps container or puncture-resistant container. Do not put used pens into the household waste but dispose of them carefully in a sharps container or puncture-resistant container as recommended by your doctor or nurse.

10. TREAT INJECTION SITE:

EXAMINE the injection site.

If you see a drop of blood you can PRESS a clean cotton ball or gauze pad against the injection site.

If you want to you can use a bandage on the injection site.

DO NOT rub the injection site as this could cause discomfort.

INJECTION COMPLETE.

Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name: COPAXONE 40 mg/ml** **Solution for injection in pre-filled syringe or pen**
Registration number: 48/34/0823	One pre-filled syringe or pen (1 ml) of solution for injection contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.