PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Actemra® SC, 162 mg/0,9 mℓ solution for Injection pre-filled pen

Tocilizumab

Sugar free

Read all of this leaflet carefully before you start taking Actemra SC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your Pharmacist
- Actemra 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 Actemra SC is and what it is used for

Actemra SC contains the active substance tocilizumab, a monoclonal antibody that blocks the action of a specific protein (cytokine) called interleukin-6.

Actemra SC is used to treat your disease called rheumatoid arthritis (RA) or giant cell arteritis (GCA), a disease of the arteries, if previous therapies did not work well enough.

Actemra SC is used to treat your child, if older than 2 years of age, if he/she has polyarticular juvenile idiopathic arthritis (pJIA), an inflammatory disease that causes pain and swelling in one or more of his/her joints.

Actemra SC is used to treat your child, aged 1 year and older, if he/she has systemic juvenile idiopathic arthritis (sJIA), an inflammatory disease that causes pain and swelling in one or more of his/her joints.

2. What you need to know before you use Actemra SC

Do not use Actemra SC

- If you or your child are allergic (hypersensitive) to Actemra SC or to any other ingredients of Actemra SC (listed under “What Actemra SC contains”).
- If you or your child have active, severe infections.
- If you have or have had active liver disease/hepatitis.
- If your liver function is impaired before or during treatment.
- You have active or chronic hepatitis B.
- You are taking medicines which could be toxic to your liver, other than methotrexate

Take special care before you use Actemra SC

If you or your child experience allergic reactions such as chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips or skin rash during or after the injection, then tell your doctor immediately.

- If you or your child experience any allergic reaction symptom after receiving Actemra SC, you or your child must not take the next dose until you have informed your doctor and your doctor has told you that you or your child may take the next dose.
- If you or your child have any kind of infection, including short- or long-term, or if you or your child often get infections. Tell your doctor immediately if you feel unwell. Actemra SC can reduce your or your child’s body’s ability to respond to infections and may make an exisiting infection worse or increase the chance of getting a new infection.

- If you or your child have had tuberculosis, tell your doctor. Your doctor will check for signs and symptoms of tuberculosis before starting Actemra SC. If symptoms of tuberculosis (persistent cough, weight loss, listnessness, mild fever) or any other infection appear during or after therapy tell your doctor immediately. Your doctor will give you or your child medicine to prevent you getting tuberculosis before you start treatment with Actemra SC and will monitor you throughout your treatment with Actemra SC.
- If you or your child have had intestinal ulcers or diverticulitis, tell your doctor. Symptoms would include abdominal pain and unexplained changes in bowel habits with a fever.
- If you or your child have liver disease tell your doctor. Before you receive Actemra SC, your doctor [may] will do a blood test to measure your or your child's liver function. Your doctor will decide whether you or your child can continue having Actemra treatment.
- If you or your child have recently got or are planning to get vaccinated, tell your doctor. Certain types of vaccines should not be given while receiving Actemra SC. You should receive all immunisations in agreement with current immunisation guidelines prior to initiating Actemra SC therapy.

- If you or your child have cancer, tell your doctor. Your doctor will have to decide if you can still be given Actemra SC.
- If you or your child have cardiovascular risk factors such as raised blood pressure and raised cholesterol levels, tell your doctor. These factors need to be monitored while receiving Actemra SC.
- If you or your child have moderate to severe kidney function problems, your doctor will monitor you or your child.

Your doctor will perform a blood test before you or your child receive Actemra SC, to determine if you or your child have a low white blood cell count, low platelet count or high liver enzymes.

Actemra SC is not recommended for use in children under the age of two years

Children and adolescents

Actemra SC is not recommended for use in children under 1 year of age. Actemra SC must not be given to children with sJIA weighing less than 10 kg.

Other medicines and Actemra SC

Using other medicines with Actemra SC

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

Actemra SC can affect the way some medicines work, and the dose of these may require adjustment. You should tell the doctor if you or your child are using medicines containing any of the following active substances:

- atorvastatin, used to reduce cholesterol levels
- calcium channel blockers (e.g.) amlodipine, used to treat raised blood pressure
- theophylline, used to treat asthma
- warfarin, used as a blood thinning agent
- phenytoin, used to treat convulsions
- ciclosporin, used to suppress your or your child's immune system during organ transplants
- benzodiazepines, used to relieve anxiety

Taking Actemra with food and drink

You or your child can take food and drink as normal while receiving Actemra SC.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, may be pregnant or intend to become pregnant or if you are breastfeeding your baby. Actemra SC should not be used during pregnancy.

It is not known whether Actemra SC is excreted in breast milk. You should stop breastfeeding your baby if you are to be given Actemra SC. Before you start[ing] breastfeeding, your last treatment with Actemra SC should be at least 3 months ago.

Driving and using machines

There are no studies on the effects of Actemra SC on the ability to drive or use machines. However, if you experience dizziness, a common side effect, then you should not drive or use machines.

3. How to use Actemra SC

Your doctor will prescribe the dose you or your child should receive and the duration of your treatment. Always use Actemra SC exactly as your or your child's doctor, pharmacist or nurse has told you. You should check with your or your child's doctor, pharmacist or nurse if you are not sure

The recommended dose is 1 pre-filled syringe containing 162 mg Actemra SC, once a week if you are taking it for rheumatoid arthritis (RA) or giant cell arteritis (GCA).

If your child is taking Actemra RA for his/her polyarticular rheumatoid arthritis (pJIA), the recommended Actemra SC dose is:

- 1 pre-filled syringe containing 162 mg once every three weeks if your child weighs less than 30 kg or
- 1 pre-filled syringe containing 162 mg once every two weeks if your child weighs 30 kg or more.

If your child is taking Actemra sJIA for his/her systemic juvenile idiopathic arthritis (sJIA), the recommended Actemra SC dose is:

- 1 pre-filled syringe containing 162 mg once every two weeks if your child weighs less than 30 kg or
- 1 pre-filled syringe containing 162 mg once every every weeks if your child weighs 30 kg or more.

Actemra SC is given by injection under the skin (subcutaneously). At the start, your doctor or nurse may inject your Actemra SC dose. However, your doctor may decide that you may inject Actemra SC yourself. In this case you will receive training on how to inject Actemra SC yourself.

Your child's doctor will give him/her the initial injection. After the first few injections [he] your doctor may assess the suitability for you or the child's guardian/carer to administer the injection to your child. In this case your doctor will train you or the child's guardian/carer on how to inject your child.

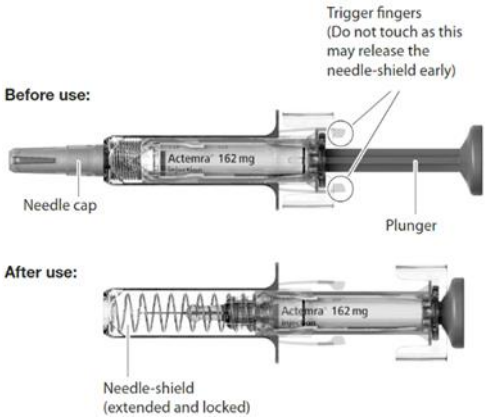
If you are injecting yourself or your child, you and your child must agree to see your doctor for follow-up consultations.

If you or your child experience any signs of an allergic reaction such as chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips or skin rash during or after the injection, you must inform your doctor or healthcare professional immediately.

Talk to your doctor if you have any questions about giving yourself or your child an injection. See detailed instructions for administration below.

PRE-FILLED SYRINGE – Self administration

Parts



You will need the following to give your injection:

Included in the box:

- Pre-filled Syringe

Not included in the box:

- Alcohol pad
- Sterile cotton ball or gauze

- Puncture-resistant container or sharps container for safe disposal of needle-cap and used syringe

A place to prepare your supplies:

- Find a well-lit, clean, flat surface such as a table

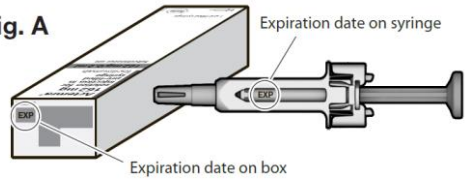
Do not shake the syringe.

Do not try to open the syringe or take it apart.

Step 1. Visually check the syringe

- Take the box containing the syringe out of the refrigerator and open the box. Do not touch the trigger fingers on the syringe as this may damage the syringe.
- Remove the syringe from the box and visually examine the syringe, as well as the medicine in the syringe. This is important to ensure that the syringe and medicine are safe to use.
- Check the expiration date on the box and syringe (See Fig. A) to make sure that it has not expired. Do not use the syringe if the expiration date has passed. This is important to ensure that the syringe and medicine are safe to use.

Fig. A



Dispose of the syringe and do not use if:

- the medicine is cloudy
- the medicine contains particles
- the medicine is any colour besides colourless to yellowish
- any part of the syringe appears to be damaged

Step 2. Allow the syringe to adjust to room temperature

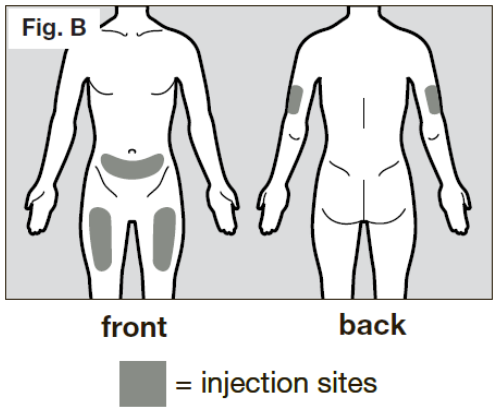
- Do not remove the needle-cap on your syringe until Step 5. Early removal of the needle-cap can cause the medicine to dry and block the needle.
- Place the syringe on a clean flat surface and allow the syringe to warm up and come to room temperature for about 25 - 30 minutes. Not allowing the syringe to come to room temperature could result in an uncomfortable injection and it may be difficult to depress the plunger.
- Do not warm up the syringe in any other way.

Step 3. Clean your hands

Wash your hands with soap and water.

Step 4. Choose and prepare an injection site

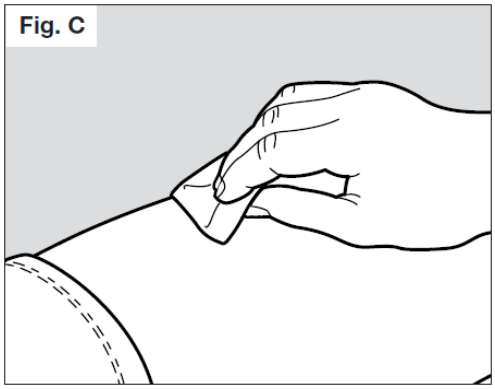
- The recommended injection sites are the front and middle of your thighs and the lower part of the abdomen below the navel (belly button) except for the five centimetre area directly around the navel. (See Fig. B)
- If a caregiver is giving the injection, the outer area of the upper arms may also be used. (See Fig. B)



- You should use a different place each time you give yourself an injection, at least three centimetres from the area you used for your previous injection.
- Do not inject into areas that could be bothered by a belt or waistband.

- Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.
- Clean the chosen injection site area using an alcohol pad (See Fig. C), to reduce the risk of infection.

Fig. C

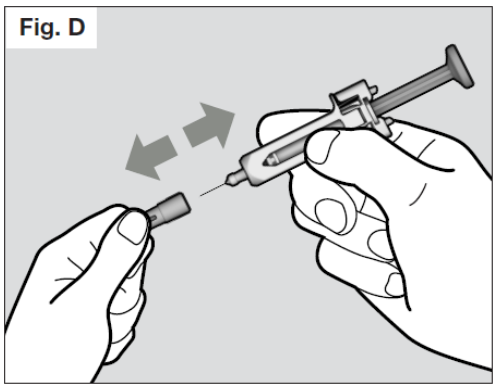


- Let the skin dry for approximately 10 seconds.
- Be sure not to touch the cleaned area prior to the injection. Do not fan or blow on the clean area.

Step 5. Remove needle-cap

- Do not hold the syringe by the plunger while removing the needle-cap.
- Hold the needle-shield of the syringe firmly with one hand and pull off the needle-cap with the other hand. (See Fig. D) If you cannot remove the needle cap you should request the help of a caregiver or contact your healthcare professional.

Fig. D



- Do not touch the needle or let it touch any surface.

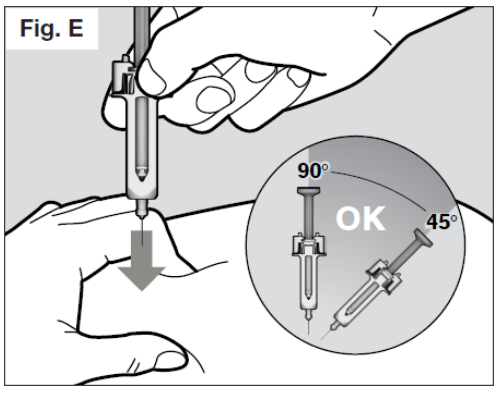
- You may see a drop of liquid at the end of the needle. This is normal.
- Throw away the needle-cap in the puncture resistant container or sharps container.

  NOTE: Once the needle-cap is removed, the syringe should be used immediately.
- If it is not used within 5 minutes of cap removal, the syringe must be disposed of in the puncture-resistant container or sharps container and a new syringe must be used. If the needle cap is removed for more than 5 minutes, it may be more difficult to perform an injection as the medicine can dry out and block the needle.

Never reattach the needle cap after removal.

Step 6. Give the injection

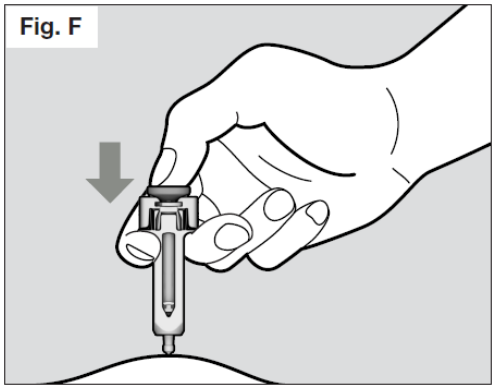
- Hold the syringe comfortably in your hand.
- To be sure the needle can be inserted correctly under the skin, pinch a fold of loose skin at the clean injection site with your free hand. Pinching the skin is important to ensure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injection into muscle could result in an uncomfortable injection.
- Do not hold or push on the plunger while inserting the needle into the skin.
- Insert the needle all the way into the pinched skin at an angle between 45° to 90° with a quick, firm action. (See Fig. E).



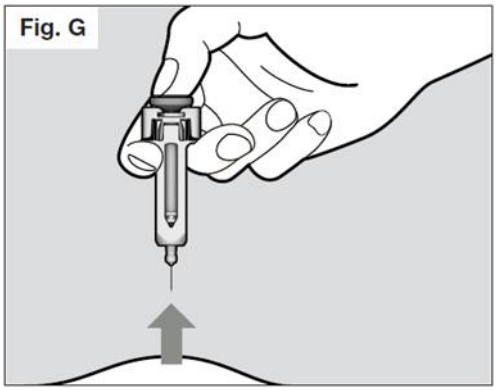
It is important to choose the correct angle to ensure the medication is delivered under the skin (into fatty tissue), otherwise the injection could be painful and the medicine may not work.

- Then keep the syringe in position and let go of the pinch of skin.
- Slowly inject all of the medicine by gently pushing the plunger all the way down. (See Fig. F). You must press the plunger all the way down to ensure that you get the full dose of medicine and to ensure the trigger fingers are completely pushed to the side. If the plunger is not fully depressed the needle shield will not extend to cover the needle when it is removed. If the needle is not covered proceed carefully, and place the syringe into the puncture resistant container to avoid injury with the needle.

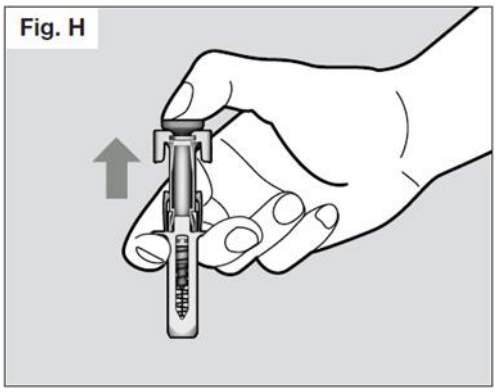
Fig. F



- Once the plunger is pushed all the way down, keep pressing down on the plunger to be sure all of the medicine is injected before taking the needle out of the skin.
- Keep pressing down on the plunger while you take the needle out of the skin at the same angle as inserted. (See Fig. G)
- If after inserting the needle, you cannot press down the plunger, then you must dispose of the pre-filled syringe in a puncture resistant container and use a new pre-filled syringe (starting again at Step 2). If you still experience difficulty, you should consult your healthcare professional.



- Once the needle is removed completely from the skin, you can release the plunger, allowing the needle-shield to protect the needle. (See Fig. H)

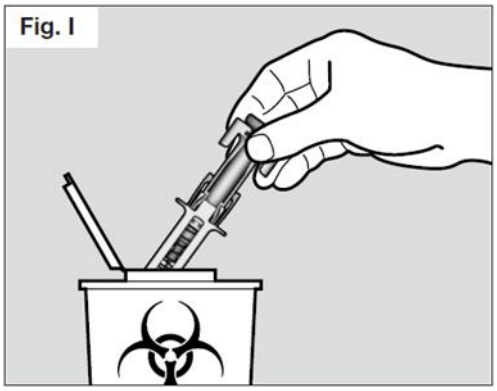


- If you see drops of blood at the injection site, you can press a sterile cotton ball or gauze over the injection site for approximately 10 seconds.

Do not rub the injection site.

Step 7. Dispose of the syringe

- Do not try to re-cap your syringe.
- Throw away used syringes in a puncture-resistant container or sharps container. Ask your healthcare professional or pharmacist for information about where you can get a "sharps" container or what other types of puncture-resistant containers you can use to safely dispose of your used syringes, if you do not have one. (See Fig. I)



Check with your healthcare professional for instructions about the right way to throw away used syringes.

Do not throw away used syringes or the puncture resistant container in household trash and do not recycle them.

- Dispose of the full container as instructed by your healthcare professional or pharmacist.

Always keep the puncture-resistant container out of the sight and reach of children.

Patient (including younger children who would be less able to communicate their symptoms) advice regarding hypersensitivity reactions (also known as anaphylaxis, if severe)

If you or your child develop symptoms such as, but not limited to skin rash, itching, chills, swelling of face, lips, tongue or throat, chest pain, wheezing, difficulty breathing or swallowing or feeling dizzy or faint at any time following an Actemra SC injection, you or your child should seek emergency care immediately.

Patient (including younger children who would be less able to communicate their symptoms) advice regarding early recognition and treatment to limit risk of a serious infection

Be alert for the first signs of infection such as:

- body aches, fever, chills
- cough, chest discomfort/tightness, shortness of breath
- redness, heat, unusual swelling of skin or joint
- abdominal pain/tenderness and/or change in bowel function

Call your or your child's doctor and seek medical attention without delay if you think you or your child might be developing an infection.

If you have any concerns or questions about your syringe, contact your healthcare professional or pharmacist for assistance.

If you or your child use more Actemra SC than you should:

Because the Actemra SC dose is given as one pre-filled syringe, it is unlikely that you or your child will be given too much. However, if you or your child did receive more than you or your child should, your doctor will take the necessary corrective actions.

If you or your child forget to take Actemra SC:

It is very important to use Actemra SC exactly as prescribed by your doctor. Keep track of your or your child's next dose. If you or your child miss your Actemra SC dose within 7 days, take the dose on the next scheduled day.

If you miss a dose after 7 days or are not sure when to inject Actemra SC, call your doctor or pharmacist.

If you stop taking Actemra SC:

You or your child should not stop using Actemra SC without discussing with your doctor first.

If you have further questions on the use of Actemra SC, then please ask your doctor or pharmacist.

4. Possible side effects

Actemra SC can cause side effects. Side effects may occur at least up to 3 months after your or your child's last dose of Actemra SC.

Possible serious side effects include serious infections and allergic (hypersensitivity) reactions, that may be life-threatening.

If you or your child notice any of the following signs of allergic reactions during or after the injection, tell your doctor immediately:

- difficulty with breathing, chest-tightness or light-headedness
- rash, itching, hives, swelling of the lips, face, tongue, throat

If you or your child notice any of the following signs of infections, tell your doctor as soon as possible:

- fever and chills

- mouth or skin blisters
- stomach ache
- persistent headaches

Elevated liver enzymes, tell your doctor immediately:

- yellowing of your skin and the whites of your eyes (jaundice)
- abdominal pain
- dark urine
- fever
- nausea and/or vomiting
- weakness and fatigue
- a general sense of feeling unwell (malaise)
- disorientation or confusion

sleepiness

The symptoms described above can be signs of the side effects listed below, all of which have been observed with Actemra SC in clinical studies and post-marketing reports:

Frequent side effects:

- upper respiratory tract infections like coughs and colds,
- high cholesterol levels, Lung infection (pneumonia),
- cold sores (oral herpes simplex), blisters,
- shingles (herpes zoster),
- skin infection sometimes with fever and chills (cellulitis),
- low white blood cell counts shown by blood tests (neutropenia, leucopenia),
- injection site reactions which include redness of the skin (erythema),

- itchiness (pruritus),
- pain and a swelling that contains blood (haematoma),
- headache,
- dizziness,
- high blood pressure,
- mouth ulceration,
- stomach pain abnormal liver function tests (increased transaminases),
- increased bilirubin shown by blood tests,
- rash and itching, hives,
- fluid retention (oedema) in the lower legs,
- cough,
- shortness of breath,
- increased weight,
- eye infection (conjunctivitis),
- allergic (hypersensitivity) reactions,
- hypofibrinogenaemia (abnormally low concentration of fibrinogen in the blood plasma).

Less frequent side effects:

- diverticulitis (fever, nausea, diarrhoea, constipation, stomach pain due to large bowel disease),
- red swollen (inflamed) areas in the mouth,
- high blood fat (triglycerides),

- stomach ulcer,
- kidney stones,
- underactive thyroid,
- low red blood cells and platelet counts,
- Stevens-Johnson syndrome (skin rash which may lead to severe blistering and peeling of the skin),
- An abnormally low level of red blood cells, white blood cells, and platelets in the blood (pancytopenia),
- medicine-induced liver injury
- inflammation of the liver (hepatitis)
- liver failure
- jaundice

Children with pJIA

In general, the side effects in children with pJIA were similar in type to those seen in adults with RA as stated above, with the exception of injection site reactions which were reported more frequently.

If any of the side effects gets serious, or if you or your child notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Not all side effects reported for Actemra SC are included in this leaflet. Should your general health worsen while taking this medicine, consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked

to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Report Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

5. How to store Actemra

Store in a refrigerator between 2 and 8 °C. Do not freeze.

Store all medicines out of reach of children.

Keep the pre-filled syringe in the outer carton in order to protect from light and keep dry.

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

Once removed from the refrigerator, Actemra SC must be administered within 8 hours and should not be kept at or above 30 °C.

Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to slightly yellowish, or if any part of the pre-filled syringe appears to be damaged.

What Actemra SC looks like and contents of the pack

Colourless to slightly yellowish, clear to strongly opalescent liquid.

4 single-use pre-filled syringes

The pre-filled syringe is composed of the following parts:

- A green plunger with a grey butyl rubber stopper.
- A type 1 glass barrel containing 0,9 ml of solution. The solution must be
- clear to strongly opalescent and colourless to slightly yellowish in colour.
- A stainless steel needle enclosed with a protective shield (needle safety device) made of an elastomer seal covered with a rigid polypropylene shell.

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd

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Building E, Vorna Valley

Midrand, Johannesburg, 1686

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

8. Registration number(s)

49/30.1/0398

Last Revision: 24 March 2023