PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Actemra 20 mg/mL concentration for solution for infusion

The active substance is Tocilizumab

Contains Sugar: (80 mg contains 200.00 mg, 200 mg contains

500.00 mg and 400 mg contains 1, 000.00 mg of sucrose).

Read all of this leaflet carefully before you start taking Actemra

- 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 is and what it is used for
2. What you need to know before you use Actemra
3. How to use Actemra
4. Possible side effects
5. How to store Actemra
6. Contents of the pack and other information

1. What Actemra is and what it is used for

The active substance is tocilizumab, which is supplied in single use vials containing 20 mg/mL.

Actemra contains the active substance tocilizumab, a monoclonal antibody that blocks the action of a specific protein (cytokine) called interleukin-6. This protein is involved in inflammatory processes of the body, and blocking it can reduce the inflammation in your body.

- Actemra is used to treat your disease called rheumatoid arthritis (RA), if previous therapies did not work well enough. Actemra helps to reduce symptoms such as pain and swelling in your joints and slows the damage to your joints and can also improve your performance of daily tasks. Actemra is usually given in combination with methotrexate.

- Actemra is used to treat your child if older than 2 years of age if he/she has active systemic juvenile idiopathic arthritis (sJIA) or active polyarticular juvenile idiopathic arthritis (pJIA), inflammatory diseases that cause pain and swelling in one or more of his/her joints. sJIA can also have fever and rash symptoms. Actemra improves the symptoms of sJIA and pJIA and can be given in combination with another medicine called methotrexate, or alone.

2. What you need to know before you use Actemra

You are not to be given Actemra

- If you are allergic (hypersensitive) to tocilizumab or to any other ingredients of Actemra (listed under “What Actemra contains”).
- If you have active, severe infections.

Take special care before you receive Actemra

- 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 infusion, then tell your doctor immediately.

- If you or your child have any kind of infection, including short- or long-term, or if you often get infections. Tell your doctor immediately if you feel unwell

- Actemra can reduce your 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.
- If you or your child have had intestinal ulcers or diverticulitis (a type of large bowel disease), tell your doctor. Symptoms would include abdominal pain and unexplained changes in bowel habits with a fever.
- 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. You or your child should receive all immunisations in agreement with current immunisation guidelines prior to initiating Actemra therapy.
- If you or your child have a history of a condition called macrophage activation syndrome, tell your doctor. Your doctor will decide if you or your child can still be given Actemra.
- If you or your child have cancer, tell your doctor. Your doctor will have to decide if you can still be given Actemra.
- 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.

- If you or your child have moderate to severe kidney function problems, your doctor will monitor you.

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

Actemra is not recommended for use in children under 2 years of age.

Other medicines and Actemra

Taking other medicines with Actemra

Please tell your doctor if you or your child are taking or have recently taken any other medicines, including medicines obtained without a prescription, complimentary or traditional medicines. Actemra can affect the way some medicines work, and the dose of these may require adjustment.

You, your child or guardians of children,

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 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.

Pregnancy and breastfeeding

Pregnancy

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

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

Driving and using machines

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

Important information about some of the ingredients of Actemra

Actemra contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before receiving Actemra.

Actemra contains 26,55 mg sodium per maximum dose of 1 200 mg (8,85 mg sodium per 400 mg vial). You should take this into consideration if you or your child is on a controlled sodium diet. Doses below 1 025 mg of Actemra contain less than 1 mmol (23 mg), i.e. essentially “sodium free”.

3. How to receive Actemra

Your doctor will prescribe the dose you or your child should receive and the duration of you or your child's treatment.

RA Patients

You will receive Actemra once every 4 weeks through a drip in your vein (intravenous infusion) over one hour.

sJIA Patients

Your child will receive Actemra once every 2 weeks through a drip in his/her vein (intravenous infusion) over one hour.

pJIA Patients

Your child will receive Actemra once every 4 weeks through a drip in his/her vein (intravenous infusion) over one hour.

If you or your child received more Actemra than you or your child should:

Since Actemra is given by a doctor or a nurse, it is unlikely that you will be given too much. However, if you or your child received more than you or your child should, your doctor will take the necessary corrective actions.

If you or your child did not receive the dose of Actemra you or your child should have received

Actemra is given by a doctor or a nurse, it is unlikely that you will miss a dose. However, if you or your child did not receive Actemra your doctor will take the necessary corrective actions.

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

4. Possible side effects

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

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen, or if you or your child experience any untoward effects while taking this medicine, consult your doctor, pharmacist or other healthcare professional for advice.

The most common side effects of Actemra are upper respiratory tract infections, with typical symptoms such as cough, blocked nose, runny nose, sore throat and headache.

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

If you or your child notice any of the following signs of:

Allergic reactions during or after infusion, tell your doctor **immediately**:

difficulty with breathing or light-headedness

rash, itching, hives, swelling of the lips, face, tongue, throat

Infections, tell your doctor **as soon as possible**:

fever and chills

mouth or skin blisters

stomach ache

persistent headaches

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

Frequent side effects:

upper respiratory tract infections like coughs and colds and

high cholesterol levels

lung infection (pneumonia)

cold sores (oral herpes simplex)

blisters

shingles (herpes zoster)

skin infection sometimes with fever and chills

low white blood cell counts shown by blood tests (neutropenia, leucopenia)

headache

dizziness

high blood pressure

mouth ulceration

stomach pain

abnormal liver function tests (increased transaminases)

increased bilirubin shown by blood tests (or a yellow colour of your eyes and skin)

injection site reaction

rash and itching

hives

fluid retention (oedema) in the lower legs

cough

shortness of breath

weight increase

eye infection (conjunctivitis) and

allergic (hypersensitivity) reactions

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 and

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),

Children with sJIA

In general, the side effects in children with sJIA were similar in type to those seen in adults with RA as stated above, with the exception of nasopharyngitis (runny nose, sore throat), lower white blood cell counts, increased liver enzymes and diarrhoea which were reported more frequently. Additional serious infections included chicken pox and earache.

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 nasopharyngitis (runny nose, sore throat), headache, nausea and lower white blood cell counts, 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.

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 all medicines out of the reach of children.
- Store in a refrigerator (between 2 °C and 8 °C). Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- Do not use after the expiry date stated on the pack.

Disposal of unused/expired medicine:

The release of pharmaceuticals in the environment should be minimised. Medicines should not be disposed of via wastewater and disposal through household waste should be avoided. Use established collection systems, if available in your location.

6. Contents of the pack and other information

What Actemra contains

The active substance is tocilizumab.

Each 4 mL vial contains 80 mg tocilizumab (20 mg/mL).

Each 10 mL vial contains 200 mg tocilizumab (20 mg/mL).

Each 20 mL vial contains 400 mg tocilizumab (20 mg/mL).

Excipients - The other ingredients are sucrose, polysorbate 80, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate and water for injections.

What Actemra looks like and contents of the pack

Actemra is a clear to opalescent, colourless to pale yellow liquid, supplied as a concentrate for infusion.

Actemra 80: A 10 mL single use clear glass vial, sealed with a grey butyl rubber stopper, a flip off cap and a green aluminium seal. Available in packs of 1 or 4 vials. Keep the vial in the outer carton to protect from light.

Actemra 200: A 20 mL single use clear glass vial, sealed with a grey butyl rubber stopper, a flip off cap and a yellow aluminium seal. Available in packs of 1 or 4 vials. Keep the vial in the outer carton to protect from light.

Actemra 400: A 20 mL single use clear glass vial, sealed with a grey butyl rubber stopper, a flip off cap and a red aluminium seal. Available in packs of 1 or 4 vials. Keep the vial in the outer carton to protect from light.

Not all pack sizes may be marketed.

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd
90 Bekker Road, Hertford Office Park,
Building E, Vorna Valley, Midrand,
Johannesburg, 1686
South Africa
Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

8. Registration number(s)

Last Revision: 26 May 2023

S2 Namibia 11/30.1/0066
S2 Botswana: BOT1502805/67