RoActemra® (tocilizumab) for Giant Cell Arteritis (GCA subcutaneous (SC) formulation

What you should know about RoActemra

This brochure provides key information to assist in the patient's understanding of the benefits and risks associated with RoActemra therapy

This educational material is provided by Roche Products Limited and is mandatory as a condition of the marketing authorisation in order to further minimise important selected risks.

For more information on RoActemra, please see the Patient Information Leaflet (PIL) that comes with your medicine.

If you have any further questions, please ask your doctor, nurse or pharmacist.

What you should know about RoActemra

All medications carry both potential benefits and potential risks to our health and it is important to understand these. Finding the balance between the two will lead you to a treatment for giant cell arteritis (GCA) treatment that works best for you. RoActemra might be that treatment.

RoActemra initially in combination with steroids, can be used to treat GCA in adult patients.

This brochure will answer some questions you may have about the side effects and potential risks of RoActemra. Talk to your doctor, nurse or pharmacist if you have any questions or problems.

This brochure does not take the place of speaking to your doctor, nurse or pharmacist.

Medicines are sometimes prescribed for purposes other than those listed. Only take RoActemra as directed for the condition for which it was prescribed.

What you should know about GCA and RoActemra

What causes GCA?

No one knows for sure. In GCA, the body's immune system doesn't work the way it should. The immune system is supposed to attack only foreign substances like germs. But when it doesn't work right, it can also attack the body itself. Diseases in which this happens, like GCA, are called autoimmune diseases. When the immune system attacks the body, it can lead to the symptoms people with GCA have. In GCA these may include headaches and vision loss.

What is IL-6?

Interleukin-6 (IL-6) is a protein that is made by the immune system. The body uses IL-6 to manage inflammation and infections.

What is RoActemra?

RoActemra is a biologic drug (a type of therapy made from living cells) that blocks the actions of IL-6 in the body. It is used in adults to treat GCA.

How has RoActemra been studied in GCA?

RoActemra has been studied in adults with GCA in combination with a gradual reduction of steroids.

How is RoActemra used in GCA?

RoActemra can be used in combination with a gradual reduction of steroids; RoActemra can also be used alone following discontinuation of steroids.

How is RoActemra given in GCA?

RoActemra is administered as a subcutaneous (under the skin) (SC) injection using a pre-filled syringe. Please refer to the relevant section below for more specific information on how RoActemra is administered.

Receiving RoActemra by subcutaneous injection by pre-filled syringe

- You and your doctor or nurse will decide if you (or your caregiver) are suitable for RoActemra SC use at home
  - In this case you will receive proper training on how to inject RoActemra SC using a pre-filled syringe
- Your doctor or nurse will give you your first RoActemra SC injection
- Injection is into your abdomen or thigh
- Dosing is set at 162 mg RoActemra, regardless of body weight
- RoActemra is given once per week

It is very important to use RoActemra exactly as prescribed by your doctor and to keep track of your doses.

If you miss your weekly injection of RoActemra but are within 7 days of when your dose was due, just take your normal dose as usual on the next scheduled day

If you miss your weekly dose by more than 7 days or are not sure when to inject RoActemra, call your doctor, nurse or pharmacist

General considerations for administration (pre-filled syringe)

RoActemra 162 mg is supplied in 0.9 ml of solution for injection as a pack of 4 single use pre-filled syringes. The following should be considered before administration:

- The pre-filled syringes should be stored at 2°C–8°C and should not be frozen
- The pre-filled syringes should be kept in the outer carton to protect them from light and should be kept dry. The pre-filled syringes should be kept out of sight and reach of children
- Inspect the pre-filled syringe visually for particulate matter and discolouration prior to administration. 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

- Once removed from the refrigerator, RoActemra 162 mg/0.9 ml must be administered within 8 hours and should not be kept above 30°C
- After removing the pre-filled syringe from the refrigerator:
  - The pre-filled syringe should be allowed to reach room temperature (18°C to 28°C) by waiting for 25 to 30 minutes, before injecting RoActemra 162 mg/0.9 ml. Do not warm up the pre-filled syringe in any other way
  - After removing the needle-cap, the injection must be started within 5 minutes to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used within 5 minutes of removing the cap, you must dispose of it in a puncture-resistant container and use a new pre-filled syringe. Never re-attach the needle-cap after removal
  - The pre-filled syringe should not be shaken
  - If following insertion of the needle you cannot depress the plunger, you must dispose of the pre-filled syringe in a puncture-resistant container and use a new pre-filled syringe.
- The first dose should be administered by a healthcare professional and after proper training in injection technique, patients may self-inject with RoActemra if it is deemed appropriate
- Any unused product or waste material should be disposed of in a puncture-resistant container.

For further information, please consult the information given in the package leaflet.

What tests will be done when I am receiving treatment with RoActemra?

At each visit to see your doctor or nurse, they may test your blood to help guide your treatment. Here are some things they may look at:

Neutrophils
Having enough neutrophils is important to help our bodies fight infections. RoActemra works on the immune system and can cause the number of neutrophils, a form of white blood cells, to drop. For this reason, your doctor may test to make sure you have enough neutrophils and monitor for signs and symptoms of infection.

Platelets
Platelets are small blood components that help stop bleeding by forming clots. Some people taking RoActemra had a drop in the number of platelets in their blood. In clinical trials, the drop in platelets was not associated with any serious bleeding.

Liver enzymes
Liver enzymes are proteins produced by your liver which may be released into your blood, sometimes indicating liver damage or disease. Some people who have taken RoActemra have had a rise in liver enzymes, which could be a sign of liver damage. Rises in liver enzymes were seen more often when medications that could be harmful to the liver were used with RoActemra. If this happens to you, your doctor should take care of this right away. Your doctor may decide to change your dose of RoActemra, or of other medication, or potentially stop treatment with RoActemra altogether.

Cholesterol
Some people who have taken RoActemra have had a rise in blood cholesterol, which is a type of lipid (fat). If this happens, your doctor may prescribe a cholesterol-lowering medication.

Can patients have vaccinations during treatment with RoActemra?

RoActemra is a medication that affects the immune system and may lower the body's ability to fight infection. Immunisation with live or live-attenuated vaccines (which contain very small amounts of the actual germ or weakened germs), such as a flu shot, should not be given during treatment with RoActemra. Patients should be brought up to date with all immunisations before starting RoActemra.

What are the most common side effects of RoActemra?

Most common side effects reported by patients in clinical trials were usually mild and usually did not result in the patient having to stop using the medication. These common side effects were:

- Upper respiratory tract infections (common cold, sinus infections)
- Headache
- Temporary rise in blood pressure
- Rash
- Dizziness – if you experience dizziness, you should not drive or use machines until it has resolved
- Injection site reactions (including erythema, pruritus, pain and hematoma)

What are the serious side effects of RoActemra?

Infections

RoActemra is a medication that affects your immune system. Your immune system is important because it helps you fight infections. Your ability to fight infections may be lowered with RoActemra. Some infections may become serious while on RoActemra. Serious infections may require treatment and hospitalisation and in some cases may lead to death. It is very important to report any signs of infection to your doctor or nurse right away

Seek immediate medical attention if you develop signs/symptoms of infection such as:

- Fever
- Persistent cough
- Weight loss
- Throat pain or soreness
- Wheezing
- Red or swollen skin blisters, skin tears or wounds
- Severe weakness or tiredness

Allergic reactions

Most allergic reactions occur during injection or within 24 hours of RoActemra administration, although allergic reactions can occur at any time. Serious allergic reactions including anaphylaxis have been reported in association with RoActemra. Such reactions may be more severe, and potentially fatal in patients who have experienced allergic reactions during previous treatment with RoActemra. Fatal anaphylaxis has been reported after marketing authorisation during treatment with intravenous RoActemra.

If an anaphylactic reaction or other serious allergic reaction occurs, administration of RoActemra should be stopped immediately, appropriate medical treatment initiated and RoActemra should be permanently discontinued.

Your doctor will assess you (or your caregiver) for your suitability to use RoActemra injections at home.

Do not take the next dose until you have informed your doctor AND your doctor has told you to take the next dose if you have experienced any allergic reaction symptoms after receiving RoActemra, if you are administering at home and you experience any symptoms suggestive of an allergic reaction.

Seek immediate medical attention if you notice any of the following signs or symptoms of allergic reactions after receiving RoActemra:

- Rash, itching or hives
- Shortness of breath or trouble breathing
- Swelling of the lips, tongue or face
- Chest pain
- Feeling dizzy or faint
- Severe stomach pain or vomiting
- Very low blood pressure

Abdominal pain

Patients taking RoActemra have on rare occasions experienced serious side effects in their stomach and intestines. Symptoms may include fever and persistent abdominal pain with change in bowel habits. Seek immediate medical attention if you develop stomach pain or colic, or notice blood in your stool.

Malignancies

Medicines which act on the immune system, like RoActemra, may increase the risk of malignancy.

Summary and contact information

This GCA patient brochure reviews some of the most important information about RoActemra. Medicines are sometimes prescribed for purposes other than those listed. Do not use RoActemra for a condition for which it was not prescribed.

Tell your doctor, nurse or pharmacist about any side effect you experience, bothers you or that does not go away. These side effects listed in this brochure are not all of the possible side effects that you could experience with RoActemra. Ask your doctor, nurse or pharmacist for more information.

Talk to your doctor, nurse or pharmacist if you have any questions or problems.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44(0)1707 367554.

By reporting side effects you can help provide more information on the safety of this medicine.

Detailed information on this medicine is available on the European Medicines Agency website (www.ema.europa.eu).

Pre-Administration Checklist for GCA - Before each administration of RoActemra, please review the points below

RoActemra may not be right for you. Before starting RoActemra, and before each administration of RoActemra, please review the points below, and tell your doctor or nurse if you checked 'yes' for any of the following:

	YES	NO
Infections		
Do you have an infection or feel unwell? (Signs of an infection may include: fever, cough, headache, open wounds or sores (as in chicken pox or shingles)	❑	❑
Are you being treated for an infection or get a lot of infections?	❑	❑
Do you have tuberculosis (TB) or have you been in close contact with someone who has had TB? (Your doctor should test you for TB before starting RoActemra.)	❑	❑
Have you had or currently have viral hepatitis or any disease of the liver?	❑	❑
Do you have diabetes or other conditions that increase the chance of infections?	❑	❑
Allergic Reactions		
Have you had any allergic reactions to previous medications, including RoActemra?	❑	❑
Gastrointestinal Complications		
Have you had or currently have gastrointestinal ulcers or diverticulitis (inflammation in parts of your large intestine)? (Symptoms my include abdominal pain and unexplained changes in bowel habits, with fever)	❑	❑
Medical History		
Have you had or do you now have impaired lung function? (For example, interstitial lung disease, where inflammation and scarring in the lungs make it difficult to get enough oxygen)	❑	❑
Have you ever had cancer?	❑	❑
Do you have heart or circulatory disease? (Examples include raised blood pressure or cholesterol levels)	❑	❑
Do you have kidney problems?	❑	❑
Do you have persistent headaches?	❑	❑

	YES	NO
Pregnancy		
Are you pregnant, possibly pregnant or do you intend to become pregnant? (Women of childbearing potential must use effective contraception during (and up to 3 months after)) treatment. RoActemra should not be used during pregnancy unless absolutely necessary).	❑	❑
Are you breast-feeding or do you intend to breast-feed?	❑	❑
Medications		
Have you recently had a vaccination (immunisation), such as a flu shot, or are scheduled to have one?	❑	❑
Are you taking other medications? Tell your doctor or nurse about all the medicines you take. This includes prescription (such as steroids) and non-prescription medications, vitamins and herbal medicines	❑	❑

You can take other medications if your doctor has told you it is okay to take them while you are taking RoActemra. RoActemra may interact with some medications. This may affect the dose you need of that medication. No effect of cumulative corticosteroid dose on RoActemra exposure was observed In GCA patients.

Tell your doctor if you are taking the following medicines:

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 the immune system during organ transplants	❑	❑
benzodiazepines (e.g. temazepam), used to relieve anxiety	❑	❑

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