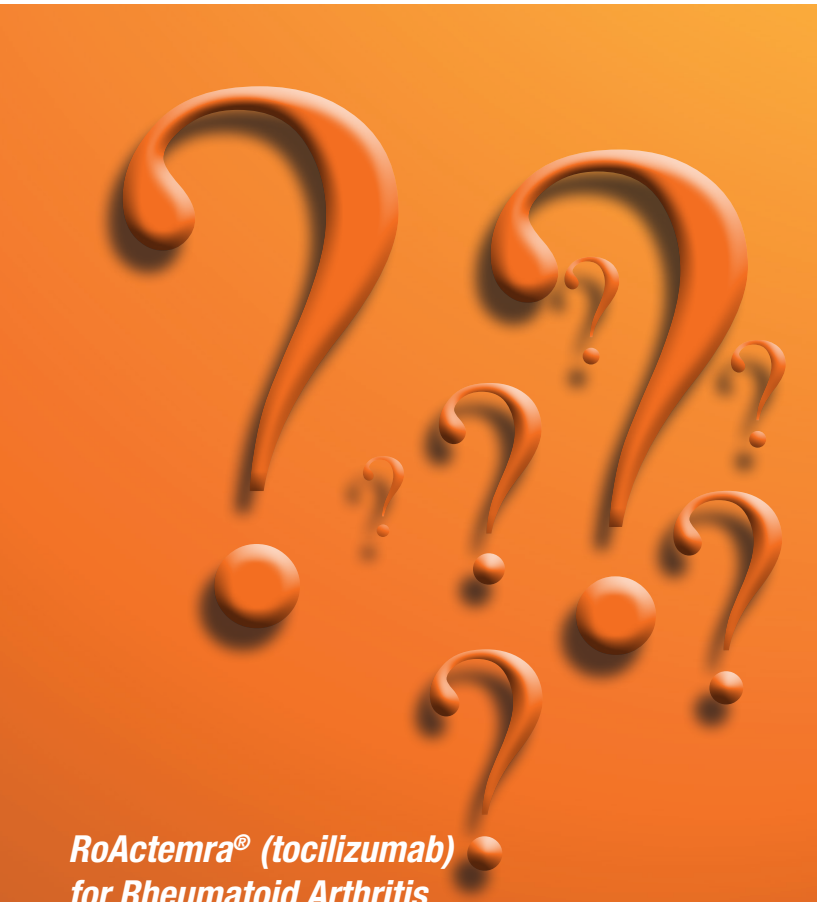

RoActemra® (tocilizumab) for Rheumatoid Arthritis

What You Should Know About

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

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This material is provided by Roche Products Limited as a licence requirement for this medicine and forms part of the Risk Management Plan

For more information on RoActemra please see the RoActemra patient information leaflet that comes with your medicine

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

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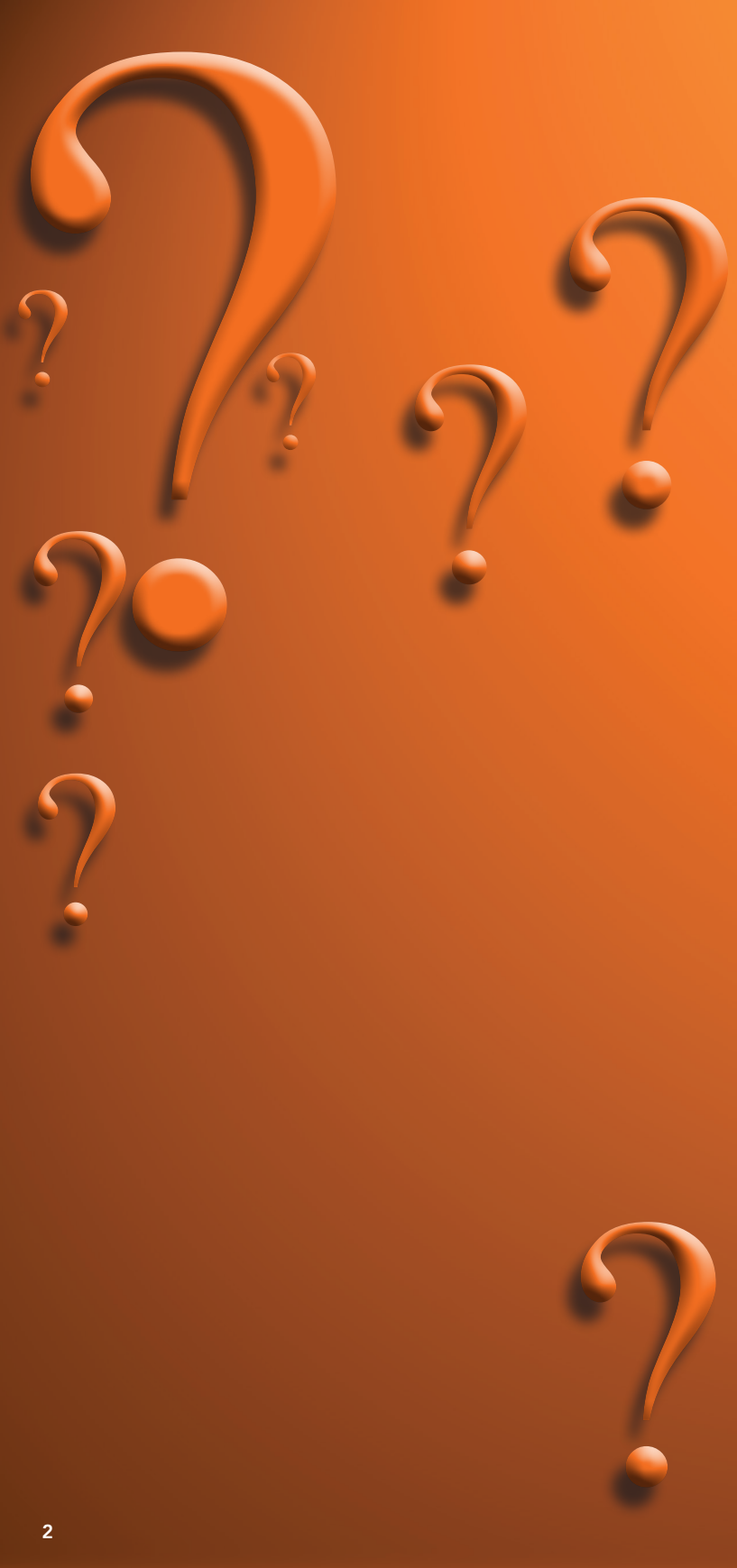

What you should know about RoActemra

Finding the right treatment for rheumatoid arthritis (RA) is very important. With today's RA medications, many people find the relief they need. All medications carry both potential benefits and potential risks to our health and it is important that you fully understand these. Finding the balance between the two will lead you to a treatment that works best for you. RoActemra might be that treatment.

RoActemra is used to treat adults with moderate to severe active RA, an autoimmune disease, if previous therapies did not work well enough. RoActemra helps to reduce symptoms such as pain and swelling in your joints and can also improve your performance of daily tasks. RoActemra has been shown to slow the damage to the cartilage and bone of the joints caused by the disease and to improve your ability to do normal daily activities.

RoActemra has been shown to work well in patients who were not helped by other medications for RA, such as methotrexate (MTX), Arava® (leflunomide), Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab) and Simponi® (golimumab).

This brochure will answer some questions you may have about the side effects and potential risks of RoActemra. It will help you determine if RoActemra is the right treatment for you. This brochure does not take the place of speaking to your doctor, nurse or pharmacist.

What you should know about RA and RoActemra

What causes RA?

No one knows for sure. In RA, 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 correctly, it can also attack the body itself. Diseases in which this happens, like RA, are called autoimmune diseases. When the immune system attacks the body, it leads to the symptoms people with RA have. These include joint pain, swelling, stiffness and fatigue.

What is IL-6?

Interleukin-6 (IL-6) is a protein that is made by some cells in the immune system. The body uses IL-6 to help manage infections. IL-6 also plays a major role in the signs and symptoms of RA. Some people with RA have too much IL-6.

What is RoActemra?

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

How has RoActemra been studied?

RoActemra has been widely studied in adults with RA. It has been studied alone and in combination with other medications for RA.

How is RoActemra used?

RoActemra can be used with MTX or on its own in cases of intolerance to MTX or where continued treatment with MTX is inappropriate. RoActemra has not been studied with, and should not be used with, other biologic drugs for RA that are injected. These may include: Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), MabThera® (rituximab), Orencia® (abatacept), Kineret® (anakinra), Cimzia® (certolizumab pegol) and Simponi® (golimumab).

How is RoActemra given?

A doctor or nurse will give you RoActemra. It is administered by an intravenous (into a vein) (IV) infusion with a needle. One dose will take approximately 60 minutes to infuse into a vein, most likely in the arm.

Dosing is based on your weight, so each person's dose may be different. Your doctor may change your dose based on how well RoActemra works for you. RoActemra is given every 4 weeks.

It is very important that you do not miss your scheduled dose of RoActemra. If this happens, call your doctor or nurse. He or she will tell you when you should get your next dose.

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 body 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 which 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 vaccination, should not be given during treatment with RoActemra. Patients with RA 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

What are the possible 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.

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 infusion 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 during treatment with RoActemra.

During an infusion, your doctor or nurse will be monitoring you closely for any signs of an allergic reaction. If an anaphylactic reaction or other serious allergic reaction occurs, administration of RoActemra should be stopped immediately, appropriate medical treatment initiated and RoActemra permanently discontinued.

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

- 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

Always tell your doctor before your next dose if you experience any allergic reaction symptoms after you receive RoActemra.

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. The risk of malignancy is increased in patients with RA. Medicinal products that act on the immune system, like RoActemra, may increase the risk of malignancy.

Before starting RoActemra, tell your doctor or nurse if you:

- Have an infection or are being treated for an infection
- Have signs of an infection, such as a fever, cough or headache, or are feeling unwell
- Have skin infections with open sores, such as herpes zoster infections (chicken pox or shingles)
- Get a lot of infections
- Have had any allergic reactions to previous medications, including RoActemra
- Have diabetes or other conditions that increase the chance for infections
- Have heart or circulatory disease such as high blood pressure
- Have tuberculosis (TB), or if you have been in close contact with someone who has had TB.
  Your doctor should test you for TB before starting RoActemra
- Have had intestinal ulcers or diverticulitis. Symptoms would include abdominal pain and unexplained changes in bowel habits with a fever
- Have liver disease
- Have recently had a vaccination (immunisation), such as a flu vaccination, or are scheduled to have one

Speak to your doctor, nurse or pharmacist if you have any questions about this information.

Tell your doctor about any side effect you experience. The 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.

For full information on all possible adverse events please see the Summary of Product Characteristics (SmPC) or the Patient Leaflet, which are available in all EU/EEA languages on the European Medicines Agency website (www.ema.europa.eu).

RoActemra may not be right for you. At each visit, tell your doctor or nurse if you:

- Are taking other medicines. Tell your doctor or nurse about all the medicines you take. This includes prescription 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. 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

- Are taking any other medications to treat RA. This includes medications, such as MTX or Arava®, and biologic drugs that are injected, such as Enbrel®, Humira®, Remicade®, MabThera®, Orencia®, Kineret®, Cimzia® and Simponi®

- Have had any allergic reactions to previous medications, including RoActemra

- Are pregnant, may be pregnant, intend to become pregnant or are breast-feeding. Women of childbearing potential must use effective contraception during (and up to 3 months after) treatment. RoActemra should not be used during pregnancy unless clearly necessary

- Have an infection or signs of an infection

- Have had or now have viral hepatitis or any disease of the liver
- Have a history of stomach ulcers or diverticulitis (inflammation in parts of the large intestine)
- Have had or now have impaired lung function (e.g. interstitial lung disease, where inflammation and scarring in the lungs make it difficult to get enough oxygen)
- Have recently had a vaccination (such as a flu vaccination) or are scheduled to have one
- Have cancer, heart or circulatory disease, such as raised blood pressure and raised cholesterol levels, or moderate to severe kidney problems

Summary and contact information

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

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

Suspected adverse reactions associated with the use of RoActemra should be reported to: Medicines Authority Post-licensing Directorate 203. Level 3. Rue D'Argens, Gzira GZR 1368, or at: http://www.medicinesauthority.gov.mt/adrportal.
Suspected adverse events should also be reported to Roche by phone on +44 (0)1707 367554, fax on +44 (0)1707 367582 or e-mail at welwyn.uk_dsc@roche.com.

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