



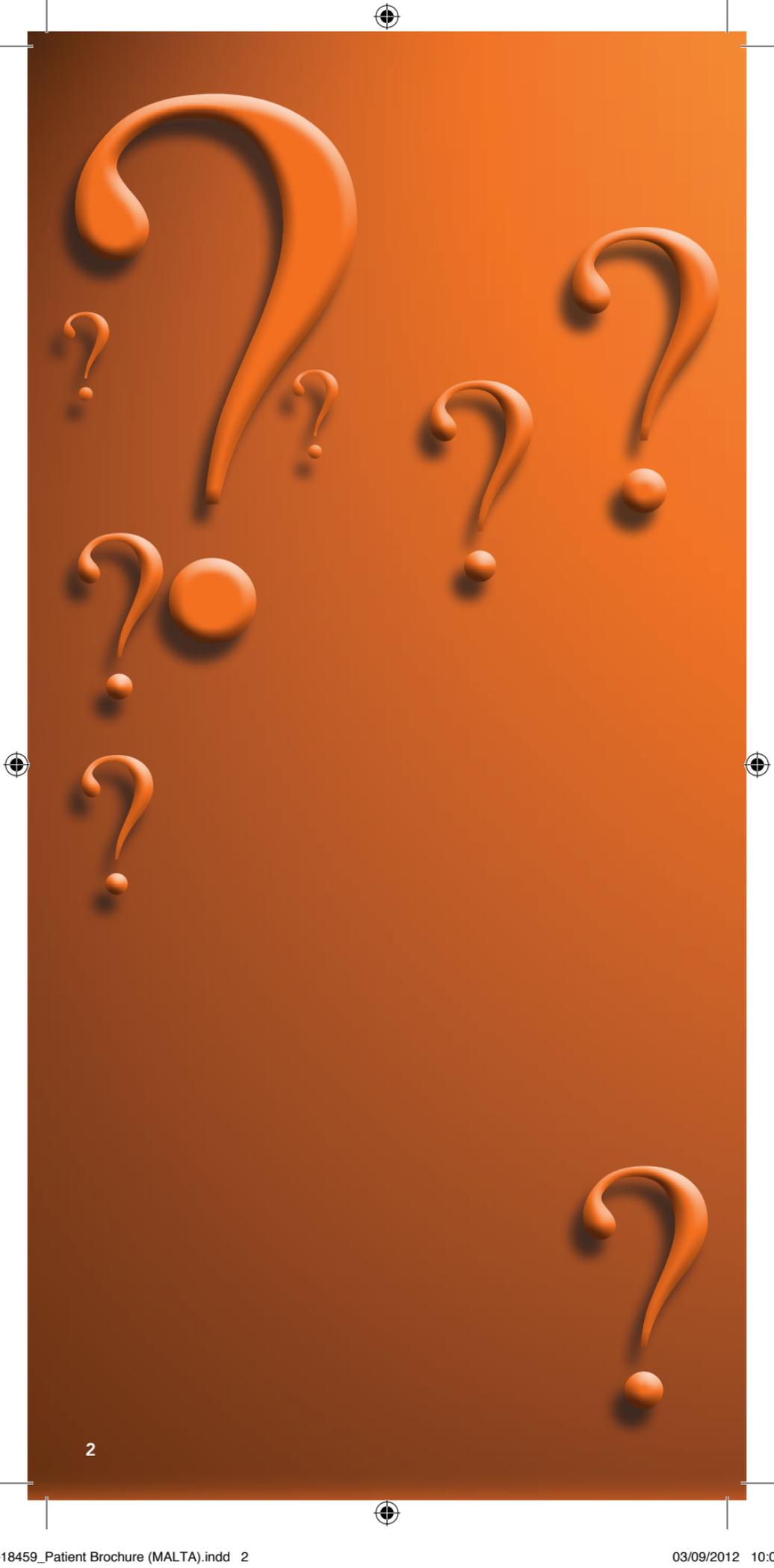
***What You
Should Know
About
RoActemra
(tocilizumab)***

Please request a copy of the patient information leaflet from your doctor.
This can be found within the tocilizumab packaging.

This information is only for RA patients prescribed tocilizumab

Roche

Copyright © 2012 by Roche Products Limited UK.
All rights reserved.



What you should know about tocilizumab

Finding the right treatment for rheumatoid arthritis (RA) is very important. With today's RA drugs, many people find the relief they need. It is important to know about the benefits and the risks of any drug.

Your doctor has prescribed RoActemra (tocilizumab). This brochure will answer some questions you may have about the side effects and potential risks of tocilizumab. You will also find important information in the Patient Information Leaflet that comes with tocilizumab. This brochure and the Patient Information Leaflet do not take the place of speaking to your doctor or nurse.

Tocilizumab, in combination with methotrexate (MTX), is used for the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying antirheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, tocilizumab can be given alone in case of intolerance to MTX or where continued treatment with MTX is inappropriate. Tocilizumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX.

Please see Important Safety Information on pages 10 and 11.

What you should know about RA and tocilizumab

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 only attack foreign substances like germs. But when it doesn't work properly, 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 signs and symptoms of RA. These include joint pain, swelling, stiffness and fatigue.

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 infections and other processes. It also plays a major role in the signs and symptoms of RA. Some people with RA have too much IL-6.

What is tocilizumab?

Tocilizumab is a drug that inhibits the actions of IL-6 in the body. It is used in adults to treat moderate to severe RA.

How is tocilizumab used?

Tocilizumab can be used with MTX or by itself in patients that are intolerant to MTX or where continued treatment with MTX is inappropriate. Tocilizumab has not been studied with, nor should be used with other biologic drugs (the newest type of drug made from living cells) for RA that are injected because of the possibility of increased risk of infection. These include: etanercept, adalimumab, infliximab, rituximab, abatacept, certolizumab, golimumab and anakinra.

How is tocilizumab given?

A doctor or nurse will give you tocilizumab. It is given by an intravenous (IV) infusion with a needle. Each dose will take approximately 1 hour to infuse into a vein, most likely in your arm.

Dosing is based on your weight, so each person's dose may be different. Your doctor may change your dose during your treatment based on results from blood tests. Tocilizumab is given every 4 weeks.

It is important that you do not miss your dose of tocilizumab. If you do, call your doctor. He or she will tell you when you should get your next dose.

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

- **Platelets.** Some people taking tocilizumab had a drop in the number of platelets in their blood. The body uses platelets to help stop bleeding. In clinical trials, the drop in platelets wasn't associated with any serious bleeding
- **White blood cells.** Having enough white blood cells is important to help your body fight infections. Tocilizumab works on the immune system and can cause the number of white blood cells to drop. Your doctor may test to make sure you have enough white blood cells and monitor for signs and symptoms of infection
- **Liver function tests.** Your doctor may test the levels of liver enzymes and bilirubin in your blood. Some people who have taken tocilizumab had a rise in liver enzymes. This did not result in injury to the liver. Rises in liver enzymes were seen more often when drugs that could be harmful to the liver were used with tocilizumab. If this happens to you, your doctor should take care of this right away. Your doctor may decide to change your dose of tocilizumab, other medication, or potentially stop treatment altogether
- **Cholesterol.** Some people who have taken tocilizumab have had a rise in cholesterol. If this happens to you, your doctor may prescribe a cholesterol-lowering drug

What are the most common side effects of tocilizumab?

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

- Upper respiratory tract infections, such as a cold
- Cellulitis (deep skin infection), pneumonia (lung infection), oral herpes simplex (cold sores), herpes zoster (e.g. chicken pox or shingles)
- Mouth ulcers, gastritis (stomach inflammation)
- Rash, pruritus (itchy skin), urticaria (hives)
- Headache, dizziness
- Increased hepatic transaminases (liver enzymes), indicating changes in the way your liver works
- Increased bilirubin shown by blood tests
- Hypertension (high blood pressure)
- Leukopenia, neutropenia which can mean a reduction in the infection fighting cells in your blood
- Hypercholesterolaemia (high cholesterol)
- Conjunctivitis (eye infection)
- Hypersensitive allergic reactions

Please see Important Safety Information on pages 10 and 11.

- 
- Abdominal pain
 - Weight gain
 - Peripheral oedema (primarily swelling of the feet)
 - Cough, shortness of breath

What are the serious side effects of tocilizumab?

Infections. Tocilizumab is a drug 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 tocilizumab. Some infections may become serious while on tocilizumab. This may require hospital treatment and can be potentially fatal if not treated. So it is very important to report any signs of infection to your doctor right away.



Allergic reactions. Most allergic reactions happen during infusion or within 24 hours after infusion. They can range from mild to severe.

- Mild to moderate reactions include:
 - Rise in blood pressure
 - Headache
 - Skin reactions, such as rash, hives and itching
- Severe reactions include:
 - Trouble breathing
 - Being lightheaded
 - Drop in blood pressure

Such reactions may be more severe, and potentially fatal in patients who have experienced hypersensitivity reactions during previous infusions.

Alert your doctor or nurse immediately if you experience any of these symptoms.

Stomach problems. Although uncommon, some patients taking tocilizumab have had serious side effects in their stomach and intestines. Symptoms may include new onset abdominal pain and/or unexplained change in bowel habits with fever. Contact your doctor or nurse right away if you have any of these symptoms.

Please see Important Safety Information on pages 10 and 11.



Malignancies. Many drugs used to suppress the immune system, such as tocilizumab, may be associated with an increased risk of cancer. Not enough is known about the effect of tocilizumab on cancer. Long-term safety studies are ongoing.

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

- 
- Are experiencing an infection (fever, cough, headache, feeling unwell, or open skin sores) or receiving treatment for an infection
 - Get a lot of infections or have diabetes or other conditions that increase the chance for infections
 - Have problems with your lungs. If your lungs are not working properly this can put you more at risk of developing infections.
 - Have tuberculosis (TB), or if you have been in close contact with someone who has had TB
 - Have had or now have viral hepatitis or any disease of the liver
 - Are taking any other medications to treat RA. This includes oral medication such as MTX and injectable medications such as etanercept, adalimumab, infliximab, rituximab, abatacept or anakinra
 - Are pregnant, want to become pregnant, or are breastfeeding. Tocilizumab has not been studied in women who are pregnant or breastfeeding
 - Have a history of diverticulitis (inflammation in parts of your large intestine) and/or gastrointestinal ulcers
 - Recently received a vaccination or are scheduled to receive a vaccination
- 

Please see Important Safety Information on pages 10 and 11.

Tocilizumab 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 over-the-counter drugs, vitamins and herbal supplements.**

You can take other drugs if your doctor has told you it is okay to take them while you are taking tocilizumab. Tocilizumab may interact with some of your medications. This may affect the dose you need of that drug. Tell your doctor if you are taking medicines that contain:

- statins, used to reduce cholesterol levels
 - calcium channel blockers (eg, 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 (eg, temazepam), used to relieve anxiety
- Are taking any other drugs to treat RA. This includes oral drugs, such as MTX and leflunomide, and biologic drugs that are injected, such as etanercept, adalimumab, infliximab, rituximab, abatacept, certolizumab, golimumab and anakinra
 - Are pregnant, want to become pregnant or are breast-feeding
 - Have an infection
 - Have recently been diagnosed with or are receiving treatment for stomach ulcers or diverticulitis (inflammation in parts of the large intestine)
 - Have recently been, or are scheduled to be vaccinated (eg, against influenza, “flu”)
 - Have had or now have impaired lung disease

Speak to your doctor if you have any questions about this information.

Tell your doctor about any side effects you may have. The side effects listed in this brochure are not all of the possible side effects with tocilizumab. Ask your doctor for more information.

Please see Important Safety Information on pages 10 and 11.



Summary and contact information

This brochure reviews some of the most important information about tocilizumab.

If you have any questions or problems, always talk to your doctor or nurse.



Please see Important Safety Information on pages 10 and 11.

Important Safety Information

What is tocilizumab?

IL-6 plays an important role in the signs and symptoms of RA. People with RA have too much IL-6 which is made by the immune system. Tocilizumab is a medicine that inhibits the action of IL-6 in the body and is used to treat adults with moderate to severe RA.

What is the most important information I should know about tocilizumab?

Tocilizumab is a medicine 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 tocilizumab. Some infections may become serious whilst on tocilizumab, leading to hospitalisation and/or death. Therefore, it is very important to report any signs of infection to your doctor or nurse right away.

Before starting tocilizumab:

Discuss your medical history and current health status with your doctor or nurse.

Tell your doctor or nurse about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

See page 7 of this booklet for details.



Tocilizumab can cause serious side effects. Possible side effects include:

- Serious infection, including reactivation of latent TB
- Allergic reactions. Signs of an allergic reaction include trouble breathing, skin rash or swollen face
- Blood problems. Your body may have a reduced number of white blood cells which help fight infections, or platelets which help stop bleeding. Symptoms include infection and bruising or bleeding very easily
- Liver function blood tests. Some patients taking tocilizumab may have abnormal liver blood tests
- Increases in cholesterol levels. Some patients taking tocilizumab may have increases in their cholesterol levels
- Abdominal pain. Patients taking tocilizumab on rare occasions have experienced serious side effects in their stomach and intestines. Symptoms may include fever and persistent abdominal pain with change in bowel habits. Contact your healthcare provider right away if you develop these symptoms
- Malignancies. Many drugs such as tocilizumab, which are used to suppress the immune system may be associated with an increased risk of cancer. Not enough is known about the effect of tocilizumab on cancer. Long-term safety studies are ongoing
- Some people on tocilizumab developed interstitial lung disease, a serious condition which can be fatal

The most common side effects with tocilizumab are upper respiratory tract infections (common cold, sinus infections), headache, temporary increases in blood pressure, rash and dizziness. (Please refer to page 5 for further common side effects)

Tell your doctor or nurse about any side effect that bothers you or that does not go away. These are not all of the possible side effects with tocilizumab. Ask your doctor or nurse for more information.

