RoActemra® (tocilizumab) for Systemic Juvenile Idiopathic Arthritis (sJIA)

PATIENT BROCHURE – WHAT YOU SHOULD KNOW

This brochure provides key information to assist patients with sJIA and their parents/guardians to understand the benefits and risks associated with RoActemra therapy

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. Full prescribing information can be found in the RoActemra Summary of Product Characteristics (SmPC) via the electronic Medicines Compendium (eMC) website: www.medicines.org.uk.

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

What you should know about RoActemra

Finding the right treatment for systemic juvenile idiopathic arthritis (sJIA) is very important and remains a challenge. New treatment options for sJIA mean more patients are likely to 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/your child. RoActemra might be that treatment.

RoActemra is indicated for the treatment of active sJIA in patients 2 years of age and older, who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. RoActemra can be given alone (in case of intolerance to methotrexate [MTX] or where treatment with MTX is inappropriate) or in combination with MTX.

RoActemra has been shown to work well in patients who were not helped by other medications, such as corticosteroids or NSAIDs.

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

What you should know about sJIA and RoActemra

What causes sJIA?

The exact cause of sJIA is unclear. Our immune system was developed to protect us from foreign substances like germs but, in sJIA, the immune system doesn't behave properly and attacks the body as well. Unlike the other forms of JIA (such as oligoarticular and polyarticular), the immune system not only attacks the joints but often causes inflammation of internal organs, leading to the symptoms people have with sJIA. These include joint and muscle pain, fever, skin rash and impaired physical function.

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. IL-6 also plays a major role in the signs and symptoms of sJIA. Some people with sJIA 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 children and young adults to treat sJIA.

How has RoActemra been studied?

RoActemra has been studied in children and young adults with sJIA. It has been studied with and without MTX for sJIA.

How is RoActemra used?

RoActemra can be given alone or in combination with MTX. RoActemra has not been studied with other biologic drugs for sJIA. RoActemra should not be used with other biologic drugs.

How is RoActemra given?

A doctor or nurse will give RoActemra to you/your child. 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/your child's weight, so each person's dose may be different and may change through the treatment course. RoActemra is given every 2 weeks.

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

What tests will be done when receiving treatment with RoActemra?

At each visit to see your doctor or nurse, they may test your/your child's blood to help guide their 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/your child has 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 you/your child has a rise in liver enzymes, your doctor should take care of this right away. Your doctor may decide to temporarily interrupt RoActemra, or change the dose of other medication you/your child may be taking, or potentially stop their 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 you/your child has an increase in cholesterol, your doctor may prescribe a cholesterol-lowering medication
- **Macrophage activation syndrome (MAS):** Patients with sJIA may develop a condition called macrophage (a type of white blood cell) activation syndrome (MAS), which can be life-threatening. RoActemra has not been studied in patients during an episode of active MAS. Your doctor will monitor for signs of this syndrome.

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 that for measles, mumps and rubella (constituents of the MMR vaccine) should not be given during treatment with RoActemra. Patients with sJIA 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)
- Nasopharyngitis
- Decrease in neutrophil count

What are the potential 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/your child's 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/your child develops 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/your child 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 the doctor before your/your child's next dose if you/your child experience any allergic reaction symptoms after they 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. If you/your child develops stomach pain or colic, or if there is blood in their stool.

Malignancies. 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/your child:

- Has an infection or is being treated for an infection
- Has signs of an infection, such as a fever, cough or headache, or is feeling unwell
- Has skin infections with open sores such as herpes zoster infections (chicken pox or shingles)
- Gets a lot of infections
- Has had any allergic reactions to previous medications, including RoActemra
- Has diabetes or other conditions that increase the chance for infections
- Has heart or circulatory disease such as high blood pressure

- Has tuberculosis (TB), or has been in close contact with someone who has had TB. Your doctor should test you/your child for TB before starting RoActemra
- Has had intestinal ulcers or diverticulitis. Symptoms would include abdominal pain and unexplained changes in bowel habits with a fever
- Has liver disease
- Has recently had a vaccination (immunisation), such as that for MMR, or is scheduled to have one
- Has a history of macrophage activation syndrome (MAS)

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

Tell your doctor about any side effect you/your child experiences. The side effects listed in this brochure are not all of the possible side effects that you/your child 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/your child. At each visit, tell your doctor or nurse if you/your child:

- **Is taking other medicines. Tell your doctor or nurse about all the medicines you/your child takes. This includes prescription and non-prescription medications, vitamins and herbal medicines.**

You/your child can take other medications if your doctor has told you it is okay to take them while you/your child is taking RoActemra. RoActemra may interact with some medications. This may affect the dose you/your child needs of that medication. Tell your doctor if you/your child is 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

- Is taking any other medications to treat sJIA. This includes oral medications, such as NSAIDs (e.g. ibuprofen), corticosteroids, methotrexate (MTX) and biologic drugs
- Has had any allergic reactions to previous medications, including RoActemra
- Has an infection or signs of an infection
- Has had or now has viral hepatitis or any disease of the liver
- Has recently had a vaccination (immunisation), such as that for MMR, or is scheduled to have one
- Is a young woman of childbearing age and may be pregnant or sexually active. Female patients 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
- Has had or now has impaired lung function (e.g. interstitial lung disease, where inflammation and scarring in the lungs make it difficult to get enough oxygen)
- Has 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.

This information is only for patients prescribed RoActemra

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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