RoACTEMRA® (tocilizumab).
Farmakoterapeutisk grupp: Immunosuppressiva medel, interleukin-hämmare; ATC-kod L04AC07. **Indikationer**: RoACTEMRA SC (Rx,F) RoACTEMRA, i kombination med metotrexat (MTX), är indicerat för behandling av måttlig till svår aktiv reumatoid artrit (RA) hos vuxna patienter som antingen inte har haft tillräcklig effekt av eller som inte tolererat tidigare behandling med en eller flera sjukdomsmodifierande antireumatiska läkemedel (DMARDs) eller tumörnekrosfaktor-(TNF)-hämmare. Hos dessa patienter kan RoACTEMRA ges som monoterapi vid intolerans mot metotrexat eller när fortsatt behandling med metotrexat är olämplig. RoACTEMRA har visats reducera progressionshastigheten av ledskadan mätt med röntgen och förbättra den fysiska funktionen, när det används i kombination med metotrexat. RoACTEMRA är indicerat för behandling av jättecellsarterit (Giant Cell Arteritis, GCA) hos vuxna patienter.
Kontraindikation: Överkänslighet mot aktiv substans eller hjälpämne. Aktiv svår infektion.
Varning och försiktighet: Tidigare sjukdomshistoria av sår i tarm eller divertikulit.
Graviditet: Bör undvikas under behandling och i 3 månader efter avslutad behandling.
Beredningsform och förpackningar: SC: Varje förfylld spruta innehåller 162 mg tocilizumab i 0,9 ml lösning. Varje förpackning à 4 sprutor.
SPC: 2018-08-23.
För mer information och aktuella priser se www.fass.se

RoACTEMRA® tocilizumab

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SE/RA/1812/0017

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MY RoACTEMRA® PASSPORT

RoACTEMRA® tocilizumab

This passport contains important safety information that patients and their parents/guardians need to be aware of before, during and after treatment with RoACTEMRA (tocilizimab).
It is also important for healtcare professionals to know that you use RoACTEMRA.

- Bring this passport if you are travelling abroad. Show this card to any healthcare professional involved in your care

Dates of RoACTEMRA Treatment / travel certificate:*

Start:.....

Most recent:.....

Next scheduled:.....

Patient´s name:.....

Date of birth: .....

Doctor:.....

Doctor´s sign:.....

Doctor contact number: .....

Number of syringes brought while traveling abroad: .....

Keep this card with you for at least 3 months after your last RoACTEMRA dose, since side effects could occur for some time after your last dose of RoACTEMRA. If you experiences any untoward effects and have been treated with RoACTEMRA in the past, contact your healthcare professional for advice.

RoACTEMRA, in combination with methotrexate (MTX), is indicated for:

- the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- 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 anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.
- the treatment of juvenile idiopathic polyarthritis (pJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX.

In the above patients, RoACTEMRA can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoACTEMRA is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoACTEMRA is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

CRP

RoACTEMRA/ACTEMRA is a drug that suppresses CRP. On suspicion of bacterial infection, a normal CRP does not rule out infection, but usually body temperature and / or the number of white blood cells rise during infection.

Infections

RoACTEMRA increases the risk of getting infections, which can become serious if not treated.

- You should not receive RoACTEMRA if you have a serious infection
- **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
- Seek medical advice if any signs/symptoms (such as persistent cough, wasting/weight loss, low-grade fever) suggestive of a tuberculsis infection occur during or after treatment with RoACTEMRA. You should have been screened and found to have no active tuberculosis prior to treatment with RoACTEMRA
- Talk to your healthcare professional about any vaccinations that you may need before you start treatment with RoACTEMRA
- If you have an infection of any kind (even a head cold) at the time of your next treatment, the treatment should be delayed until you are feeling better

Allergic reactions

Most allergic reactions occur during or within 24 hours of the 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 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 and appropriate medical treatment initiated
- **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 receiving RoACTEMRA.

Complications of diverticulitis

Patients using RoACTEMRA may develop complications of diverticulitis, which can become serious if not treated.

- **Seek immediate medical attention** if you develop stomach pain or colic, or if there is blood in your stool

*Please make sure you also have a list of all your other medicines with you at any visit to a healthcare professional.