PRESCRIBING INFORMATION

RoActemra® (tocilizumab): 20mg/ml concentrate for solution for intravenous infusion; 162 mg in 0.9ml solution for subcutaneous use.

Please refer to RoActemra SPC for full prescribing information.

Indications: ***IV & SC:*** For use in combination with methotrexate (MTX) for severe, active and progressive RA in adults not previously treated with MTX, or for use in combination with MTX for moderate to severe active RA in adults who have responded inadequately to, or were intolerant of DMARDs or anti-TNFs. Can be used as monotherapy in these patients, if intolerant to MTX, or if continued treatment with MTX is inappropriate.

SC: For the treatment of Giant Cell Arteritis (GCA) in adult patients.

Dose and Administration: Provide Patient Alert Card. Always record batch number. Monitor neutrophils, platelets, ALT, AST and lipids 4-8 weekly on initiation of treatment. See SPC.

IV: For RA, 8mg/kg infusion given over 1 hour once every 4 weeks. Doses exceeding 800mg per infusion are not recommended. See SPC for detailed instructions.

SC: For RA and GCA, 162mg (0.9ml) SC injection once weekly. For GCA, use initially with a tapering course of glucocorticoids, then can be used alone. RoActemra monotherapy should not be used for treatment of acute relapses in GCA.

IV & SC: Dose adjustments may be required for abnormalities of liver enzymes, neutrophil and platelet counts (see precautions and SPC for details).

Contraindications: Hypersensitivity to tocilizumab or excipients. Active, severe infection.

Precautions: Exercise caution in patients with hepatic impairment, recurrent or chronic infection, diverticulitis, diabetes, ILD or conditions predisposing to infection. Initiation not recommended if ALT or AST >5x ULN or ANC $<2x10^9$/L. Dose may require adjustment for raised liver enzymes, low neutrophil or platelet count. See SPC for details. Exercise caution if platelet count $<100x10^3$/µL. Recommended to discontinue if ANC $<0.5x10^9$/L or platelets $<50x10^3$/µL. Interrupt treatment in event of serious infection. Exercise vigilance for central demyelinating disorders and symptoms of hepatic injury. Screen for and treat TB prior to initiation of treatment. Do not use live or live attenuated vaccines. Do not use with other biological agents. Monitor patients taking products metabolised via CYP 450 3A4, 1A2 or 2C9 as doses may require adjustment. See SPC for details. Women of child-bearing potential should use contraception during and up to 3 months after treatment.

Adverse Events: For more information, see SPC. *Common:* upper respiratory tract infections, hypercholesterolaemia, cellulitis, pneumonia, herpes infection, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, raised LFTs, weight gain, hypertension, leukopenia, neutropenia, hypofibrinogenaemia, peripheral oedema, hypersensitivity, conjunctivitis, cough, dyspnoea. Injection site reactions for SC administration. *Serious:* GI perforation, hypersensitivity reactions, severe and fatal infection, ILD, Stevens-Johnson Syndrome, anaphylaxis, nephrolithiasis, hypothyroidism, hepatotoxicity, drug-induced liver injury and hepatic failure.

Legal Category: POM

NHS Costs: Pre-filled syringes, 4 pack £913.12. Pre-filled pen, 4 pack £913.12. 20mg/ml concentrate 4ml vial (80mg) £102.40; 10 ml vial (200 mg) £256.00; 20 ml vial (400 mg) £512.00.

Marketing Authorisation Numbers:

IV: EU/1/08/492/01 (80mg), EU/1/08/492/03 (200mg), EU/1/08/492/05 (400mg).

Pre-filled syringe: EU/1/08/492/07.

Pre-filled pen: EU/1/08/492/09.

Supplied by:

Roche Products Limited
6 Falcon Way, Welwyn Garden City
Herts, AL7 1TW.
RoActemra is a registered trade mark.

Date of Preparation: October 2019
RCUKMEDI00027(5)

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.

As RoActemra is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.

GCA LIVE 2020 WEBINAR

Join the Global discussion on GCA patient management

Thursday 30th January 2020

RoACTEMRA®
tocilizumab

This is a promotional meeting organised and funded by F. Hoffmann-La Roche Ltd and will contain the discussion of Roche medicines

Join the Global discussion on GCA patient management

In recent years we have seen advances in how giant cell arteritis is managed, highlighting the importance of understanding how to successfully navigate this complex disease. Challenges exist around patient diagnosis, identifying the right treatment for the right patient and how clinical decisions can be successfully implemented.

That is why we're delighted to invite you to GCA Live; a Global web-based discussion dedicated to sharing practical advice from our expert faculty. Use this opportunity to learn from real experiences in managing patients with this complex disease.

Here are our expert speakers who will be presenting at GCA LIVE 2020

Professor John Stone
Professor of Medicine
Harvard Medical School - USA

Principal investigator GiACTA trial

Professor Justin Mason
Professor of Vascular Rheumatology
Hammersmith Hospital - UK

RoACTEMRA®
tocilizumab

TEN YEARS OF ROACTEMRA 10

Webinar date and times:

Thursday 30th January 2020 - 08:00 GMT | 16:00 GMT | 18:30 GMT

Agenda:

5 mins - Opening and introduction - Professor Stone

15 mins - Case 1: Challenges with GCA diagnosis - Professor Mason
Professor Mason illustrates the challenges with diagnosis in a patient with large vessel vasculitis, and his approach to inducing remission.

15 mins - Case 2: Optimising patient outcomes - Professor Stone
Professor Stone presents the impact of misdiagnosis of a patient with severe cranial symptoms, and his approach to sustaining remission.

10 mins - Interactive Q & A
Your opportunity to ask our experts a question.

Registration

Please visit the registration website or scan the QR code below for more information on the GCA LIVE 2020 event.

Scan or Visit:
https://go.roche.com/GCALIVE2020