IBD clinical ROADMAP 2021

MD education

Introducing a new scientific initiative for clinicians in IBD from MD Education and Celltrion Healthcare UK Ltd

Dr. Fraser Cummings

Clinical lead for IBD services and consultant gastroenterologist at Southampton General Hospital doing a mix of ward work, outpatients, endsocopy and research. Dr Cummings looks after general gastroenterology patients and has a sub-specialty interest in inflamatory bowel disease (IBD). He spent five years developing this clinical and research interest at the John Radcliffe Hospital, Oxford, prior to starting work in Southampton.

Pearl Avery MSc, clinical nurse specialist

Based at Dorset County Hospital NHS Trust, Pearl has been awarded Gastrointestinal/IBD Nurse of the Year 2018 for her pioneering work to introduce a new IBD patient management system which has earned national recognition. It incorporates the IBD registry and the BÜHLMANN IBDoc calprotectin home test.

Every month, Dr. Cummings will be joined by a clinical expert for a 30 minute debate to dive deep into a hot topic in IBD. Each live debate will be followed by a questions and answer session with downloadable slides to enhance understanding. Nurse Avery will join Dr Cummings and another clinical expert on several discussions to provide a nurse perspective.

If you would like additional information or have any questions, please email to: office@md-education.com.

Organized by:

MD education

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Supported by:

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The clinical roadmap has been funded by Celltrion Healthcare UK Ltd.
Celltrion Healthcare have had no involvement in speakers or topics of discussion

These promotional webinars are intended for UK Healthcare Professionals

Follow this link to register at :
ibdroadmapuk.md-education.com

CTHC-UK-436
May 2021

Prescribing information can be found overleaf

2021

March — Pregnancy and IBD — Christian Selinger

April — How do adverse event profiles influence our choice of treatment? Chris Probert

May — Optimal use of steroids — Alan Lobo

June — Acute severe ulcerative colitis — Shaji Sebastian

July — What's the future? New treatments for IBD — Nick Powell

August — Building your IBD team in 2021 — Trevor Smith

September — IBD and registries: can they improve patient care? Stuart Bloom

October — Optimal use of anti-TNF's — Tariq Ahmad

November — IBD nursing: what next? — Karen Kemp

December — Right treatment, right patient, right time? — Ailsa Hart

2022

Prescribing information

Remsima® SC (infliximab)

Remsima 120 mg solution for injection in pre-filled syringe and pre-filled pen. Prescribing information. United Kingdom. Please read the Summary of Product Characteristics (SPC) before prescribing.

Presentation Each 1 mL single dose pre-filled syringe and in pre-filled pen contains 120 mg of infliximab for subcutaneous injection. **Indications** *Rheumatoid Arthritis (RA)*: ***Remsima***, in combination with methotrexate (MTX), is indicated for the reduction of signs and symptoms, as well as the improvement in physical function, in adult patients with active RA when the response to disease-modifying anti-rheumatic drugs (DMARDs), including MTX, has been inadequate; and in adult patients with severe, active and progressive RA not previously treated with MTX or other DMARDs. *Adult Crohn's Disease (CD)*: ***Remsima*** is indicated for the treatment of moderately to severely active CD in adult patients who have not responded to a full and adequate course of, are intolerant of, or have medical contraindications to therapy with a corticosteroid and/or an immunosuppressant; and fistulising active CD in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). *Ulcerative Colitis (UC)*: ***Remsima*** is indicated for the treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. *Ankylosing Spondylitis (AS)*: ***Remsima*** is indicated for the treatment of severe, active AS, in adult patients who have responded inadequately to conventional therapy. *Psoriatic Arthritis (PsA)*: ***Remsima*** is indicated for the treatment of active and progressive PsA, in adult patients when the response to previous DMARD drug therapy has been inadequate. Administration should be in combination with MTX or alone in patients who show intolerance to MTX or for whom MTX is contraindicated. In patients with polyarticular symmetrical subtypes of PsA a reduction in the rate of progression of peripheral joint damage has been shown, as measured by X-ray. *Psoriasis (PsO)*: ***Remsima*** is indicated for the treatment of moderate to severe plaque PsO in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, MTX or PUVA. **Dosage and administration** ***Remsima*** should be initiated and supervised by physicians experienced in the diagnosis and treatment of RA, inflammatory bowel diseases, AS, PsA and PsO. Patients treated with ***Remsima*** should be given the package leaflet and the patient alert card. The following includes the recommended dosing regimens for each indication, however please see the SPC. *RA*: Treatment with ***Remsima*** administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 3 mg/kg given 2 weeks apart. The recommended dose for Remsima subcutaneous formulation is 120 mg once every 2 weeks. *Adult moderately to severely active CD*: Treatment with ***Remsima*** administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. The recommended dose for ***Remsima*** subcutaneous formulation is 120 mg once every 2 weeks. If a patient does not respond after 2 doses of intravenous infusions, no additional treatment with infliximab should be given. *Adult, fistulising, active CD*: ***Remsima*** 120 mg given as a subcutaneous injection 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. The recommended dose for ***Remsima*** subcutaneous formulation is 120 mg once every 2 weeks. If a patient does not respond after 6 doses, no additional treatment with infliximab should be given. *UC*: Treatment with Remsima administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. *AS*: Treatment with ***Remsima*** administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. If a patient does not respond by 6 weeks, no additional treatment with infliximab should be given. *PsA*: Treatment with ***Remsima*** administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. *PsO*: Treatment with ***Remsima*** administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. If a patient shows no response after 14 weeks (i.e. 2 intravenous infusions and 5 subcutaneous injections), no additional treatment with infliximab should be given. *Re-administration*: In case maintenance therapy is interrupted, and there is a need to restart treatment, use of a re-induction regimen of intravenous infliximab is not recommended (see section 4.8). In this situation, infliximab should be re-initiated as a single dose of intravenous infliximab followed by the maintenance dose recommendations of subcutaneous infliximab described above given 4 weeks after the last administration of intravenous infliximab. *Switching to and from Remsima subcutaneous formulation across indications*: When switching from the maintenance therapy of infliximab intravenous formulation to the subcutaneous formulation of ***Remsima***, the subcutaneous formulation may be administered 8 weeks after the last administration of the intravenous infusions of infliximab. **Contraindications** Tuberculosis or other severe infections such as sepsis, abscesses and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV); hypersensitivity to infliximab, other murine proteins or any of the excipients. **Precautions and warnings** Please check SPC before prescribing. *Systemic injection reaction/ localized injection site reaction/ hypersensitivity*: Infliximab has been associated with systemic injection reactions, anaphylactic shock and delayed hypersensitivity reactions. Acute reactions including anaphylactic reactions may develop during (within seconds) or within a few hours following administration of infliximab. For this reason, the initial intravenous administrations should take place where emergency equipment, such as adrenaline, antihistamines, corticosteroids and an artificial airway is immediately available. Patients may be pre-treated with e.g., an antihistamine, hydrocortisone and/or paracetamol to prevent mild and transient effects. Localised injection site reactions predominantly of mild to moderate in nature included the following reactions limited to injection site: erythema, pain, pruritus, swelling, induration, haematoma, oedema, bruising, coldness, irritation, paraesthesia, ulcer, urticaria, haemorrhage, rash and scab were reported to be associated with infliximab subcutaneous treatment. Most of these reactions may occur immediately or within 24 hours after subcutaneous injection. Most of these reactions resolved spontaneously without any treatment. Available data suggest an increased risk for delayed hypersensitivity with increasing infliximab free interval. Patients should be advised to seek immediate medical advice if they experience any delayed adverse reaction. If patients are re-treated after a prolonged period, they must be closely monitored for signs and symptoms of delayed hypersensitivity. *Infections*: Patients must be monitored closely for infections, including tuberculosis, before, during and up to 6 months after treatment with ***Remsima***. Caution in patients with chronic infection or a history of recurrent infection. Patients should be advised of potential risk factors for infections. Suppression of TNFα may mask symptoms of infection such as fever. Tuberculosis, bacterial infections (including sepsis and pneumonia), invasive fungal, viral and other opportunistic infections, have been observed, some of which have been fatal. Infections were reported more frequently in paediatric populations than in adult populations. There have been reports of active tuberculosis in patients receiving infliximab. Before ***Remsima*** treatment, patients must be evaluated for active or latent tuberculosis and tests should be recorded on the Patient Alert Card. ***Remsima*** therapy must not be initiated if active tuberculosis is diagnosed. If latent tuberculosis is diagnosed, a physician with expertise in treatment of tuberculosis should be consulted and the benefit/risk of therapy should be considered. Treatment with anti-tuberculosis therapy must be initiated before initiation of ***Remsima***. Patients should be advised to seek medical advice if symptoms of tuberculosis appear during or after treatment. An invasive fungal infection such as aspergillosis, candidiasis, pneumocystosis, histoplasmosis, coccidioidomycosis or blastomycosis should be suspected if a serious systemic illness develops. A physician with expertise in the diagnosis and treatment of invasive fungal infections should be consulted at an early stage. Patients with fistulising CD with acute suppurative fistulas must not initiate ***Remsima*** therapy until possible source of infection is excluded. *Hepatitis B (HBV) reactivation*: Reactivation of HBV has occurred in patients receiving infliximab who are chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment and closely monitored for signs and symptoms of active HBV infection. *Hepatobiliary events*: Cases of jaundice and non- infectious hepatitis, some with features of autoimmune hepatitis, have been observed. Isolated cases of liver failure resulting in liver transplantation or death have occurred. ***Remsima*** should be discontinued if jaundice and/or ALT elevations ≥5 times the upper limit of normal develop. *Vaccinations/ therapeutic infectious agents*: Patients should be brought up to date with all vaccinations prior to initiating therapy. Patients may receive concurrent vaccinations but the concurrent administration of live vaccines or therapeutic infectious agents is not recommended. In infants exposed in utero to infliximab, fatal outcome due to disseminated Bacillus CalmetteGuérin (BCG) infection has been reported following administration of BCG vaccine after birth. A six month minimum waiting period following birth is recommended before the administration of live vaccines to infants exposed in utero to infliximab. *Autoimmune processes*: If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with ***Remsima*** and is positive for antibodies against double-stranded DNA, treatment must be discontinued. *Neurological events*: Anti-TNF agents have been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and risks of anti-TNF treatment should be carefully considered before initiation. Discontinuation of ***Remsima*** should be considered if these disorders develop. *Malignancies and lymphoproliferative disorders*: A risk of the development of lymphomas and other malignancies in patients (including children and adolescents) cannot be excluded. Caution in patients with history of malignancy, in patients with increased risk for malignancy due to heavy smoking, when considering continuing treatment in patients who develop a malignancy, in patients with PsO and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Possible increased risk of cervical cancer; periodic screening should continue in women treated with ***Remsima***, including those over 60 years of age. Post-marketing cases of hepatosplenic T-cell lymphoma have been reported which is usually fatal. Most cases have occurred in patients with CD or UC treated concomitantly with AZA or 6-MP. Melanoma and Merkel cell carcinoma have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. Patients with UC at increased risk for, or with a prior history of dysplasia or colon carcinoma should be screened for dysplasia before therapy and at regular intervals throughout their disease course. Kaposi's sarcoma has been reported, a rare cancer related to infection with human herpes virus 8. *Heart failure*: Caution in patients with mild heart failure (NYHA class I/II) and discontinue in patients who develop new or worsening symptoms of heart failure. *Haematologic reactions*: Discontinuation should be considered in patients with confirmed significant haematologic abnormalities, including pancytopenia, leukopenia, neutropenia and thrombocytopenia. *Others*: Patients requiring surgery whilst on ***Remsima*** therapy should be closely monitored for infections. *Special populations*: Particular attention regarding the risk of infection should be paid when treating the elderly (>65 years). May have a minor influence on the ability to drive and use machinery. **Interactions** No interaction studies have been performed. Combination of ***Remsima*** with anakinra and abatacept as well as other biological therapeutics used to treat the same conditions as ***Remsima***, is not recommended. **Fertility, pregnancy and lactation** Women of childbearing potential should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last ***Remsima*** treatment. ***Remsima*** should only be used during pregnancy if clearly needed. Administration of ***Remsima*** is not recommended when breast-feeding. Cases of agranulocytosis in infants have been reported. Effects of infliximab on fertility and general reproductive function are unknown. **Undesirable effects** Frequencies are defined at very common (≥1/10), common (≥1/1000 to <1/100), not known (cannot be estimated from the available data). ***Very common:*** viral infection (e.g. influenza, herpes virus infection), headache, upper respiratory tract infection, sinusitis, abdominal pain, nausea, pain. ***Common:*** bacterial infections (e.g. sepsis, cellulitis, abscess), neutropenia, leukopenia, anaemia, lymphadenopathy, allergic respiratory symptom, depression, insomnia, vertigo, dizziness, hypoaesthesia, paresthesia, conjunctivitis, tachycardia, palpitation, hypotension, hypertension, ecchymosis, hot flush, flushing, lower respiratory tract infection (e.g. bronchitis, pneumonia), dyspnea, epistaxis, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastrointestinal reflux, constipation, hepatic function abnormal, transaminases increased, new onset or worsening psoriasis including pustular psoriasis (primarily palm and soles), urticarial, rash, pruritis, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, althralgia, myalgia, back pain, urinary tract infection, chest pain, fatigue, fever, injection site reaction, chills, oedema. ***Not known:*** vaccine breakthrough infection (after ***in utero*** exposure to infliximab, hepatosplenic T-cell lymphoma (primarily in adolescents and young adult males with Crohn's disease and ulcerative colitis), Merkel cell carcinoma, transient visual loss occurring during or within 2 hours of infusion, myocardial ischaemia/myocardial infarction, liver failure, worsening of symptoms of dermatomyositis, Kaposi's sarcoma. **Serious, including fatal, adverse reactions have been reported**, including HBV reactivation, CHF (congestive heart failure), serious infections (including sepsis, opportunistic infections and TB), serum sickness (delayed hypersensitivity reactions), haematologic reactions, systemic lupus erythematosus/lupus-like syndrome, demyelinating disorders, hepatobiliary events, lymphoma, HSTCL, leukaemia, Merkel cell carcinoma, melanoma, sarcoidosis/sarcoid-like reaction, and serious infusion reactions. **Other less common and rarely reported adverse reactions are listed in the SmPC.** Prescribers should consult the Summary of Product Characteristics for full prescribing information.

Special precautions for storage Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the medicinal product in its outer carton in order to protect from light. The medicinal product may be stored at temperatures up to a maximum of 25°C for a period of up to 28 days. The medicinal product must be discarded if not used within the 28-day period.

Legal category POM

Presentations and basic NHS costs: Remsima SC (infliximab) 120 mg solution for injection in pre-filled pen (pack size 2 is £755.32, £377.66 per unit)**;** Remsima SC (infliximab) 120 mg solution for injection in pre-filled syringe (pack size 2 is £755.32, £377.66 per unit)

Marketing Authorisation numbers EU/1/13/853/001

Marketing Authorisation holder

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For medical information enquiries, please contact UKmedical@celltrionhc.com

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Celltrion Healthcare
and its authorised commercialisation partners by calling
+44 (0)1279 406759 (Diamond Pharma Services)

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