CELLTRION care®

CelltrionCare

A complimentary Patient Support Service for patients in Australia who have been prescribed a Celltrion medication for approved indications.

Simple Healthcare Professional registration and access

Simple patient registration and access to support services

*Refer to the Product Information for full listing of the approved indications

FOR HEALTHCARE PROFESSIONALS ONLY

About CelltrionCare

The **CelltrionCare** program is designed to support healthcare professionals and their patients, by delivering services that fit in the patient's treatment journey. Patients who enrol in **CelltrionCare** can access the following while on treatment.

WELCOME KIT AND TRAVEL BAG

delivered to newly enrolled patients

1800 SUB CUT [782 288]
Weekdays
(excluding public holidays)
9:00 am – 5:00 pm AEST

SELF-INJECTION TRAINING

Including how-to videos, downloadable instructions, self-injection training (virtual or home visit) with a nurse

MEDICATION REMINDERS

Email or SMS reminders to help patients keep track of their injections

Please scan this QR code to access www.celltrioncare.com

WEB-PORTAL

Access to disease and product information, injection training support materials and resources available to you at all times

MEDICATION HOME DELIVERY

Delivery of the patient's medication directly to their home

CelltrionCare ensures that your patients receive support and advice about accessing services that are relevant to their individual needs and situation

Patients can opt-in or out of any of these services at any time by contacting the CelltrionCare Clinical Liaison on **1800 SUB CUT (782 288) or support@celltrioncare.com**

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How does the program support my patients?

- The **CelltrionCare** Clinical Liaison is a registered nurse, who can liaise with the patient to ensure they receive support and advice about accessing services that are relevant to their individual needs and situation during their treatment journey. The information and advice they provide aims to complement and align with the guidance and treatment advice provided by yourself. They are not intended to replace the advice or services you provide.

- You will also have access to program resources, request samples and receive updates on your patients through the web portal www.celltrioncare.com, confirming details of their upcoming injection appointments and reports on their progress to ensure continuity of care.

Enrolling in *CelltrionCare* is easy

How can I enrol in the program?

Please scan this QR code to access www.celltrioncare.com

1800 SUB CUT (782 288)

Email: support@celltrioncare.com

Contact your Celltrion Rep

How can patients enrol in the program?

Please provide patients with the filled out Program Enrolment Card with the program access code

Please scan this QR code to access www.celltrioncare.com

1800 SUB CUT (782 288)

Email: support@celltrioncare.com

Once the patient completes the enrolment process, the **CelltrionCare** Clinical Liaison will be in touch to introduce them to the program and organise the delivery of their welcome kit.

If you or your patients have any questions or require help with enrolment
contact **1800 SUB CUT (782 288).**
This freephone line is staffed on weekdays from
9.00 am to 5.00 pm AEST (excluding NSW public holidays)

*Refer to the Product Information for full listing of the approved indications

Yuflyma® adalimumab

PBS Information: Rheumatoid Arthritis and Ankylosing Spondylitis: Authority required (telephone/immediate online assessment) for initial treatment. Authority required (STREAMLINED) for first and subsequent continuing treatment courses. This product is not PBS listed for the treatment of Uveitis. **All other indications:** Authority required for initial and first continuing treatment courses. Authority required (STREAMLINED) for subsequent continuing courses. Refer to PBS schedule for full authority information.

Before prescribing, please review full Product Information available on request from Celltrion Healthcare Medical Information Service (Phone: 1800 325 228) or www.ebs.tga.gov.au

MINIMUM PRODUCT INFORMATION. YUFLYMA containing 40 mg adalimumab for subcutaneous (SC) injection in a single dose pre-filled pen or syringe. **INDICATIONS:** Rheumatoid arthritis (RA), Yuflyma is indicated for reducing signs and symptoms, as well as inhibiting the progression of structural damage in adult patients with moderate to severely active RA. This includes the treatment of patients with recently diagnosed moderate to severely active disease who have not received methotrexate (MTX). Yuflyma can be used alone or in combination with methotrexate.; Juvenile Idiopathic Arthritis, in combination with MTX in patients (≥ 2 years of age) with active polyarticular juvenile idiopathic arthritis who have had an inadequate response to disease-modifying anti-rheumatic drugs (DMARDs). YUFLYMA can be given as monotherapy in case of intolerance to MTX or when continued MTX treatment is inappropriate; YUFLYMA is indicated for the treatment of active enthesitis-related arthritis in patients ≥ 6 years of age, who have had an inadequate response to, or who are intolerant of, conventional therapy; Ankylosing spondylitis (AS): YUFLYMA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. Psoriatic arthritis (PsA), YUFLYMA is indicated for the treatment of signs and symptoms, as well as inhibiting the progression of structural damage, of moderate to severely active psoriatic arthritis in adult patients where response to previous DMARDs has been inadequate; Psoriasis (PsO), for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. YUFLYMA is indicated for the treatment of severe chronic plaque psoriasis in children and adolescent patients ≥ 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. Hidradenitis suppurativa (HS), in adults and adolescents ≥ 12 years of age with moderate to severe HS (acne inversa) with an inadequate response to conventional systemic HS therapy. Crohn's disease (CD): in adults and children ≥ 6 years of age to reduce the signs and symptoms of the disease and to induce and maintain clinical remission in patients; (1) who have had an inadequate response to conventional therapies or, (2) who have lost response to or are intolerant to infliximab. Ulcerative Colitis (UC): in adult patients who have had an inadequate response to conventional therapy or who are intolerant to or have medical contraindications for such therapies. Patients should show a clinical response within 8 weeks of treatment to continue treatment beyond that time; Uveitis, in adults for the treatment of non-infectious intermediate, posterior and pan-uveitis who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any excipients listed in the Product Information (PI); active tuberculosis or other severe infections such as sepsis, and opportunistic infections; moderate to severe heart failure (NYHA class III/IV). **PRECAUTIONS:** Infections: monitor closely for infections including TB before, during and after treatment. YUFLYMA should not be initiated in patients with active infections including chronic or localised until they are controlled. Caution with a history of recurrent infection, underlying conditions and new infection while undergoing treatment with YUFLYMA. Hepatitis B (HBV) reactivation: reactivation of HBV has occurred in chronic carriers when receiving adalimumab. Test for HBV infection before initiating treatment and closely monitor for symptoms of active HBV. Neurological events: anti-TNF agents are associated with new onset or exacerbation of clinical symptoms and/or radiographic evidence of CNS demyelinating disease, including multiple sclerosis and optic neuritis, and peripheral demyelinating disease, including Guillain-Barré syndrome. Malignancies and lymphoproliferative disorders: risk of development of lymphomas/leukaemia/other malignancies cannot be excluded. Caution with history of malignancy, with increased risk for malignancy, and treating patients who develop a malignancy. Haematologic reactions: consider discontinuation when significant haematologic abnormalities, including pancytopenia and cytopenia. Vaccinations: prior to therapy vaccinations should be up to date. Patients on YUFLYMA may receive concurrent vaccinations, except for live vaccines. Administration of live vaccines to infants exposed to adalimumab in utero is not recommended for 5 months following the mother's last adalimumab injection during pregnancy. Congestive Heart failure: caution with mild heart failure (NYHA class I/II) and discontinue when new or worsening symptoms of heart failure develop. Autoimmune processes: discontinue treatment if symptoms suggestive of a lupus-like syndrome and positive for antibodies against double-stranded DNA. Use in the elderly: particular attention regarding the risk for infection should be paid. Fertility, pregnancy and lactation: women of childbearing potential should consider adequate contraception to prevent pregnancy and continue use for ≥5 months after treatment. Due to its inhibition of TNFα, adalimumab administered during pregnancy could affect normal immune responses in the newborn. Adalimumab should only be used during pregnancy if clearly needed. YUFLYMA can be used during breastfeeding. **INTERACTIONS:** Combination with anakinra or abatacept is contraindicated, and not recommended due to increased risk of serious infection. YUFLYMA can be taken together with: methotrexate, certain dMARDs, steroids or pain medications including NSAIDs. **ADVERSE EFFECTS (AEs):** The most commonly reported adverse reactions are infections (such as nasopharyngitis, upper respiratory tract infection and sinusitis), injection site reactions (erythema, itching, haemorrhage, pain or swelling), headache and musculoskeletal pain. For more information on reported AEs see full PI. **DOSAGE AND ADMINISTRATION:** YUFLYMA is available as 40 mg presentations in pre-filled syringe and/or pre-filled pen. RA, PsA, AS: 40mg every other week (EOW). In RA, methotrexate, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs or analgesics may be continued while using YUFLYMA. Polyarticular Juvenile Idiopathic Arthritis: patients ≥2 years of age (≥30kg) can use 40mg EOW. Active Enthesitis-Related Arthritis: patients ≥6 years of age (≥30kg) can use 40mg EOW. PsO: for adult patients – 1st dose of 80mg (2 x 40 mg injections in 1 day), followed by 40mg EOW starting 1 week after 1st dose. Paediatric Plaque PsO: See PI. Hidradenitis Suppurativa: see PI. CD (adult and paediatric patients ≥ 40kg) & UC (adult patients) - induction of 160mg (4 x 40 mg in 1 day or 2 x 40mg per day for 2 consecutive days), followed by 80mg (2 x 40mg in 1 day) 2 weeks later. Thereafter, 40mg EOW. Uveitis: see PI

Remsima® Infliximab

PBS Information: Authority required. Refer to PBS Schedule for full authority information.

Before prescribing, please review full Product Information available on request from Celltrion Healthcare Medical Information Service (Phone: 1800 325 228) or www.ebs.tga.gov.au

MINIMUM PRODUCT INFORMATION. REMSIMA® SC containing 120 mg infliximab for subcutaneous (SC) injection in a 1-mL single dose pre-filled pen or syringe. **INDICATIONS (Adults ≥18 years):** Rheumatoid arthritis (RA), in combination with methotrexate (MTX), for the reduction of signs and symptoms and prevention of structural joint damage in patients with active disease despite treatment with MTX, and patients with active disease who have not previously received MTX. REMSIMA® SC should be given in combination with MTX; Ankylosing spondylitis (AS), to reduce signs and symptoms and improve physical function in patients with active disease; Psoriatic arthritis (PsA), to treat signs and symptoms, as well as for the improvement in physical function in patients with active and progressive disease who responded inadequately to disease-modifying anti-rheumatic drug (DMARD) therapy; Psoriasis (PsO), in patients with moderate to severe plaque PsO for whom phototherapy or conventional systemic treatments were inadequate or are inappropriate; Moderate to severe Crohn's disease (CD), to reduce the signs and symptoms and to induce and maintain clinical remission in patients who have an inadequate response to conventional therapies; Refractory fistulising CD, to reduce the number of draining enterocutaneous and rectovaginal fistulas and maintain fistula closure; Moderately severe to severe active ulcerative colitis (UC), in patients who had an inadequate response to conventional therapy. **CONTRAINDICATIONS:** Severe infections (e.g. sepsis, abscesses, tuberculosis and opportunistic infections); history of hypersensitivity to IFX, other murine proteins or any excipient; concurrent administration with anakinra; congestive heart failure or moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS:** Systemic injection reactions, anaphylactic shock and delayed hypersensitivity reactions have been reported. Localised injection site reactions have been reported following SC administration. Malignancies and lymphoproliferative disorders: risk of development of lymphomas/other malignancies cannot be excluded. Caution with history of malignancy, with increased risk for malignancy, and treating patients who develop a malignancy. Infections: monitor closely for infections including TB before, during and up to 6 months after treatment. Caution with chronic infection or a history of recurrent infection. Suppression of TNF may mask symptoms of infection such as fever. Fistulising CD patients with acute suppurative fistulas must not initiate Remsima® SC until possible source of infection is excluded. Hepatitis B (HBV) reactivation: reactivation of HBV has occurred in chronic carriers when receiving IFX. Test for HBV infection before initiating treatment and closely monitor for symptoms of active HBV. Hepatobiliary events: 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. Vaccinations/therapeutic infectious agents: prior to therapy vaccinations should be up to date. Live vaccines or therapeutic infectious agents not recommended. Min. 6-month waiting period after birth before use of live vaccines to infants exposed in utero to IFX. Autoimmune processes: discontinue treatment if symptoms suggestive of a lupus-like syndrome and positive for antibodies against double-stranded DNA. Neurological events: anti-TNF agents are associated with new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. Heart failure: caution with mild heart failure (NYHA class I/II) and discontinue when new or worsening symptoms of heart failure develop. Haematologic reactions: consider discontinuation when significant haematologic abnormalities, including pancytopenia, leukopenia, neutropenia and thrombocytopenia. Use in the elderly: caution in the treatment of elderly patients (greater frequency of decreased hepatic, renal and/or cardiac function and concomitant disease and/or other drug therapy). Fertility, pregnancy and lactation: women of childbearing potential should consider adequate contraception to prevent pregnancy and continue use for ≥6 months after treatment. Not recommended for use during pregnancy and lactation. Breastfeeding should be discontinued for ≥6 months after treatment. Paediatric use: safety and efficacy of subcutaneous IFX therapy in children <18 years is not established. **INTERACTIONS:** No specific drug interaction studies conducted. Combination with anakinra is contraindicated, use with abatacept as well as other biological therapeutics used to treat the same conditions not recommended. **ADVERSE EFFECTS:** Very common, localised injection site reactions. Common, viral infection, fever, serum-sickness-like reactions, headache, vertigo/dizziness, flushing, upper respiratory tract infection, lower respiratory tract infection, dyspnoea, sinusitis, nausea, diarrhoea, abdominal pain, dyspepsia, abnormal hepatic function, rash, pruritus, urticaria, increased sweating, dry skin, fatigue, chest pain, infusion-related reactions. The safety profile of REMSIMA® SC in clinical trials was overall similar to the safety profile of the IV formulation. For other less common and rarely reported AEs see full PI. **DOSAGE AND ADMINISTRATION:** AS, PsA, CD, fCD, UC, PsO: treatment with Remsima® SC should be initiated as maintenance therapy 4 weeks after the last administration of two IV infusions of infliximab 5 mg/kg given 2 weeks apart. The recommended dose for Remsima® SC is 120 mg once every 2 weeks. RA: treatment with Remsima® SC may be initiated with or without IV loading doses of IFX. Without IV loading, Remsima® SC 120 mg should be given as a SC injection followed by additional SC injections at 1, 2, 3 and 4 weeks after the first injection, then every 2 weeks thereafter. If two IV loading doses of IFX are given to initiate treatment, Remsima® SC should be initiated as maintenance therapy 4 weeks after the last administration of two IV infusions of infliximab 3 mg/kg given 2 weeks apart. The recommended dose for Remsima® SC is 120 mg once every 2 weeks. Switching from IV maintenance to SC (all indications): administer first dose of Remsima SC eight weeks after last IV dose.

Celltrion encourages the reporting of adverse events (AE), special situations and product quality complaints (PQC) in relation to its products. Celltrion's medical (pharmacovigilance) team may wish to contact you for further information regarding any AEs, special situations and PQCs, reported by your patients during their participation in the program. Your agreement to this is voluntary, and you will be given the option to indicate your consent to this during the provision of the program services. The information may be disclosed to local and overseas regulatory authorities or other third parties (such as those providing AE case processing activities, or license partners), for the purposes of meeting pharmacovigilance requirements.

Terms & conditions and Privacy Policy of the CelltrionCare program can be found at: www.celltrioncare.com

The CelltrionCare program is administered by DKSH Healthcare Australia Pty Ltd (DKSH) on behalf of the Sponsor Celltrion Healthcare Australia Pty Ltd. Celltrion and DKSH Healthcare will collect, hold, and use your personal information to deliver the program to your enrolled patients and to continue to improve the program, including contacting you for follow-up purposes and providing you with materials related to the program. The privacy policy of DKSH Healthcare https://www.dksh.com/au-en/home/privacy contains further information about how you may access and/or correct the personal information held about you as required by law, as well as information about making a complaint about a breach of the Privacy Act and how Celltrion and DKSH Healthcare will deal with such a complaint.

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CELLTRION care®

Yuflyma® adalimumab

Remsima® Infliximab