Yuflyma®
adalimumab

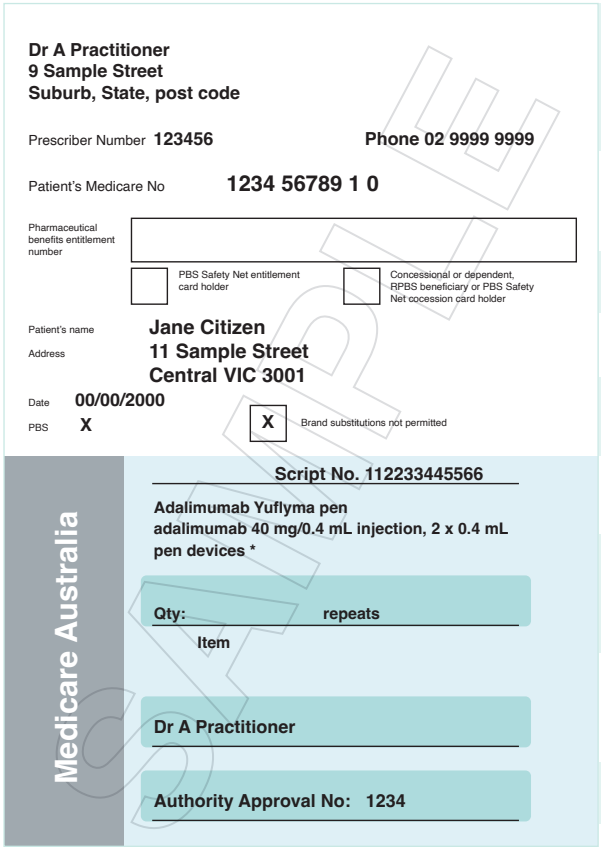
Yuflyma®

Prescriber Guide

Rheumatology

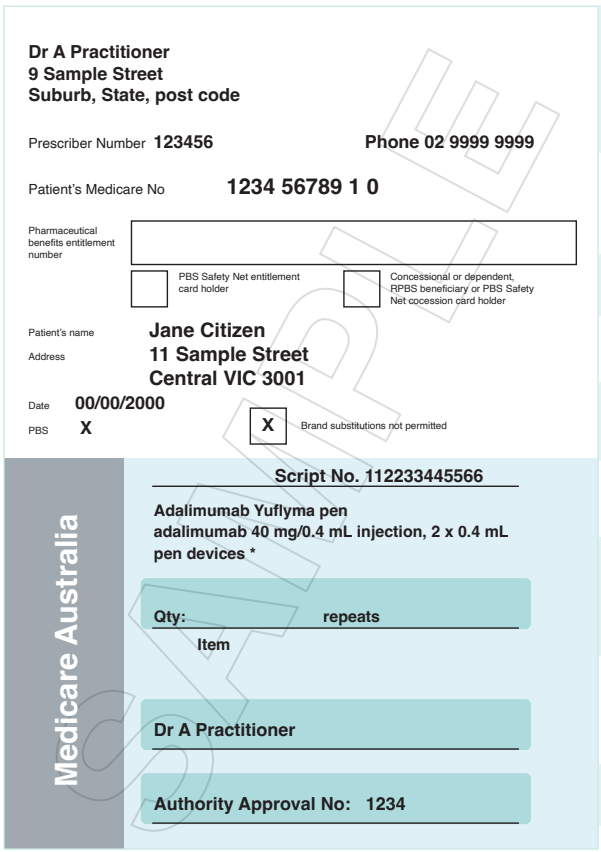
HEALTHCARE
CELLTRION

1 Ankylosing Spondylitis



Initial treatment	1st Continuing treatment	Subsequent continuing treatment
Authority required PBS code 13764K	STREAMLINED PBS code 13226D	STREAMLINED PBS code 13226D
SA: PB073		
Brand substitutions not permitted - box needs to be ticked so that Yuflyma brand is not substituted.		
Qty: 2 1 item 3 repeats	**Qty: 2** 1 item 5 repeats	**Qty: 2** 1 item 5 repeats
* initial dose: 40mg at week 0, then 40mg every other week		
N/A	14683	14701

2 Severe Active Rheumatoid Arthritis



Initial treatment	1st Continuing treatment	Subsequent Continuing treatment
Authority required PBS code 13691N	STREAMLINED PBS code 13703F	STREAMLINED PBS code 13227E
SA: PB109		
Brand substitutions not permitted - box needs to be ticked so that Yuflyma brand is not substituted.		
Qty: 2 1 item 3 repeats	**Qty: 2** 1 item 5 repeats	**Qty: 2** 1 item 5 repeats
* initial dose: 40mg at week 0, then 40mg every other week		
N/A	14567	14499

Abbreviations: SA, Services Australia, **n/a**, not applicable, **PBS**, Pharmaceutical Benefit Scheme

3 Severe Psoriatic arthritis

Dr A Practitioner
9 Sample Street
Suburb, State, post code

Prescriber Number 123456 Phone 02 9999 9999

Patient's Medicare No 1234 56789 1 0

Pharmaceutical benefits entitlement number

☐ PBS Safety Net entitlement card holder ☐ Concessional or dependent, RPBS beneficiary or PBS Safety Net cocession card holder

Patient's name Jane Citizen
Address 11 Sample Street
Central VIC 3001

Date 00/00/2000
PBS X

☒ Brand substitutions not permitted

Medicare Australia

Script No. 112233445566

Adalimumab Yuflyma pen
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *

Qty: repeats
Item

Dr A Practitioner

Authority Approval No: 1234

Initial treatment	1st Continuing treatment	Subsequent Continuing treatment
Authority required PBS code 12362P	Authority required PBS code 12375H	STREAMLINED PBS code 13214L
SA: PB105	SA: PB106	
Brand substitutions not permitted - box needs to be ticked so that Yuflyma brand is not substituted.		
Qty: 2 1 item 3 repeats	**Qty: 2** 1 item 5 repeats	**Qty: 2** 1 item 5 repeats
* initial dose: 40mg at week 0, then 40mg every other week		
N/A	N/A	11523

4 Severe Chronic Plaque Psoriasis - Adult

Dr A Practitioner
9 Sample Street
Suburb, State, post code

Prescriber Number 123456 Phone 02 9999 9999

Patient's Medicare No 1234 56789 1 0

Pharmaceutical benefits entitlement number

☐ PBS Safety Net entitlement card holder ☐ Concessional or dependent, RPBS beneficiary or PBS Safety Net cocession card holder

Patient's name Jane Citizen
Address 11 Sample Street
Central VIC 3001

Date 00/00/2000
PBS X

☒ Brand substitutions not permitted

Medicare Australia

Script No. 112233445566

Adalimumab Yuflyma pen
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *

Qty: repeats
Item

Dr A Practitioner

Authority Approval No: 1234

Initial treatment	1st Continuing treatment	Subsequent Continuing treatment
Authority required PBS code 12342N	Authority required PBS code 12377K	STREAMLINED PBS code 13215M
SA: PB112	SA: PB113	
Brand substitutions not permitted - box needs to be ticked so that Yuflyma brand is not substituted.		
Qty: 2 1 item 4 repeats	**Qty: 2** 1 item 5 repeats	**Qty: 2** 1 item 5 repeats
* 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.		
N/A	N/A	11635 (whole body) 11606 (face, hand, foot)

PBS Information:

For rheumatoid arthritis and ankylosing spondylitis: Authority required (telephone/immediate online assessment) for initial treatment course. Authority required (STREAMLINED) for continuing treatment courses.

For all other indications: Authority required (written) 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 the 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

Celltrion Healthcare Australia Pty Ltd. ABN 66 625 407 105
Suite 13.03, 31 Market Street, Sydney NSW 2000, Australia
Medical Information Phone 1800 325 228
Email: info-anz@celltrionhc.com

www.celltrionhealthcare.com.au

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