Yuflyma®
adalimumab

Yuflyma®

adalimumab biosimilar by Celltrion Healthcare

HEALTHCARE
CELLTRION

Yuflyma®

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***Note:** For further information, please refer to Yuflyma product Information (PI).

Table of Contents

01 Overview of the Product

1 Brief Portrait of Yuflyma®[1,2]

Yuflyma® 40 mg solution for injection in pre-filled syringe with needle guard

Yuflyma® 40 mg solution for injection in pre-filled pen

Composition:

Yuflyma® contains the active substance adalimumab. Adalimumab is a recombinant human monoclonal antibody produced in Chinese Hamster Ovary cells.

Pharmacotherapeutic group:

Immunosuppressants, Tumor Necrosis Factor alpha (TNF-α) inhibitors (ATC code: L04AB04)

Ingredients:

Yuflyma® is supplied at a concentration of 100 mg/mL in either 40 mg solution for injection in pre-filled syringe or 40 mg solution for injection in pre-filled pen. Each 0.4 ml single dose pre-filled syringe contains 40 mg of adalimumab. Each 0.4 ml single dose pre-filled pen contains 40 mg of adalimumab.

Other non-medicinal ingredients:

Acetic acid, sodium acetate trihydrate, glycine, polysorbate 80, water for injections.

2 Storage and Shelf Life[1,2]

Storage:

Store in a refrigerator (2°C ~ 8°C). Do not freeze.

A single Yuflyma® pre-filled syringe or pre-filled pen may be stored at temperatures up to a maximum of 25°C, for a period of up to 30 days.

The syringe or pen must be protected from light and discarded if not used within the 30-day period.

Shelf Life:

3 Years.

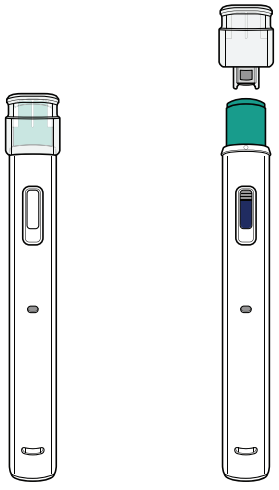
3 Packaging

Yuflyma® 40 mg solution for injection in pre-filled pen:[1]

Solution for injection in a pre-filled pen for patient use containing a pre-filled syringe. The syringe inside the pen is made from type 1 glass with a plunger stopper (bromobutyl rubber) and a needle with a needle shield (thermoplastic elastomer).

Packs of:

- 2 pre-filled pens (0.4 ml sterile solution), each with 1 alcohol pad.

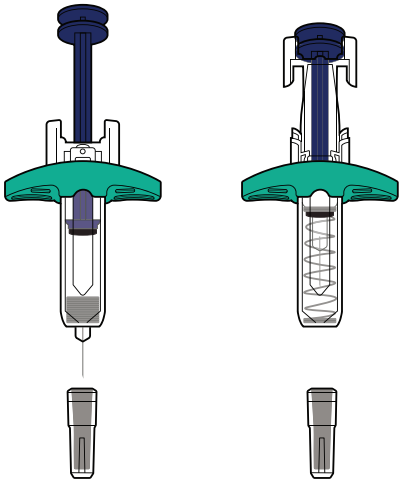


Yuflyma® 40 mg solution for injection in pre-filled syringe with needle guard:[2]

The syringe is made from type I glass with a plunger stopper (bromobutyl rubber) and a needle with a needle shield (thermoplastic elastomer).

Packs of:

- 2 pre-filled syringes with needle guard (0.4 ml sterile solution), each with 1 alcohol pad.



02 Indications and Device Types

1 Indications of Yuflyma®[1,2]

Yuflyma® is indicated for the treatment of:

Rheumatoid arthritis (RA)	Crohn's disease (CD) in Adults and Children*
Juvenile idiopathic arthritis (JIA)	Ulcerative colitis (UC)
Ankylosing spondylitis (AS)	Uveitis (UV)+
Psoriatic arthritis (PsA)	Psoriasis (PsO) in Adults and Children**
Hidradenitis Suppurativa (HS) in Adults and Adolescents***	

Ω

2 Yuflyma® Injection Types[1,2]

Yuflyma® is available in two types of self-injection devices: Pre-filled pen and pre-filled syringe with needle guard.

Initial doses of Yuflyma® must be given by qualified, trained healthcare professionals. After proper training in the injection technique, patients may self-inject with Yuflyma® if their physician determines that it is appropriate, with necessary medical follow-up.

CELLTRION care

CelltrionCare, the patient support program for Yuflyma, offers patients injection training by nurses either face-to-face or virtual.

* CD in children from 6 years of age ≥ 40kg
**PsO in children from 4 years of age ≥40kg.
***HS in adolescents from 12 years
+ Uveitis is not listed on the PBS

3 Treatment with Yuflyma®[1,2]

Treatment with Yuflyma® must be prescribed by a healthcare professional who is specialized in the diagnosis and treatment of conditions for which Yuflyma® is indicated.

>> Patients should use the information provided in their Welcome Kit during their treatment.[#]

Yuflyma® Welcome Kit Package Box

Yuflyma® Patient Starterbook

Yuflyma® Instructions for Use

Yuflyma® Patient Passport

Patients who sign up for the CelltrionCare Patient Support Program can order the Welcome Kit and more during the sign up process: celltrioncare.com 1800 78 22 88 (1800 SUBCUT)

03 Recommended Doses and Clinical Response
Adults

Recommended Dose According to Yuflyma®'s Indications[1,2]

Indications	Recommended Dose at Initiation	Continued Therapy
Rheumatoid arthritis (RA)	40 mg at Week 0	40 mg every other week
Ankylosing spondylitis / Psoriatic arthritis	40 mg at Week 0	40 mg every other week
Psoriasis (PsO)	80 mg at Week 0	40 mg every other week, starting at Week 1
Crohn's disease (CD) in adult patients	**Initial Dose:** 160 mg at Day 0, OR 80 mg per day at Day 0 and Day 1. **Second Dose:** 80mg at Day 14.	**Maintenance:** 40 mg at Day 28 and continuing every other week.
Ulcerative colitis (UC)	160 mg at Week 0, 80 mg at Week 2	40 mg every other week
Uveitis (UV)	80 mg at Week 0	40 mg every other week, starting at Week 1
Hidradenitis suppurativa (HS) in adults	**Initial Dose:** 160 mg at Day 0, OR 80 mg per day at Day 0 and Day 1. **Second Dose:** 80mg at Day 15.	40 mg every week OR 80 mg every other week, starting at Day 29

*Yuflyma® is only available as 40 mg pre-filled syringe and 40 mg pre-filled pen. Thus, it is not possible to administer Yuflyma® to patients that require less than a full 40 mg dose. If an alternate dose is required, other adalimumab products offering such an option should be used.

Assessment of Therapy Response[1,2]

Assessment
Clinical response is usually achieved in 12 weeks. Continued therapy should be reconsidered in a patient not responding within this period.
Clinical response is usually achieved in 12 weeks. Continued therapy should be reconsidered in a patient not responding within this period.
Continued therapy beyond 16 weeks should be carefully reconsidered in a patient not responding within this time period. Beyond 16 weeks, patients with inadequate response to Yuflyma® 40 mg every other week may benefit from an increase in dosage to 40 mg every week or 80 mg every other week. Response should be periodically evaluated (for example, every 12 weeks). Patients with continued inadequate response should discontinue treatment. If an adequate response is achieved with an increased dosing frequency, the dose may subsequently be reduced to 40 mg fortnightly.
Some patients who experience a decrease in their response may benefit from an increase in dosage to 40 mg Yuflyma every week, or 80 mg fortnightly. Aminosalicylates, corticosteroids, and/or immunomodulatory agents (e.g., 6-mercaptopurine and azathioprine) may be continued during treatment with Yuflyma.
During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. Patients who experience decrease in their response to 40 mg every other week may benefit from an increase in dosage to 40 mg Yuflyma every week or 80 mg every other week (maintenance therapy). Yuflyma should not be continued in patients who do not achieve a clinical response in the first 8 weeks of treatment.
It is recommended that the benefit and risk of continued long-term treatment should be evaluated on a yearly basis.
In patients without any benefit after 12 weeks of treatment, therapy should be discontinued.

03 Recommended Doses and Clinical Response
Juvenile/Paediatric

Recommended Dose According to Yuflyma®'s Indications[1,2]

Indications	Age or Body Weight	Recommended Dose at Initiation
Polyarticular juvenile idiopathic arthritis	Children and adolescents from 2 years of age ≥ 30 kg	40 mg at Week 0
Enthesitis-related arthritis	Children and adolescents from 6 years of age ≥ 30 kg	40 mg at Week 0
Plaque psoriasis (PsO)	Children and adolescents from 4 to 17 years of age ≥ 40 kg	40 mg at Week 0 and 1
Crohn's disease (CD)	Children and adolescents from 6 years of age ≥ 40 kg	160 mg at Week 0 80 mg at Week 2
Hidradenitis suppurativa (HS)	Adolescents from 12 to 17 years of age ≥ 30 kg	80 mg at Week 0

*Yuflyma® is only available as 40 mg pre-filled syringe and 40 mg pre-filled pen. Thus, it is not possible to administer Yuflyma® to patients that require less than a full 40 mg dose. If an alternate dose is required, other adalimumab products offering such an option should be used.

Assessment of Therapy Response[1,2]

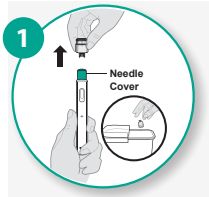
Continued Therapy	Assessment
40 mg every other week	Clinical response is usually achieved within 12 weeks. Continued therapy should be reconsidered in patient not responding within this period.
40 mg every other week	
40 mg every other week	Continued therapy beyond 16 weeks should be carefully considered in a patient not responding within this time period. If retreatment with adalimumab is indicated, the guidance on dose and treatment duration should be followed. The safety of adalimumab in paediatric patients with plaque psoriasis has been assessed for a mean of 13 months.
40 mg every other week	Continued therapy should be carefully considered in a subject not responding by week 12.
40 mg every other week, starting at Week 1	In adolescent patients with inadequate response to Yuflyma 40mg fortnightly, an increase in dosage frequency to 40mg every week or 80mg fortnightly may be considered. Antibiotics maybe continued during treatment with Yuflyma if necessary. It is recommended that the patient should use a topical antiseptic wash on their HS lesions on a daily basis during treatment with Yuflyma. In patients without any benefit after 12 weeks of treatment, therapy should be discontinued. Should treatment be interrupted, Yuflyma may be re-introduced as appropriate. The benefit and risk of continued long-term treatment should be periodically evaluated. There is no relevant use of Yuflyma in children aged less than 12 years of age with HS.

04 Preparation and Administration of the Yuflyma® Injection

Preparation for the Injection:[1,2]

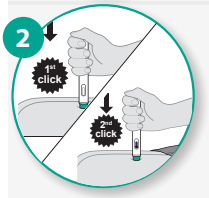
- Yuflyma® device, alcohol swab, cotton ball or gauze, adhesive bandage, sharps disposal container must be prepared for the injection.
- The pre-filled pen or syringe must be inspected to check the label, dosage, and expiration date. The liquid should be clear, colorless to pale brown and free of particles.
- The pre-filled pen or syringe should be at room temperature (leave outside of fridge for 15-30 minutes)

Administering Yuflyma® Pre-filled Pen[1]



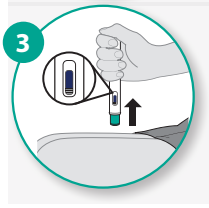
Step 1: Remove the Cap

- The cap should be removed by holding the pen by the body and pulling the cap straight off.



Step 2: Give the Injection

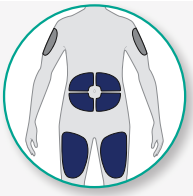
- Without pinching or stretching the skin, place the pen over the injection site at a 90-degree angle.
- Press firmly against the skin. When the injection starts, there will be a loud 1st "click". Keep holding the pen and listen for the 2nd loud "click". After the 2nd "click" continue to hold the pen for 5 seconds.
- After making sure the blue plunger rod has filled the viewing window completely, remove the pen from skin and gently press a cotton ball or gauze over injection site.



After the Injection[1,2]

- Yuflyma® device should be discarded in a special sharps disposal container immediately after use.

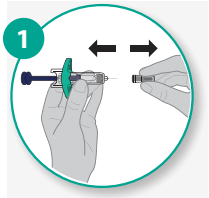
Possible Injection Sites Include:[1,2]



Front of the thighs, abdomen, except for the 5 cm around the navel area, outer area of the upper arms (ONLY IF given by a caregiver).

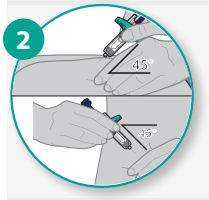
= Caregiver ONLY
= Self-injection and Caregiver

Administering Yuflyma® Pre-filled Syringe[2]



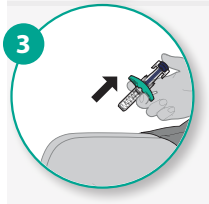
Step 1: Remove the Cap

- The cap should be removed by holding the syringe by the body and pulling the cap straight off.



Step 2: Give the Injection

- Gently pinch a fold of skin at injection site and insert the needle completely at a 45-degree angle.
- After inserting the needle, let go of the pinched skin.
  Push the plunger down slowly all the way down until the syringe is empty.
- If using the Pre-filled Syringe with needle guard: slowly lift thumb from plunger until needle is completely covered by automatic needle guard.
- Gently press a cotton ball or gauze over injection site.



05 Clinical Data

Study Design

A randomised, double-blind phase 3 study in which subjects with active RA at 52 centers were randomised (1:1) to receive Yuflyma® or EU-adalimumab 40 mg subcutaneously every 2 weeks until week 52. The primary endpoint was 20% improvement by American College of Rheumatology criteria (ACR20) response rate at week 24. Equivalence was concluded if the corresponding confidence intervals (CIs) for the estimate of treatment difference were within predefined equivalence margins: – 15 to 15% (95% CI; European Medicines Agency assumption); – 12 to 15% (90% CI; Food and Drug Administration assumption). Additional efficacy, pharmacokinetic, usability, safety, and immunogenicity endpoints were evaluated.[3]

	Yuflyma® (n=324)	EU-adalimumab (n=324)
Age (years), median (range)	53.5 (18–75)	54.0 (19–75)
Sex, n (%)		
Male	75 (23.1)	59 (18.2)
Female	249 (76.9)	265 (81.8)
RA disease duration (years), mean (SD)	6.79 (6.76)	6.59 (6.81)
SDAI at screening, n (%)		
SDAI ≤ 26	30 (9.3)	34 (10.5)
SDAI > 26	294 (90.7)	290 (89.5)
SDAI, mean (SD)	40.0 (11.5)	39.8 (11.1)
CDAI, mean (SD)	39.0 (11.0)	38.7 (10.8)
DAS28-CRP, mean (SD)	5.538 (0.8738)	5.547 (0.8525)
Tender joint count, mean (SD)	20.5 (10.2)	20.1 (10.1)
Swollen joint count, mean (SD)	14.0 (6.33)	14.0 (6.46)
Subject's assessment of pain, mean (SD)a	69.7 (18.7)	70.0 (16.2)
Subject's global assessment of disease activity, mean (SD)[a]	69.8 (17.8)	69.6 (16.3)
Physician's global assessment of disease activity, mean (SD)[a]	67.5 (14.7)	67.0 (15.5)
HAQ estimate of physical ability, mean (SD)	1.41 (0.59)	1.48 (0.56)
CRP (mg/dl), mean (SD)	0.975 (1.60)	1.10 (1.91)
ESR (mm/h), mean (SD)	42.3 (15.98)	42.9 (16.94)

Table 1: Demographics and baseline disease characteristics (ITT population, unless otherwise specified)[3]

Note: There were no significant differences between the CT-P17 and EU-adalimumab groups for any parameter ($p > 0.05$). For age (years), mean (SD) values were used for the statistical analysis

[a]Assessed by 100-mm visual analog scale

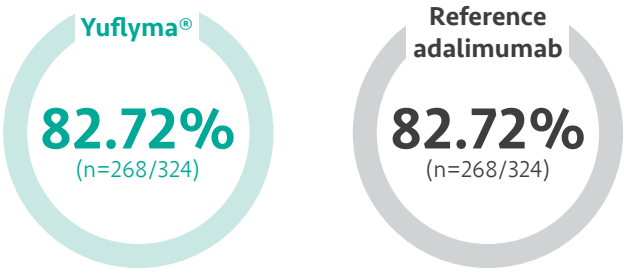
Anti-CCP anti-cyclic citrullinated peptide; **CDA**I Clinical Disease Activity Index; **CRP** C-reactive protein; **DAS28** Disease Activity Score in 28 joints; **ESR** erythrocyte sedimentation rate; **EU-adalimumab** European Union-approved adalimumab; **HAQ** Health Assessment Questionnaire; **ITT** intention-to-treat; **RA** rheumatoid arthritis; **RF** rheumatoid factor; **SD** standard deviation; **SDAI** Simplified Disease Activity Index

1 Efficacy of Yuflyma®

Yuflyma® demonstrated equivalence to reference adalimumab in terms of efficacy at Week 24.[3]

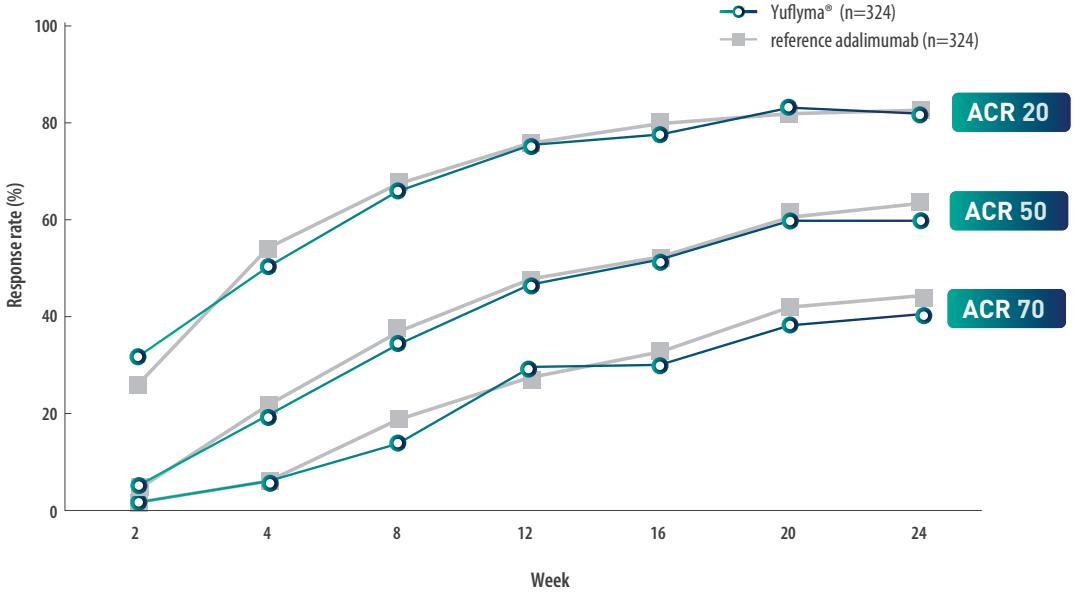
The ACR20 response rate at Week 24 in patients with active moderate-to-severe RA was the same in both Yuflyma® and reference adalimumab treatment groups, with an estimated treatment difference of 0.[3]

ACR20 response rate at Week 24: ITT populations



The ACR20/50/70 response rates up to Week 24 also showed a similar trend between Yuflyma® and reference adalimumab treatment groups.[3]

ACR20/50/70 response rates up to Week 24: ITT populations[3]



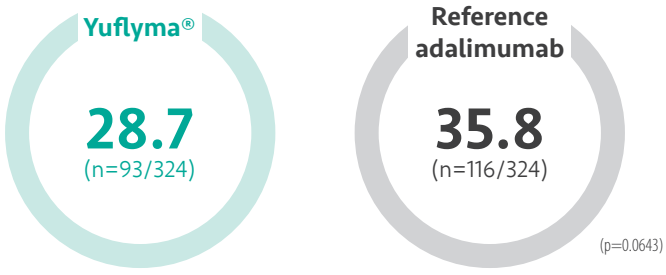
05 Clinical Data

2 Safety of Yuflyma®

Yuflyma® demonstrated a comparable safety profile to reference adalimumab.[3]

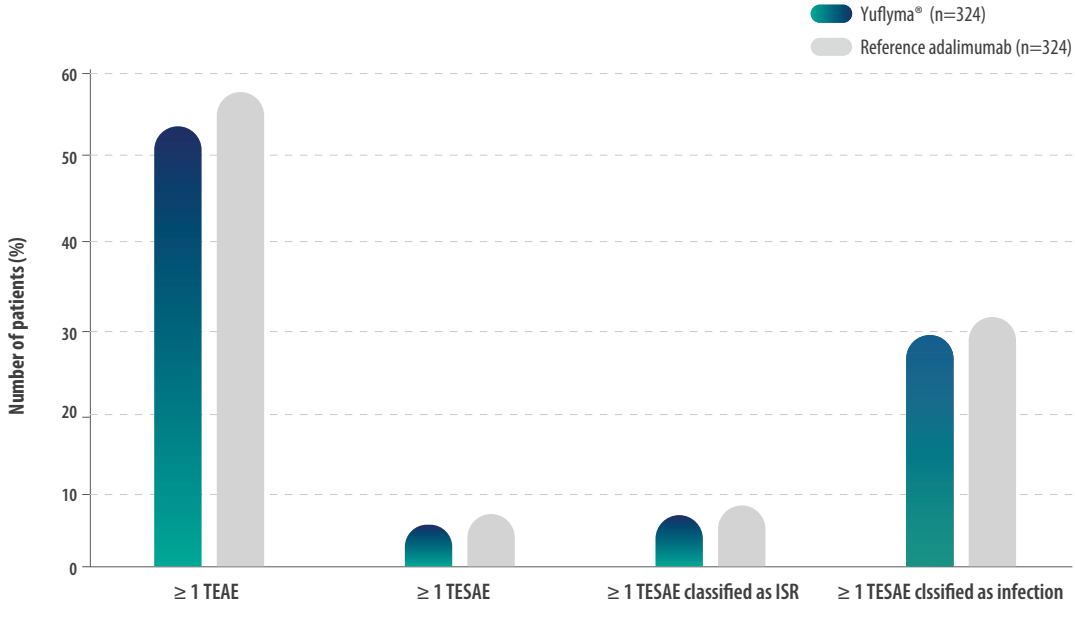
Yuflyma® showed a slightly lower proportion of patients who had ADA compared to reference adalimumab at Week 24.[3]

Proportion of patients with ADA at Week 24



The safety profile of Yuflyma® was similar to that of reference adalimumab with majority of events being grade 1 and 2 in intensity.[3]

Summary of adverse events: safety populations[3]



*There were no significant differences between the Yuflyma® and EU-adalimumab groups for any parameter (p > 0.05)

	Yuflyma® (n=324)	EU-adalimumab (n=324)
Subjects with ≥ 1 TEAE, n (%)	169 (52.2)	184 (56.8)
Study drug-related	88 (27.2)	99 (30.6)
TEAEs reported in ≥ 5% of subjects in either treatment group		
ISR	16 (4.9)	22 (6.8)
Nasopharyngitis	17 (5.2)	20 (6.2)
Upper respiratory tract infection	17 (5.2)	20 (6.2)
Neutropenia	14 (4.3)	17 (5.2)
Subjects with ≥ 1 TESAE, n (%)	10 (3.1)	16 (4.9)
Subjects with ≥ 1 TEAE leading to study drug discontinuation, n (%)	5 (1.5)	8 (2.5)
Subjects with ≥ 1 TEAE classified as hypersensitivity/ allergic reactions, n (%)	2 (0.6)	4 (1.2)
Subjects with ≥ 1 TEAE classified as ISR, n (%)	16 (4.9)	22 (6.8)
Subjects with ≥ 1 TEAE classified as infection, n (%)	97 (29.9)	103 (31.8)
Subjects with ≥ 1 TEAE classified as malignancy, n (%)	1 (0.3)[a]	0
Total number of TEAEs leading to death	0	0

Table 2 Treatment-emergent adverse events (safety population)3

Note: There were no significant differences between the Yuflyma® and EU-adalimumab groups for any parameter ($p > 0.05$)

[a]Breast cancer that was considered unrelated to study drug; the subject's family history of breast cancer was considered a risk factor by the investigator

TEAE treatment-emergent adverse event; **EU-adalimumab** European Union-approved adalimumab; **ISR** injection-site reaction; **TESAE** treatment-emergent serious adverse event

Celltrion Healthcare

1 Celltrion Healthcare

Celltrion Healthcare is a global biopharmaceutical company focused on the global marketing, distribution and sales of biologics and biosimilars developed by Celltrion. Celltrion Healthcare is committed to delivering innovative and affordable medications and enabling patient access to advanced therapies. We are proud to offer healthcare providers and their patients high-quality cost-effective and innovative solutions through an extensive global network that spans more than 110 different countries.[4]

2 Our Mission

Celltrion is a combination of the terms "cell" in our body and "trions," a guiding star that is also known as the Big Dipper. The name of our company conveys our will to promote the health and welfare of humanity by becoming a "guiding star" in the bio industry. We, Celltrion Healthcare, are continuously working to achieve our dream of "rewriting the world bio-history."[4]

We aim to create a richer and healthier future for humanity that emphasizes the significance of coexistence and prosperity.[4]

Creativity

We solve problems by going beyond the usual way of thinking and enhancing creative thinking.

Compliance with Principles

We solve problems by going beyond the usual way of thinking and enhancing creative thinking.

The Pursuit to Be the World's Best

We strive to set new standards and lead the global markets.

The Spirit of Challenge

We make every effort to find new ways despite challenges.


BD
Yuflyma
40 mg/0.4 ml
40 mg/0.4 ml
Yuflyma™ 40 mg
injection

PBS Information: Rheumatoid Arthritis and Ankylosing Spondilitis: 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 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

References: 1. Yuflyma® pre-filled pen Approved Australian Product Information available at https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-02304-1&d=20230530172310101 Last accessed: 05.03.2024. **2.** Yuflyma® pre-filled syringe Approved Australian Product Information available for at https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-02306-1 Last accessed: 05.03.2024. **3.** Kay J et al., Efficacy and safety of biosimilar CT-P17 versus reference adalimumab in subjects with rheumatoid arthritis: 24-week results from a randomized study. Arthritis Res Ther. 2021;23(1):51.**4.** Data on File, Celltrion Healthcare. 2021.

* Yuflyma® is not PBS- listed for the treatment of paediatric patients where a dose of <40mg is required such as for paediatric patients with severe Crohn's disease or plaque psoriasis weighing ≤40kg and patients with severe juvenile idiopathic arthritis weighing ≤30kg.

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