Idacio ▼ (adalimumab) 40 mg

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See below for how to report adverse reactions.
Idacio 40 mg solution for injection in pre-filled syringe
Idacio 40 mg solution for injection in pre-filled pen
Idacio 40 mg solution for injection in vial for paediatric use
Presentation and method of administration: Each single dose 0.8 ml pre-filled syringe, 0.8 ml pre-filled pen or 0.8 ml vial contains 40 mg of adalimumab for subcutaneous injection. **Indications and Dosage:** Please refer to SmPC for full information. Idacio treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Idacio is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Idacio. Patients treated with Idacio should be given a patient alert card. After proper training in injection technique, patients may self-inject with Idacio if their physician determines that it is appropriate and with medical follow-up as necessary. During treatment with Idacio, other concomitant therapies (e.g., corticosteroids and/or immunomodulatory agents) should be optimised. **Rheumatoid arthritis (RA), adults:** In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX. In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces rate of progression of joint damage on X-ray and improves physical function, in combination with MTX. Dosage:40 mg single dose every other week (EOW). Concomitant MTX should be continued. In monotherapy, patients may require 40 mg every week or 80 mg EOW if they experience a decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose interruption, e.g. before surgery or if serious infection occurs. Reintroduction after 70 days or longer of discontinuation gave same magnitudes of clinical response and similar safety profile as before dose interruption. **Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above:** In combination with MTX for active pJIA with inadequate response to one or more DMARDs. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Dosage: 10 kg to < 30 kg 20 mg single dose EOW. If ≥ 30 kg: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Enthesitis-related arthritis (ERA), paediatrics 6 years and above:** For active ERA with inadequate response to or intolerance to conventional therapy. Dosage: 15 kg to < 30 kg: 20 mg single dose EOW. If ≥ 30 kg: 40 mg single dose EOW. **Ankylosing spondylitis (AS), adults:** For severe active AS with inadequate response to conventional therapy. Dosage: adults: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults:** For severe nr-axSpA with objective signs of inflammation (elevated CRP and/or MRI), and an inadequate response to or intolerance to nonsteroidal anti-inflammatory drugs. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriatic arthritis (PsA), adults:** For active and progressive PsA with inadequate response to DMARDs. Reduces rate of progression of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriasis, adults:** For moderate to severe chronic plaque psoriasis in candidates for systemic therapy. Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time (refer to SmPC). **Paediatric Plaque Psoriasis, 4 years and above:** For severe chronic plaque psoriasis with inadequate response to or if topical therapy and phototherapies are inappropriate. Dosage: 15 kg to < 30 kg: 20 mg dose initially followed by 20 mg EOW starting one week after initial dose. If ≥ 30 kg: 40 mg dose initially followed by 40 mg EOW starting one week after initial dose. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. **Hidradenitis suppurativa (HS), adults and adolescents from 12 years and above:** For active moderate to severe HS (acne inversa) with inadequate response to conventional systemic HS therapy. Dosage: HS, adults: 160 mg dose initially at Day 1, followed by 80 mg two weeks later at Day 15. Two weeks later (Day 29) continue with a dose of 40 mg every week or 80 mg EOW.HS, adolescents 12 years and above ≥ 30 kg: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. If there is inadequate response to 40 mg EOW, an increase in dosage to 40 mg every week or 80 mg EOW may be considered. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions is recommended to be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no improvement in that time. Reintroduction of Idacio after treatment interruption as appropriate. Evaluate periodically the benefit and risk of continued long-term treatment. **Crohn's disease (CD), adults:** For moderately to severely active CD with no response despite a full and adequate course of, intolerance to or contraindication for a corticosteroid and/or an immunosuppressant therapy. Dosage: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If decrease in clinical response, can increase dosage to 40 mg every week or 80 mg EOW. Patients with no response by Week 4 may benefit from continued maintenance therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Paediatric Crohn's disease (CD), 6 years and above:** For moderately to severely active CD with inadequate response to, intolerance to or contraindication for conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator. Dosage: < 40 kg: Induction: 40 mg dose at Week 0, followed by 20 mg at Week 2. For a more rapid response: 80 mg at Week 0, followed by 40 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 20 mg dose EOW from week 4. If insufficient response, consider an increase in dosing frequency to 20 mg every week. If ≥ 40 kg: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW from week 4. If insufficient response, consider an increase in dosage to 40 mg every week or 80 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Ulcerative colitis (UC), adults:** For moderately to severely active UC with inadequate response to, intolerance to or contraindication for conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA). Dosage: Induction: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If insufficient response, consider an increase in dosage to 40 mg every week or 80 mg EOW. Treatment beyond 8 weeks should not be continued if no clinical response in that time. **Uveitis, adults:** For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Idacio. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. **Paediatric Uveitis, 2 years and above:** For chronic non-infectious anterior uveitis with inadequate response to or intolerance to conventional therapy, or in whom conventional therapy is inappropriate. Dosage: < 30 kg: 20 mg dose EOW in combination with MTX. Optional 40 mg (for patients < 30 kg) or 80 mg (for patients ≥ 30 kg) loading dose one week prior to start of maintenance therapy. No clinical data in use of loading dose < 6 years of age (see SmPC). If ≥ 30 kg: 40 mg dose EOW in combination with MTX. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. Idacio may be available in other strengths and/or presentations depending on the individual treatment needs. **Contraindications:** Hypersensitivity to the active substance or to any excipients (see SmPC); Active tuberculosis (TB) or other severe infections such as sepsis and opportunistic infections; Moderate to severe heart failure (NYHA class III/IV). **Warnings and precautions:** Clearly record the name and batch number of administered product to improve traceability of biological products. **Infections:** Patients taking TNF-antagonists are more susceptible to serious infections. Impaired lung function may increase the risk for developing infections. Monitor for infections, including TB, before, during and for at least 4 months after

treatment. Treatment with Idacio should not be initiated in patients with active infections including chronic or localised infections until infections are controlled. In patients who have been exposed to tuberculosis and patients who have travelled in areas of high risk of tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, the risk and benefits of treatment with Idacio should be considered prior to initiating therapy. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections, including the use of concomitant immunosuppressive medications. **Serious infections:** Serious infections, including those associated with hospitalisation or death, were reported in patients receiving treatment. **TB:** Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (disseminated), were reported. Screen all patients before therapy initiation for active or inactive (latent) TB. Appropriate screening tests (i.e. tuberculin skin test and chest X-ray) should be performed in all patients. If latent TB is suspected, consult physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Idacio. Despite prophylaxis, TB reactivation has occurred on adalimumab. If active TB is diagnosed, do not initiate Idacio treatment. **Other opportunistic infections:** Opportunistic infections were observed in patients receiving adalimumab. Stop treatment in patients with signs and symptoms of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients. **Hepatitis B reactivation:** Reactivation of HBV has occurred in chronic carriers (surface antigen positive). Patients should be tested for HBV infection before initiating treatment. HBV carriers should consult a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of treatment. If reactivation occurs, stop treatment and initiate appropriate antiviral and supportive treatment. **Neurological events:** Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinuation of treatment should be considered if any of these disorders develop. Neurologic evaluation should be performed in patients with non-infectious intermediate uveitis prior to initiation of treatment and regularly during treatment, to assess for pre-existing or developing central demyelinating disorders. **Allergic reactions:** Reports of serious allergic reactions including anaphylaxis received. For serious allergic or anaphylactic reaction, stop Idacio immediately and initiate appropriate therapy. **Malignancies and lymphoproliferative disorders:** A possible risk has been reported of malignancy, including lymphomas and leukaemia, in all patients, including paediatric patients, treated with Tumour Necrosis Factor (TNF) antagonists. Examine all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment, for non-melanoma skin cancer prior to and during treatment; caution in COPD patients, and in patients with increased risk for malignancy due to heavy smoking. Consider the potential risk with the combination of azathioprine or 6-mercaptopurine and adalimumab (hepatosplenic T-cell lymphoma has occurred). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk of developing dysplasia or colon cancer is unknown. Patients with UC with increased risk of dysplasia or colon carcinoma, or history of dysplasia or colon carcinoma, to be screened for dysplasia before treatment and throughout disease course. **Haematological reactions:** Adverse events of the haematological system reported with adalimumab. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias develop while on treatment. **Vaccinations:** Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to initiating Idacio treatment. **Congestive heart failure:** See contraindications. Caution is advised with mild heart failure (NYHA class I/II). Discontinue treatment if new or worsening symptoms of congestive heart failure. **Autoimmune processes:** Autoimmune antibodies may form with Idacio. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. **Surgery:** Consider the long half-life of Idacio for planned surgical procedures. Monitor closely for infections. Elderly patients: Serious infections were higher in patients over 65 years of age, some of which had a fatal outcome. Consider risk of infections in these patients. **Interactions:** Antibody formation was lower when adalimumab was given together with MTX in comparison with use as monotherapy. Combination of Idacio with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Fertility, pregnancy and lactation:** Idacio should only be used during pregnancy if clearly needed. Women of childbearing age should consider the use of adequate contraception and continue its use for at least 5 months after the last treatment. No administration of live vaccines (e.g. BCG) to infants exposed to Idacio in utero for 5 months following mother's last Idacio treatment during pregnancy. Idacio can be used during breast-feeding. **Adverse Reactions:** Very common ≥ 1/10: Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leukopenia (including neutropenia and agranulocytosis), anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction (including injection site erythema). Common ≥ 1/100 to < 1/10: Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, cellulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection), urinary tract infections (including pyelonephritis), fungal infections, joint infections, skin cancer excluding melanoma (including basal cell carcinoma and squamous cell carcinoma), benign neoplasm, leucocytosis, thrombocytopenia, hypersensitivity, allergies (including seasonal allergy), hypokalaemia, uric acid increased, blood sodium abnormal, hypocalcaemia, hyperglycaemia, hypophosphatemia, dehydration, mood alterations (including depression), anxiety, insomnia, paraesthesias (including hypoesthesia), migraine, nerve root compression, visual impairment, conjunctivitis, blepharitis, eye swelling, vertigo, tachycardia, hypertension, flushing, haematoma, asthma, dyspnoea, cough, GI haemorrhage, dyspepsia, gastroesophageal reflux disease, sicca syndrome, worsening or new onset of psoriasis (including palmoplantar pustular psoriasis), urticaria, bruising (including purpura), dermatitis (including eczema), onychoclasis, hyperhidrosis, alopecia, pruritus, muscle spasms (including blood creatine phosphokinase increased), renal impairment, haematuria, chest pain, oedema, pyrexia, coagulation and bleeding disorders (including activated partial thromboplastin time prolonged), autoantibody test positive (including double stranded DNA antibody), blood lactate dehydrogenase increased, impaired healing. Serious, including fatal, adverse reactions have been reported including infections/sepsis, TB, opportunistic infections, allergic reactions (including anaphylaxis), HBV reactivation and malignancies (including leukaemia, lymphoma and hepatosplenic T-cell lymphoma). Serious haematological, neurological and autoimmune reactions have also been reported. These include rare reports of pancytopenia, aplastic anaemia, central and peripheral demyelinating events and reports of lupus, lupus-related conditions and Stevens-Johnson syndrome. Other less common and rarely reported adverse reactions are listed in the SmPC. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kröner-Straße 1, 61352 Bad Homburg v.d.Höhe, Germany. **Marketing authorisation numbers:** EU/1/19/1356/001, EU/1/19/1356/002, EU/1/19/1356/003 **Package size and cost:** UK / ROI - Idacio 40mg/0.8ml vial x 1: £316.93 / €309.31, Idacio 40mg/0.8ml pre-filled syringe x 2: £633.86 / €618.63, Idacio 40mg/0.8ml pre-filled pen x 2: £633.86 / €618.63 **Further information:** available from Fresenius Kabi Ltd., Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533 **Date of preparation of PI:** April 2020 001/API/IDACIO/FKUK-IRL

Adverse events should be reported.
Reporting forms and information can be found at:
yellowcard.mhra.gov.uk
www.hpra.ie/homepage/about-us/report-an-issue
Adverse events should also be reported to Fresenius Kabi Ltd.
Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT
Tel +44 (0)1928 533 533