| Product name: | Te | erritory: |
|-----------------------|-----------------|-----------|
| IDACIO 40MG AI | U | К |
| Type of packaging: | Dosage: | |
| Leaflet | 40 mg | |
| Material number: | 2-D-Matrix-Code | : |
| M080411/07 UK | M080411/07 UK | |
| Pharma-Code (Laetus): | EAN-Code: | |
| - | - | |
| Dimension: | Font: | Size: |
| 151,5 x 90 mm | Interstate | 7 |
| | | |

Idacio®

(adalimumab) for

40mg

7. Instructions For Use

| Colours: | Indication only – not to be printed: | 1 |
|------------------|--------------------------------------|---|
| Black | | 1 |
| • Cyan | | 2 |
| Magenta | | 3 |
| Yellow | | 4 |
| | | 5 |
| | | 6 |
| | | 7 |
| | | 8 |
| | | 9 |
| Operator: | | Т |
| Christina Frauer | eder | |



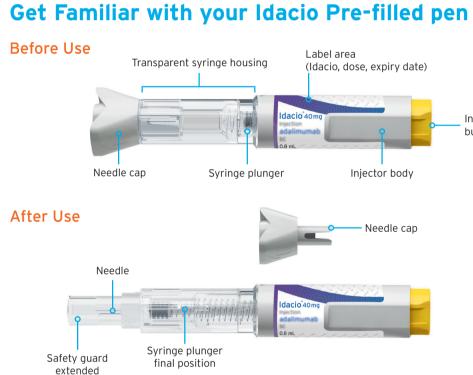
• Only use Idacio pre-filled pen if your healthcare professional has trained you how to use it correctly.

- The Idacio pre-filled pen comes as a ready to use single use pre-filled pen to give a full dose of adalimumab.
- Always inject using the technique your healthcare professional taught you.
- Children under 12 years of age are not allowed to inject themselves and injection must be done by a trained adult.
- Keep the Idacio pre-filled pen out of the reach of children. • Do not insert your fingers into the opening of the safety guard.
- Do not use an Idacio pre-filled pen that has been frozen or left in direct sunlight.
- Talk to your healthcare professional if you have any questions or concerns.

Storage Information

- Store the pre-filled pen in its original box to protect it from light.
- Store the pre-filled pen in a refrigerator between 2°C to 8°C. • If needed, for example when traveling, a single pre-filled pen can be stored at room

temperature for up to 28 days.



Step 1 Prepare for your Injection

Each box of Idacio pre-filled pen comes with two or six pre-filled pens.

- **1.1** Prepare a clean flat surface, such as a table or
- countertop, in a well-lit area.
- **1.2** You will also need (Figure A): an alcohol pad (included in the box)
- a cotton ball or gauze, and • a sharps disposal container.
- **1.3** Remove the box from the refrigerator (Figure B).
- **1.4** Check the expiry date on the side of the box (Figure C). Warning: Do not use if expiry date has passed.
- **1.5** Take a pre-filled pen out of the original box: • place two fingers on the label area • pull the pre-filled pen straight up and out of the packaging (Figure D). Put it on a clean flat surface.
- **1.6** Place the remaining pre-filled pen(s) in its original box back in the refrigerator (Figure E). Refer to Storage Information for how to store your unused pre-filled pen.
- **1.7** Leave the pre-filled pen at room temperature for at least 30 minutes to allow the medicine to warm up (Figure F). Injecting cold medicine may be painful. Warning: Do **not** warm the pre-filled pen any other way, such as in a microwave, hot water, or direct sunlight. **Warning:** Do **not** remove the needle cap until you are ready to inject.



Figure A

Figure B

Figure C

Figure D

Figure E

minutes

Figure F

EXP: MM/YYYY



Idacio

FRESENIUS М КАВІ

40 mg solution for injection in pre-filled pen

adalimumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

 Keep this leaflet. You may need to read it again. Your doctor will also give you a patient reminder card, which contains important safety information that you need to be aware of before you are given Idacio and during treatment with Idacio. Keep this

Package leaflet: Information for the patient

- patient reminder card with you during your treatment and for 4 months after your (or your child's) last injection of Idacio. - If you have any further questions, please ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even
- if their signs of illness are the same as yours. - If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).
- What is in this leaflet 1. What Idacio is and what it is used for 2. What you need to know before you use Idacio
- 3. How to use Idacio Possible side effects

5. How to store Idacio 6. Contents of the pack and other information

7. Instructions for use

1. What Idacio is and what it is used for Idacio contains the active substance adalimumab, a medicine that acts on your body's immune

(defence) system. Idacio is intended for the treatment of the following inflammatory diseases:

rheumatoid arthritis, • polyarticular juvenile idiopathic arthritis,

 enthesitis-related arthritis, ankylosing spondylitis,

• axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, psoriatic arthritis,

 psoriasis, hidradenitis suppurativa.

Crohn's disease, · ulcerative colitis and

non-infectious uveitis

The active substance in Idacio, adalimumab, is a monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target in the body. The target of adalimumab is another protein called tumour necrosis factor (TNF α), which is present at increased levels in the inflammatory diseases listed above. By attaching to TNFa, Idacio blocks its action and reduces the inflammation in these diseases.

Rheumatoid arthritis Rheumatoid arthritis is an inflammatory disease of the joints.

Idacio is used to treat rheumatoid arthritis in adults. If you have moderate to severe active rheumatoid arthritis, you may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, you will be given Idacio to treat your rheumatoid arthritis. Idacio can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment

Idacio can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function. Usually, Idacio is used with methotrexate. If your doctor considers that methotrexate is inappropriate, Idacio can be given alone.

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis are inflammatory diseases

of the joints that usually first appear in childhood. Idacio is used to treat polyarticular juvenile idiopathic arthritis in children and adolescents aged 2 to 17 years and enthesitis-related arthritis in children and adolescents aged 6 to 17 years. Patients or pain medicines including non-steroidal anti-inflam may first be given other disease-modifying medicines, such as methotrexate. If these medicines do You should not take Idacio with medicines containin not work well enough, patients will be given Idacio to treat their polyarticular juvenile idiopathic due to increased risk of serious infection. The c arthritis or enthesitis-related arthritis.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing If sk for infections, including serious infections If you have questions, please ask your doctor. <u>spondylitis</u> Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, are inflammatory diseases of the spine.

Idacio is used in adults to treat these conditions. If you have ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, you will first be given You are advised to avoid becoming pregnant and r other medicines. If these medicines do not work well enough, you will be given Idacio to reduce the Idacio and for at least 5 months after the last Idacio signs and symptoms of your disease.

<u>Psoriatic arthritis</u> Psoriatic arthritis is an inflammatory disease of the joints associated with psoriasis. Idacio is used to treat psoriatic arthritis in adults. Idacio can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function.

Plaque psoriasis in adults and children Plaque psoriasis is an inflammatory skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened your Idacio use during your pregnancy before the bal

and lift away from the nail bed which can be painful. Psoriasis is believed to be caused by a problem with the body's immune system that leads to an increased production of skin cells. Idacio is used to treat moderate to severe plaque psoriasis in adults. Idacio is also used to treat Idacio may have a minor influence on your ability to severe plaque psoriasis in children and adolescents adolescents aged 4 to 17 years for whom sensation (vertigo) and vision disturbances may occu medicines applied to the skin and treatment with UV light have either not worked very well or are not suitable.

Hidradenitis suppurativa in adults and adolescents Hidradenitis suppurativa (sometimes called acne inversa) is a long-term and often painful

inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas. Idacio is used to treat hidradenitis suppurativa in adults and adolescents from 12 years of age. Idacio can reduce the number of nodules and abscesses you have, and the pain that is often associated with the disease. You may first be given other medicines. If these medicines do not work well enough, you will be given Idacio.

Crohn's disease in adults and children

Crohn's disease is an inflammatory disease of the gut.

Idacio is used to treat Crohn's disease in adults and children aged 6 to 17 years. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Idacio to reduce the signs and symptoms of your Crohn's disease. Ulcerative colitis in adults and children

Ulcerative colitis is an inflammatory disease of the large intestine.

Idacio is used to treat moderate to severe ulcerative colitis in adults and children aged 6 to 17 years.

If you have ulcerative colitis you may first be given other medicines. If these medicines do not work well enough, you will be given Idacio to reduce the signs and symptoms of your disease. Non-infectious uveitis in adults and children Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye. The inflammation leads to a decrease of vision and/or the presence of floaters in the eye (black dots or

wispy lines that move across the field of vision). Idacio works by reducing this inflammation. Idacio is used to treat: • adults with non-infectious uveitis with inflammation affecting the back of the eye children from 2 years of age with chronic non-infectious uveitis with inflammation affecting the front

of the eve. 2.What you need to know before you use Idacio

Do not use Idacio

- if you are allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6). - if you have a severe infection, including tuberculosis, sepsis (blood poisoning) or other opportunistic infections (unusual infections associated with a weakened immune system). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems

(see "Warnings and precautions"). if you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see "Warnings and precautions").

Warnings and precautions

Talk to your doctor or pharmacist before using Idacio Allergic reaction

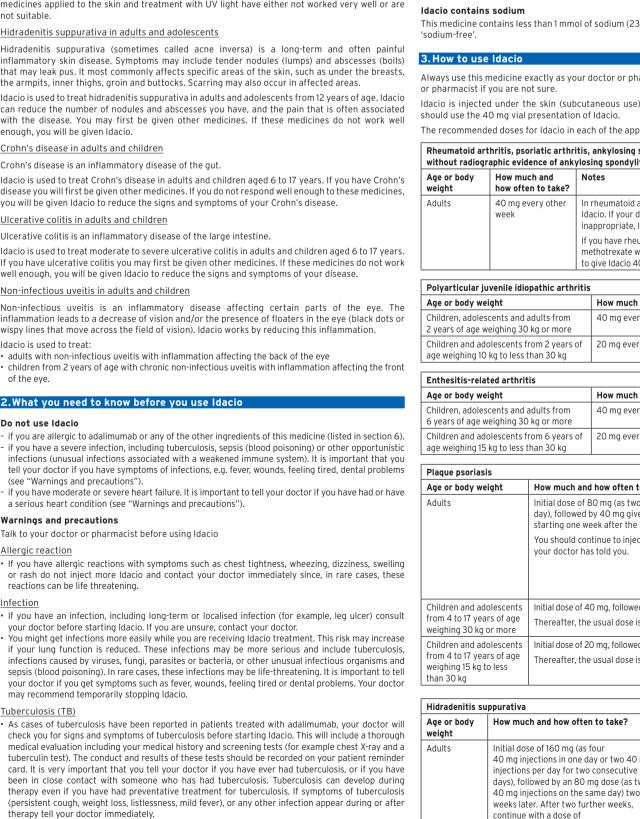
therapy tell your doctor immediately.

 If you have allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Idacio and contact your doctor immediately since, in rare cases, these reactions can be life threatening.

Infection • If you have an infection, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting Idacio. If you are unsure, contact your doctor. You might get infections more easily while you are receiving Idacio treatment. This risk may increase if your lung function is reduced. These infections may be more serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other unusual infectious organisms and sepsis (blood poisoning). In rare cases, these infections may be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may recommend temporarily stopping Idacio.

<u>Tuberculosis (TB)</u>

check you for signs and symptoms of tuberculosis before starting Idacio. This will include a thorough medical evaluation including your medical history and screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your patient reminder card. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. Tuberculosis can develop during therapy even if you have had preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after



arms or legs or numbness or tingling in any part of Vaccine · Certain vaccines contain living but weakened forr should not be given during treatment with Idacio doctor before you receive any vaccines. It is recomm scheduled vaccinations for their age before they st while you are pregnant, your baby may be at higher months after the last dose you received during predoctors and other health care professionals about yo lecide when your baby should receive any vaccine. Heart fa<u>ilure</u> It is important to tell your doctor if you have had mild heart failure and you are being treated with I monitored by your doctor. If you develop new or wors of breath, or swelling of your feet), you must contact Fever, bruising, bleeding or looking pale In some patients the body may fail to produce enough

Surgery or dental procedures

 Do not give Idacio to children with polyarticular juve · Do not use the 40 mg pre-filled syringe or 40 mg Other medicines and Idacio

Tell your doctor or pharmacist if you are taking, have re Idacio can be taken together with methotrexate or ce (sulfasalazine, hydroxychloroguine, leflunomide and

TNF-anta nd anakinra or abatacent is not r risk for infections, including serious infections and Pregnancy and breast-feeding If you think you may be pregnant or are planning to I

advice before taking this medicine. see your doctor.

received adalimumab during pregnancy compared w receive adalimumab. Idacio can be used during breast-feeding. If you receive Idacio during your pregnancy, your infection. It is important that you tell your baby's do see section on vaccination) Driving and using machines Idacio contains sodium

This medicine contains less than 1 mmol of sodium (2 'sodium-free'. 3. How to use Idacio

> Initial dose of 160 mg (as four 40 mg injections in one day or two 40 injections per day for two consecutiv days), followed by an 80 mg dose (as 40 mg injections on the same day) tw weeks later. After two further weeks, 40 mg every week or 80 mg every other week, as prescribed by your doctor

| T 1/ | | | | | | | | | | |
|--|---|---|--|--|--|---|---|--|---|--|
| Travel/recurrent infection Tell your doctor if you have lived or travelled in regions where fungal infections such as a coccidioidomycosis or blastomycosis are common. Tell your doctor if you have a history of recurrent infections or other conditions that risk of infections. | | | | | | , , | Hidradenitis su Adolescents from 12 to 17 years of age | Initia injec | itiva al dose of 80 m ctions in one da y other week st | |
| you think you m reactivate HBV | if you are hight be at infection ii | risk of contra n people who | actin o cai | g HBV. Your docto rry this virus. In so | or should test you fo ome rare cases, esp | tive HBV infection or if r HBV. Adalimumab can ecially if you are taking can be life-threatening. | weighing 30 kg or more Crohn's disease | | | |
| doctor should p important to te or dental probl Surgery or dent | 65 years y bay specia ell your do ems. <u>cal proced</u> t to have s ommend t | l attention to ctor if you g <u>lures</u> urgery or de | o sig et s ntal | ns of infection why ymptoms of infec procedures tell ye | hile you are being t tions, such as feve | ng Idacio. You and your reated with Idacio. It is r, wounds, feeling tired are taking Idacio. Your | Age or body wei Children, adolescents and adults from 6 years of age weighing 40 kg or more | | How much an Initial dose of day), followed If a faster ress prescribe an injections in a for two conse 40 mg injecti Thereafter, th | |
| If you have or onerves, such as Idacio. Tell your arms or legs or Vaccine | develop de multiple s doctor im numbnes | clerosis), you imediately if s or tingling | ur d you in a | octor will decide if get symptoms lik ny part of your bo | f you should receive e changes in your v ody. | ating layer around the or continue to receive ision, weakness in your | Children and adolescents from 6 to 17 years of age weighing less than 40 kgInitial dose later.If a faster re prescribe a in one day), | | | |
| should not be doctor before y scheduled vacc while you are p months after t doctors and oth | Certain vaccines contain living but weakened forms of disease-causing bacteria or viruses and should not be given during treatment with Idacio in case they cause infections. Check with your doctor before you receive any vaccines. It is recommended that, if possible, children be given all the scheduled vaccinations for their age before they start treatment with Idacio. If you receive Idacio while you are pregnant, your baby may be at higher risk for getting an infection for up to about five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Idacio use during your pregnancy so they can decide when your baby should receive any vaccine. | | | | | | Ulcerative colit Age or body weight Adults | Ho | Thereafter, th w much and ho tial dose of 160 y or as two 40 n | |
| decide when your baby should receive any vaccine. <u>Heart failure</u> It is important to tell your doctor if you have had or have a serious heart condition. If you have mild heart failure and you are being treated with Idacio, your heart failure status must be closely monitored by your doctor. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of your feet), you must contact your doctor immediately. <u>Fever, bruising, bleeding or looking pale</u> In some patients the body may fail to produce enough of the blood cells that fight off infections or help you to stop bleeding. If you develop a fever that does not go away, or you bruise or bleed very | | | | | | status must be closely t failure (e.g. shortness , fight off infections or | Children and adolescents from 6 to 17 years of age weighing 40 kg | cor inje The Init day cor 40 | secutive days), ections in one d ereafter, the us ial dose of 160 y or two 40 mg isecutive days) mg injections i ereafter, the us | |
| easily or look v Cancer • There have bee or other TNFα l long time may h blood cells and cancers may inc | ery pale, c en very rar blockers. P have a high bone mar crease. On | e cases of ce eople with m her than aver rrow). If you rare occasior | ertai iore age taki | ight away. Your d in kinds of cancer serious rheumato risk of getting lym e Idacio the risk of specific and sevel | loctor may decide to bid arthritis who hay nphoma and leukaer of getting lymphom re type of lymphom | | or more Children and adolescents from 6 to 17 years of age weighing less than 40 kg | day inje The | ial dose of 80 r () initially, follow ection) two wee ereafter, the using is | |
| or mercaptopui In addition case new areas of da change appear There have be disease called you have COPE a TNFa blocker On rare occasion | rine. Tell yc es of non-n amaged sk ance, tell y en cases o chronic ob), or are a l r is approp ons, treatn | bur doctor if y nelanoma sk in appear du your doctor. of cancers, o heavy smoke riate for you nent with Ida | you in ca iring othe lmo er, yo acio | are taking azathic ancer have been c g or after treatme r than lymphoma nary disease (COI ou should discuss could result in lu | oprine or mercaptop observed in patients int or if existing mai a, in patients with a PD) treated with ar ; with your doctor w upus-like syndrome. | purine with Idacio. Is taking adalimumab. If the or areas of damage a specific type of lung other TNF α blocker. If the ther treatment with Contact your doctor if | Adults | | How much and kake? nitial dose of 80 40 mg injection 40 mg every oth one week after t You should cont | |
| Children and ad Vaccinations: if Do not give Ida | possible c cio to chilo e 40 mg p | t s children shou dren with pol | ıld b yart | e up to date with ticular juvenile idi | | | Idacio for as lor has told you. Children and adolescents from 2 years of age weighing less than 30 kg 20 mg every ot | | | |
| Idacio can be tak (sulfasalazine, h | or pharmad en togeth ydroxychl | cist if you are er with meth oroquine, le | notr flun | exate or certain o omide and inject | disease-modifying | e any other medicines. anti-rheumatic agents tions), corticosteroids | Children and adolescents fror 2 years of age weighing at leas 30 kg | n | 40 mg every oth | |
| TNF-antagonists risk for infection If you have ques Pregnancy and If you think you i advice before ta You are advised Idacio and for at see your doctar. Idacio should on According to a p received adalimur receive adalimur Idacio can be usi If you receive la infection. It is im your Idacio use of see section on vi Driving and usi Idacio may have sensation (vertion Idacio contains This medicine co 'sodium-free'. 3. How to use Always use this m or pharmacist if Idacio is injecte should use the 4 The recommend | and anak s, includi tions, plea breast-f may be pre- king this n to avoid least 5 m ly be used oregnancy umab during dacio during dacio during dacio during dacio during ortant th during you accination ing machi a minor i jo) and visis s sodium intains les lidacio ed doses f thritis, psc aphic evid How mut how ofte | inra or abata ng serious i isse ask your eeding egnant or ar nedicine. becoming p onths after I during a pro- r study, ther ng pregnance breast-feedi ing your pre fat you tell y ur pregnancy in disturba s than 1 mmo exactly as yo ot sure. he skin (sub presentation for Idacio in priatic arthri ence of anky | acep nfec doc re pl preg the egn cour you nce our you nce bl of eac tis, /los | bit is not recommen- tions and other tions and other tor. anning to have a nant and must u last Idacio inject ancy if needed. as no higher risk pompared with mo ancy, your baby baby's doctors a fore the baby rec ur ability to drive is may occur afte sodium (23 mg) loctor or pharma aneous use). Pat Idacio. h of the approved ankylosing spond ing spondylitis | ended based upon i potential pharmad baby, ask your do- use adequate cont tion. If you become k of birth defects others with the sam may have a high ind other health car ceives any vaccine e, cycle or use mad er taking Idacio. per 0.8 ml dose, th ticist has told you. C tients requiring a d d uses are shown in dylitis or axial spon | hab as well as other the possible increased cological interactions. actor or pharmacist for raception while using pregnant, you should when the mother had the disease who did not ar risk for getting an the disease who did not ar risk for getting an the professionals about (for more information hines. Room spinning at is to say essentially heck with your doctor dose less than 40 mg in the following table. dyloarthritis | Method and rou Idacio is adminis Detailed instruct If you use more If you accidental explain that you you, even if it is of If you forget to If you forget to If you forget to If you forget to or remember. Then not forgotten a c If you stop usin The decision to s upon stopping tr If you have any f A.Possible sid Like all medicine side effects are effects are effects are you heart failure: severe rash, hit swollen face, ha trouble breathi shortness of br Tell your doctor signs and sympi urination, feelin symptoms of nu signs of skin ca signs and sympi The following sid Very common (r injection site re respiratory trac headache; abdominal (bell nausea and you | tered ions of e idac (y inje have empty use take lose. ang ida top u urthe de ef or s, thi mild ur up t ttent tes; ands, sw eath erve p ncer s coms s e effinay a nactio ct infe y) pai | I by injection u on how to injection cio than you see cit Idacio more taken more the y. Idacio ourself an injection your next dos acio using Idacio she ent. er questions or ffects is medicine ca to moderate. to 4 months or ion urgently, feet; vallowing; with exertion or con as possib s of infection s ak or tired or c problems such such as a bump suggestive of bl ects have beer ffect more tha ns (including p ections (including in in; | |
| | | | lda ina lf y me | acio. If your doctor appropriate, Idacio you have rheumato ethotrexate with yo | r decides that metho o can be given alone. oid arthritis and you o | trexate is do not receive our doctor may decide | abdominal (beily) pain, nausea and vomiting; rash; pain in the muscles. Common (may affect up to 1 in 10 pe serious infections (including blood intestinal infections (including gast skin infections (including cellulitis a | | | |
| Children, adolescents and adults from 2 years of age weighing 30 kg or more 40 mg ever Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg 20 mg ever Enthesitis-related arthritis Age or body weight How much Children, adolescents and adults from 6 years of age weighing 30 kg or more 40 mg ever | | | | | Notes Not applicable Not applicable | skin infections; ear infections; mouth infection; reproductive tr urinary tract in fungal infection; benign tumours; skin cancer; | ns (ind act in fectio ns; | cluding tooth ir fections; | | |
| | | | How much and h 40 mg every oth 20 mg every oth | | Notes Not applicable Not applicable | allergic reaction dehydration; mood swings (i anxiety; difficulty sleepi sensation disor migraine; symptoms of no | nclud ng; ders s erve r | ing depression such as tingling | | |
| Plaque psoriasis Age or body weight How much and how often to ta Adults Initial dose of 80 mg (as two 40 day), followed by 40 mg given estarting one week after the init You should continue to inject logy our doctor has told you. You should continue to inject logy our doctor has told you. | | O mg (as two 40 m y 40 mg given eve ek after the initial tinue to inject Idac s told you. | mg injections in one very other week al dose. acio for as long as acio for as long as box to the model acio for as long as acio for as long as box to 40 mg every week or 80 mg every other week. | | vision disturbances; eye inflammation; inflammation of the eye lid and eye vertigo (sensation of room spinning, sensation of heart beating rapidly; high blood pressure; flushing; haematoma (a solid swelling with cl cough; asthma; shortness of breath; gastrointestinal bleeding; dyspepsia (indigestion, bloating, he | | | | | |
| Children and adolescents from 4 to 17 years of age weighing 30 kg or moreInitial dose of 40 mg, followed by 4 Thereafter, the usual dose is 40 mChildren and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kgInitial dose of 20 mg, followed by 20 Thereafter, the usual dose is 20 m | | | ng every other week 0 mg one week later. | Not applicable | acid reflux dise sicca syndrome itching; itchy rash; bruising; inflammation o breaking of fing; increased sweat | (incl f the jer na | skin (such as e | | | |
| Hidradenitis su | | | | | | | hair loss;new onset or w | orsen | ing of psoriasi | |
| Age or body weight How much and how often to take? Adults Initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by an 80 mg dose (as two 40 mg injections on the same day) two weeks later. After two further weeks, | | | | our ay or two 40 mg consecutive ng dose (as two ame day) two | Notes It is recommended antiseptic wash da areas. | | muscle spasms blood in urine; kidney problem chest pain; oedema (a build fever; reduction in blc impaired healin | ; s; d-up c bod pl | of fluid in the b | |

| 80 mg (as two 40 mg one day), followed by 40 n veek starting one week lat | ng your doctor ter. frequency to 80 mg every It is recomm | loes not work well enough, may increase the dose o 40 mg every week or o ther week. ended that you use an ash daily on the affected | neurological infections (including viral meningitis); eye infections; bacterial infections; diverticulitis (inflammation and infection of the large intestine); cancer, including cancer that affects the lymph system (lymphoma) and melanoma (a type of skin cancer); immune disorders that could affect the lungs, skin and lymph nodes (most commonly as a condition called sarcoidosis); vasculitis (inflammation of blood vessels); tremor; | | | |
|---|--|---|---|--|--|--|
| uch and how often to take? Notes dose of 80 mg (as two 40 mg injections in one ollowed by 40 mg two weeks later. If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg injections per day or two 40 mg injections per day increase the dose frequency to 40 mg every week or 80 mg every week or 80 mg every other week. | | e If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week. | neuropathy (nerve damage); stroke; double vision; hearing loss, buzzing; sensation of heart beating irregularly such as skipped beats; heart problems that can cause shortness of breath or ankle swelling; heart attack; a sac in the wall of a major artery, inflammation and clot of a vein, blockage of a blood vessel; lung diseases causing shortness of breath (including inflammation); pulmonary embolism (blockage in an artery of the lung); pleural effusion (abnormal collection of fluid in the pleural space); | | | |
| fter, the usual dose is 40 mg every other week. lose of 40 mg, followed by 20 mg two weeks leter response is required, your doctor may be a first dose of 80 mg (two 40 mg injections day), followed by 40 mg two weeks later. | | If this dose does not work well enough, your doctor may increase the dose frequency to 20 mg every week. | inflammation of the pancreas which causes severe pain in the abdomen and back; difficulty in swallowing; facial oedema (swelling); gallbladder inflammation, gallbladder stones; fatty liver (build-up of fat in liver cells); night sweats; scar; | | | |
| fter, the usual dose is 20 m | ig every other week. | Notes | abnormal muscle breakdown; systemic lupus erythematosus (an immune disorder including inflammation of skin, heart, lung, joints and other organ systems); sleep interruptions; | | | |
| of 160 mg (as four 40 mg injections in one o 40 mg injections per day for two days), followed by 80 mg (as two 40 mg one day) two weeks later.If this dose does not work well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week.of 160 mg (as four 40 mg injections in one to mg injections per day for two days) initially, followed by 80 mg (as two tions in one day) two weeks later.If this dose does not work well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week.of 160 mg (as four 40 mg injections in one to mg injections per day for two days) initially, followed by 80 mg (as two tions in one day) two weeks later.Patients who turn 18 years of age while on 80 mg every other week, should continue their prescribed | | well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week. Patients who turn 18 years of age while on 80 mg every other week, should | impotence; inflammations. Rare (may affect up to 1 in 1,000 people) leukaemia (cancer affecting the blood and bone marrow); severe allergic reaction with shock; multiple sclerosis; nerve disorders (such as inflammation of the optic nerve to the eye, and Guillain-Barré syndrome, a condition that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body); heart stops pumping; pulmonary fibrosis (scarring of the lung); intestinal perforation (hole in the wall of the gut); hepatitis (liver inflammation); | | | |
| he usual dose is 80 mg every other week. dose. f 80 mg (as two 40 mg injections in one followed by 40 mg (as one 40 mg oweeks later. Patients who turn 18 years of age while on 40 mg every other week, should continue their prescribed dose. | | of age while on 40 mg every other week, should continue their prescribed | reactivation of hepatitis B infection; autoimmune hepatitis (inflammation of the liver caused by the body's own immune system); cutaneous vasculitis (inflammation of blood vessels in the skin); Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and blistering rash); facial oedema (swelling) associated with allergic reactions; erythema multiforme (inflammatory skin rash); lupus-like syndrome; angioedema (localized swelling of the skin); | | | |
| h and how often to | Notes | | lichenoid skin reaction (itchy reddish-purple skin rash). Not known (frequency cannot be estimated from available data) hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal); | | | |
| e of 80 mg (as two ections), followed by ery other week starting after the initial dose. d continue to inject as long as your doctor | Corticosteroids or other medicines that influence the immune system may be continued while using Idacio. Idacio can also be given alone. | | Merkel cell carcinoma (a type of skin cancer); Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin; liver failure; worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness); weight gain (for most patients, the weight gain was small). Some side effects observed with adalimumab may not have symptoms and may only be discovered through blood tests. These include: | | | |
| ou. ery other week | | ended for use in | Very common (may affect more than 1 in 10 people) • low blood measurements for white blood cells; • low blood measurements for red blood cells; • increased lipids in the blood; • raised liver enzymes. | | | |
| ery other week | Your doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose. Idacio is recommended for use in combination with methotrexate. | | Common (may affect up to 1 in 10 people) • high blood measurements for white blood cells; • low blood measurements for platelets; • increased uric acid in the blood; • abnormal blood measurements for sodium; • low blood measurements for calcium; | | | |
| stration tion under the skin (by s o inject Idacio are provi you should | | | low blood measurements for phosphate; high blood sugar; high blood measurements for lactate dehydrogenase; autoantibodies present in the blood; low blood potassium. | | | |
| ore than required. Alwa | iys take the outer | ur doctor or pharmacist and carton of the medicine with | Uncommon (may affect up to 1 in 100 people) raised bilirubin measurement (liver blood test). Rare (may affect up to 1 in 1,000 people): low blood measurements for white blood cells, red blood cells and platelet count. Reporting of side effects | | | |
| xt dose as you would ha | ave on your origin | ose of Idacio as soon as you ally scheduled day, had you | If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below: | | | |
| ons on the use of this m | , | Your symptoms may return doctor or pharmacist. | United Kingdom Yellow Card Scheme Website: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store | | | |
| erate. However, some i oths or more after the la | may be serious a ast Idacio injection | | Ireland HPRA Pharmacovigilance Website: <u>www.hpra.ie</u> By reporting side effects you can help provide more information on the safety of this medicine. | | | |
| ently, if you notice any of the following signs of allergic reaction or ;; tion or upon lying down or swelling of the feet. ossible, if you notice any of the following: tion such as fever, feeling sick, wounds, dental problems, burning on ed or coughing; such as tingling, numbness, double vision or arm or leg weakness; | | | 5. How to store Idacio Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the label/ carton after EXP. The expiry date refers to the last day of that month. Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the pre-filled pen in the outer carton in order to protect from light. Alternative Storage: When needed (for example when you are travelling), a single Idacio pre-filled pen may be stored at | | | |
| a bump or open sore that doesn't heal; <i>v</i> e of blood disorders such as persistent fever, bruising, bleeding, paleness. e been observed with adalimumab: re than 1 in 10 people) ding pain, swelling, redness or itching); ncluding cold, runny nose, sinus infection, pneumonia); | | | room temperature (up to 25°C) for a maximum period of 28 days - be sure to protect it from light. Once removed from the refrigerator for room temperature storage, your pre-filled pen must be used within 28 days or discarded , even if it is later returned to the refrigerator. You should record the date when the pen is first removed from refrigerator, and the date after which it should be discarded. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to | | | |
| | | | throw away medicines you no longer use. These measures will help protect the environment. | | | |
| n 10 people) blood poisoning and influenza); g gastroenteritis); ulitis and shingles); ooth infections and cold sores); | | | What Idacio contains The active substance is adalimumab. Each pre-filled pen contains 40 mg of adalimumab in 0.8 ml of solution. The other ingredients are sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, mannitol, sodium chloride, citric acid monohydrate, sodium citrate, polysorbate 80, sodium hydroxide and water for injections. | | | |
| easonal allergy); | | | What Idacio looks like and contents of the pack Idacio 40 mg solution for injection (injection) in pre-filled pen is supplied as a sterile 0.8 ml clear, colourless solution of 40 mg adalimumab. The Idacio pre-filled pen contains a pre-filled syringe with Idacio. Each pack contains 2 or 6 pre-filled pens with 2 or 6 alcohol pads. Idacio is available as a vial, a pre-filled syringe and a pre-filled pen. | | | |
| ession); | | | Marketing Authorisation Holder Fresenius Kabi Ltd | | | |
| ingling, prickling or numbness; pression (including low back pain and leg pain); | | | Cestrian Court Eastgate Way, Manor Park Runcorn, Cheshire, WA7 1NT United Kingdom | | | |
| nd eye swelling; inning); pidly; | | | Manufacturer Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria | | | |
| with clotted blood); | | | This leaflet was last revised in October 2023. Other sources of information Detailed information on this medicine is available on the European Medicines Agency web site: | | | |
| ng, heart burn); y eyes and dry mouth); | | | 7. Instructions for use | | | |
| h as eczema); oe nails; | | | Be sure that you read, understand, and follow these Instructions for Use before injecting Idacio. Your healthcare provider should show you how to prepare and inject Idacio properly using the pre- filled pen before you use it for the first time. Talk to your healthcare provider if you have any questions. | | | |
| oriasis; | | | | | | |
| | | | | | | |
| the body which causes | the affected tissue | to swell); | | | | |

body which causes the affected tissue to swell); increases risk of bleeding or bruising;

disease is lowered:

Uncommon (may affect up to 1 in 100 people) • unusual infections (which include tuberculosis and other infections) that occur when resistance to