Template PP 130 x 540 mm
in order to fit in technical data

Stand: Dezember 2022/wdm

Haupt Pharma Münster GmbH

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LEFUNAR
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S4

LEFUNAR 10, film-coated tablets
LEFUNAR 20, film-coated tablets
Leflunomide
Contains sugar (lactose monohydrate, 80,00 mg per 10 mg film-coated tablet and 160,00 mg per 20 mg film-coated tablet)
Contains lecithin (derived from soybeans, 0,06 mg per 10 mg film-coated tablet and 0,12 mg per 20 mg film-coated tablet)

Read all of this leaflet carefully before you start taking LEFUNAR
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist nurse or other healthcare provider.
- LEFUNAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LEFUNAR is and what it is used for
LEFUNAR tablets contain a medicine called leflunomide. It belongs to a group of medicines called anti-rheumatic medicines.

LEFUNAR is used to treat adult patients with active rheumatoid arthritis and to improve physical function.
It works by slowing down the process of joint damage and relieves the symptoms of the disease, such as inflammation of joints, swelling, difficulty moving and pain.

2. What you need to know before you take LEFUNAR
Do not take LEFUNAR if:
- you are allergic (hypersensitive) to leflunomide or any of the other ingredients of LEFUNAR listed in section 6 (especially a serious skin reaction, often accompanied by fever, joint pain, red skin stains, or blisters e.g. Stevens-Johnson syndrome)
- you have any liver problems
- you suffer from any problem which affects your immune system (e.g. AIDS)
- you have any problem with your bone marrow, or if you have low numbers of red or white cells in your blood or a reduced number of blood platelets
- you are suffering from a serious infection
- you have moderate to severe kidney problems
- you have severely low numbers of proteins in your blood (hypoproteinaemia)
- you are pregnant, think you may be pregnant, or are breastfeeding
- you are under 18 years of age.

Warnings and Precautions
Take special care with LEFUNAR:
- if you are taking other anti-rheumatic medicines or your doctor want to switch your anti-rheumatic medicines (refer to Other medicines with LEFUNAR). This can cause an increase in side effects.
- if your doctor determines that LEFUNAR is damaging your liver, you may be given treatment to quickly eliminate LEFUNAR from your body.
- if you have ever had tuberculosis or if you have been in close contact with someone who has or has had tuberculosis. Your doctor may perform tests to see if you have tuberculosis.
- if you have ever suffered from inflammation of the lung (interstitial lung disease).
- if you are male and wish to father a child. As it cannot be excluded that LEFUNAR passes into semen, reliable contraception should be used during treatment with LEFUNAR. Men wishing to father a child should contact their doctor who may advise them to stop taking LEFUNAR and take certain medicines to remove LEFUNAR rapidly and sufficiently from their body. You will then need a blood test to make sure that LEFUNAR has been sufficiently removed from your body, and you should then wait for at least another 3 months before attempting to father a child.
- LEFUNAR can interfere with the blood test used to determine calcium levels. Tell your doctor that you are taking LEFUNAR before performing blood tests.

LEFUNAR can occasionally cause some problems with your blood, liver, lungs, or nerves in your arms or legs. It may also cause some serious allergic reactions (including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)) or increase the chance of a severe infection (see section 4).

DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

Tell your doctor if you have unexplained chronic diarrhoea. Your doctor may perform additional tests to determine the cause of the diarrhoea.

Your doctor will carry out blood tests at regular intervals, before and during treatment with LEFUNAR, to monitor your blood cells and liver. Your doctor will also check your blood pressure regularly as LEFUNAR can cause an increase in blood pressure.

Other medicines and LEFUNAR
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

LEFUNAR may affect or be affected by some other medicines. Medicines which may have an effect on LEFUNAR:
- Other medicines for rheumatoid arthritis such as antimalarials (e.g. chloroquine and hydroxychloroquine), intramuscular or oral gold, D-penicillamine, azathioprine and other immunosuppressive medicines (e.g. methotrexate). These combinations are not advisable, as it may lead to increased risk for blood or liver side effects
- warfarin and other oral medicines used to prevent blood clots, close monitoring of your blood clotting is necessary as LEFUNAR may reduce the effect of these medicines
- a medicine called cholestyramine (used to reduce high cholesterol) or activated charcoal as these medicines can reduce the amount of LEFUNAR which is absorbed by the body
- rifampicin, for tuberculosis as it may increase the levels of LEFUNAR
- repaglinide or pioglitazone, for diabetes. LEFUNAR may increase the effect of these medicines
- daunorubicin, doxorubicin, paclitaxel, or topotecan for cancer. LEFUNAR may increase the effect of these medicines
- duloxetine for depression and anxiety as LEFUNAR may reduce the effect of these medicines
- theophylline for asthma, chronic bronchitis and other lung diseases as LEFUNAR may reduce the effect of these medicines
- oral contraceptives containing ethinylestradiol and levonorgestrel as LEFUNAR may increase the levels of these medicines
- cefaclor, benzylpenicillin, ciprofloxacin for infections as LEFUNAR may increase the levels of these medicines
- cimetidine, for stomach and intestinal ulcers as LEFUNAR may increase the levels of this medicine
- indomethacin, ketoprofen for pain or inflammation as LEFUNAR may increase the levels of these medicines
- furosemide, a diuretic (water pill) as LEFUNAR may increase the levels of this medicine
- zidovudine for HIV infection as LEFUNAR may increase the levels of this medicines
- rosuvastatin, simvastatin, atorvastatin, pravastatin for high cholesterol. LEFUNAR may increase the effect of these medicines
- sulfasalazine for inflammatory bowel disease or rheumatoid arthritis. LEFUNAR may increase the effect of this medicine.

If you are already taking a nonsteroidal anti-inflammatory drug (NSAID) and/ or corticosteroids, you may continue to take them after starting LEFUNAR.

Vaccinations:
If you have to be vaccinated, ask your doctor for advice. Certain vaccinations should not be given while taking LEFUNAR, and for a certain amount of time after stopping treatment.

LEFUNAR with food, drink and alcohol
You should avoid consuming alcohol while on treatment with LEFUNAR as the risk of side effects are increased.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking LEFUNAR.

LEFUNAR may cause serious birth defects when taken while pregnant. Do not take LEFUNAR if you are pregnant.
If you are pregnant or become pregnant while taking LEFUNAR, the risk of having a baby with serious birth defects is increased. Women of childbearing potential must not take LEFUNAR without using reliable contraceptive measures. Tell your doctor if you plan to become pregnant after stopping treatment with LEFUNAR, as you need to ensure that all traces of LEFUNAR have left your body before trying to become pregnant. This may take up to 2 years. This may be reduced to a few weeks by taking certain medicines which speed up removal of LEFUNAR from your body. In either case it should be confirmed by a blood test that LEFUNAR has been sufficiently removed from your body and you should then wait for at least another month before you become pregnant. For further information on the laboratory testing please contact your doctor.

If you suspect that you are pregnant while taking LEFUNAR or in the two years after you have stopped treatment, you must contact your doctor immediately for a pregnancy test.
LEFUNAR passes into breast milk. Women should not breastfeed their babies while taking LEFUNAR.

Driving and using machines
LEFUNAR can make you feel dizzy which may impair your ability to concentrate and react. If this happens to you, do not drive or use any tools or machines.
It is not always possible to predict to what extent LEFUNAR may interfere with the daily activities of a patient. You should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which LEFUNAR affects you.

LEFUNAR contains lactose monohydrate and lecithin
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LEFUNAR.

LEFUNAR contains lecithin, derived from soybeans. If you are allergic to peanut or soya, do not use this medicine.

3. How to take LEFUNAR
Do not share medicines prescribed for you with any other person.
Always take LEFUNAR exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with LEFUNAR will last. Do not stop treatment early because your symptoms have cleared up. If you have the impression that the effect of LEFUNAR is too strong or too weak, talk to your doctor or pharmacist.

The usual starting dose of LEFUNAR is one 10 mg tablet once daily for the first three days.
After this, the maintenance dose is: 10 or 20 mg LEFUNAR once daily.
Your doctor will tell you how many tablets to take. It may take about 4 weeks or longer until you start to feel an improvement in your condition. Some patients may even feel further improvements after 4 to 6 months of therapy.

LEFUNAR should only be prescribed by specialists experienced in the treatment of rheumatoid diseases.

Swallow the tablet whole with a glass of water. You may take LEFUNAR with or without food.

If you take more LEFUNAR than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Always take the box, this leaflet and any tablets that are left over with you, if you can. Signs of an overdose may include abdominal pain, nausea, diarrhoea and rash.

If you forget to take LEFUNAR
If you forget to take your tablets, take them as soon as you remember. If it is nearly time for the next dose, take the dose as usual. Do not take a double dose to make up for forgotten individual doses.

If you stop taking LEFUNAR
Do not stop taking LEFUNAR tablets without first discussing it with your doctor.

After stopping treatment with LEFUNAR, traces of LEFUNAR will remain in your body for up to 2 years. If your treatment was stopped due to serious side effects or pregnancy, or planned pregnancy (both male and female patients), your doctor may reduce the levels of LEFUNAR in your body within a few days to weeks by giving you certain medicines which speed up the removal of LEFUNAR from your body. Speak to your doctor or healthcare provider if this is applicable to you.

4. Possible side effects
LEFUNAR can have side effects.
Not all side effects reported for LEFUNAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LEFUNAR, please consult your healthcare provider for advice.

If any of the following happens, stop taking LEFUNAR and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing and fainting
- severe rash or itching, may include blistering and peeling of your skin, bleeding under the skin, accompanied by fever and joint stiffness

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LEFUNAR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- any symptoms of an infection such as fever, sore throat or cough, as this medicine may increase the chance of a severe infection which may be fatal
- pale skin, tiredness, or bruising, as these may indicate blood disorders caused by an imbalance in the different types of cells which make up blood
- severe increase in blood pressure
- cough or breathing problems as these may indicate problems of the lung (interstitial lung disease or pulmonary hypertension), which may be fatal
- yellowing of the skin and eyes, also called jaundice, accompanied by fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine. This may indicate liver damage.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- dizziness, headache
- abnormal skin sensations like tingling (paraesthesia)
- unusual tingling, weakness or pain in your hands or feet as these may indicate problems with your nerves (peripheral neuropathy)
- mild increase in blood pressure
- colitis (inflammation of the colon) – you may notice blood in your stool, abdominal pain and cramps
- diarrhoea
- feeling sick (nausea)
- being sick (vomiting)
- inflammation of the mouth or mouth ulcers
- stomach pain
- increased hair loss
- eczema, dry skin
- inflammation of a tendon – you may experience pain, swelling and difficulty moving the affected joint
- loss of appetite, weight loss
- tiredness (asthenia)

Less frequent side effects:
- nervousness, worrying
- taste disturbances
- inflammation of the pancreas – you may experience upper abdominal pain, nausea and vomiting
- severe liver injury such as liver failure or necrosis which may be fatal
- hives
- tendon rupture, which will cause immediate bruising and severe pain which gets worse with tendon use.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/-Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LEFUNAR.

5. How to store LEFUNAR
Store at or below 25 °C. Store in the original container until required for use.
Do not use after the expiry date printed on the label/ carton.
Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information
What LEFUNAR contains
The active substance is leflunomide.
The other ingredients are:
Tablet core: Low-substituted hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, sodium laurilsulfate, tartaric acid.
Film coating: Opadry AMB white consisting of lecithin, poly (vinyl alcohol), talc, titanium dioxide, xanthan gum.

What LEFUNAR looks like and contents of the pack
LEFUNAR 10 mg: White to off-white, round, biconvex film-coated tablets.
LEFUNAR 20 mg: White to off-white, round, biconvex film-coated tablets with one-sided break-mark.

LEFUNAR 10 and LEFUNAR 20 are packed in white round or square HDPE bottles closed with white PP closures with desiccant insert.
Pack size: 30 or 100 tablets.

Holder of Certificate of Registration
Biotech Laboratories (Pty) Ltd.
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This leaflet was last revised in
19 March 2024

Registration/Application number
LEFUNAR 10: 56/3.1/0178.176
LEFUNAR 20: 56/3.1/0179.177

PIL 560178.176/79.177-1

pharmacode reading direction

LEFUNAR
PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S4

LEFUNAR 10, filmbedekte tablette
LEFUNAR 20, filmbedekte tablette
Leflunomied
Bevat suiker (laktosemonohidraat, 80,00 mg per 10 mg filmbedekte tablet en 160,00 mg per 20 mg filmbedekte tablet)
Bevat lesitien (afgelei van sojabone, 0,06 mg per 10 mg filmbedekte tablet en 0,12 mg per 20 mg filmbedekte tablet)

Lees die hele pamflet noukeurig deur voordat jy LEFUNAR begin neem
- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- LEFUNAR is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat hierdie pamflet bevat

1. Wat LEFUNAR is en waarvoor dit gebruik word
LEFUNAR tablette bevat 'n medisyne genaamd leflunomied. Dit behoort aan 'n groep medisyne wat anti-rumatiese medisyne genoem word.

LEFUNAR word gebruik om volwasse pasiënte met aktiewe rumatoïede artritis te behandel en om fisiese funksie te verbeter.
Dit werk deur die proses van gewrigskade te vertraag en verlig die simptome van die siekte, soos inflammasie van gewrigte, swelling, moeilikheid om te beweeg en pyn.

2. Wat jy moet weet voordat jy LEFUNAR neem
Moenie LEFUNAR neem nie indien:
- jy allergies (hipersensitief) is vir leflunomied of enige van die ander bestanddele van LEFUNAR wat in afdeling 6 gelys is (veral 'n ernstige velreaksie, wat dikwels gepaard gaan met koors, gewrigspyn, rooi velvlekke of blase, bv. Stevens-Johnson-sindroom)
- jy enige lewerprobleme het
- jy/ jy aan enige probleem wat jou immuunstelsel affekteer (bv. VIGS)
- jy enige probleem met jou beenmurg het, of as jy lae getalle rooi of wit selle in jou bloed of 'n verminderde aantal bloedplaatjies het
- jy aan 'n ernstige infeksie lý
- jy matige tot ernstige nierprobleme het
- jy ernstige lae getalle proteïene in jou bloed het (hipoproteïenemie)
- jy swanger is, dink jy is dalk swanger, of borsvoed
- jy jonger as 18 jaar is.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met LEFUNAR:
- indien jy ander anti-rumatiese medisyne gebruik of jou dokter jou anti-rumatiese medisyne wil verander (verwys na Ander medisyne saam met LEFUNAR). Dit kan 'n toename in newe-effekte veroorsaak.
- indien jou dokter bepaal dat LEFUNAR jou lewer beskadig, kan jy behandeling kry om LEFUNAR vinnig uit jou liggaam uit te skei.
- indien jy al ooit tuberkulose gehad het of as jy in noue kontak was met iemand wat tuberkulose het of gehad het. Jou dokter kan toetse uitvoer om te sien of jy tuberkulose het.
- indien jy al ooit aan longontsteking (interstisiële longsiekte) gely het.
- indien jy manlik is en 'n kind wil verwek. Aangesien dit nie uitgesluit kan word dat LEFUNAR in sperm oorgaan nie, moet betroubare voorbehoeding tydens behandeling met LEFUNAR gebruik word. Mans wat 'n kind wil verwek, moet hul dokter kontak wat hulle kan aanraai om op te hou om LEFUNAR te neem en sekere medisyne te neem om LEFUNAR vinnig en voldoende uit hul liggaam te verwyder. Jy sal dan 'n bloedtoets nodig hê om seker te maak dat LEFUNAR voldoende uit jou liggaam verwyder is, en jy moet dan vir ten minste nog 3 maande wag voordat jy probeer om 'n kind te verwek.
- LEFUNAR kan inmeng met die bloedtoets wat gebruik word om kalsiumvlakke te bepaal. Vertel jou dokter dat jy LEFUNAR neem voordat jy bloedtoetse doen.

LEFUNAR kan soms probleme met jou bloed, lewer, longe of senuwees in jou arms of bene veroorsaak. Dit kan ook 'n paar ernstige allergiese reaksies veroorsaak (insluitend geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS)) of die kans op 'n ernstige infeksie verhoog (sien afdeling 4).

DRESS verskyn aanvanklik as griepagtige simptome en 'n uitslag op die gesig, dan 'n uitgebreide uitslag met 'n hoë temperatuur, verhoogde vlakke van lewerensieme wat in bloedtoetse gesien word en 'n toename in 'n tipe witbloedsel (eosinofilie) en vergrote limfknope.

Vertel jou dokter indien jy onverklaarbare chroniese diarree het. Jou dokter kan bykomende toetse uitvoer om die oorsaak van die diarree te bepaal.

Jou dokter sal bloedtoetse met gereelde tussenposes uitvoer, voor en tydens behandeling met LEFUNAR, om jou bloedselle en lewer te monitor. Jou dokter sal ook jou bloeddruk gereeld kontroleer aangesien LEFUNAR 'n toename in bloeddruk kan veroorsaak.

Ander medisyne en LEFUNAR
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

LEFUNAR kan sommige ander medisyne beïnvloed of daardeur beïnvloed word. Medisyne wat 'n effek op LEFUNAR kan hê:
- Ander medisyne vir rumatoïede artritis soos antimalariamiddels (bv. chloorokien en hidroksichlorokien), binnespierse of orale goud, D-penisillamien, asatioprien en ander immuunonderdrukkende medisyne (bv. metotreksaat). Hierdie kombinasies is nie raadsaam nie, aangesien dit kan lei tot verhoogde risiko vir bloed- of lewer newe-effekte
- warfarien en ander orale medisyne wat gebruik word om bloedklonte te voorkom, noukeurige monitering van jou bloedstolling is nodig aangesien LEFUNAR die effek van hierdie medisyne kan verminder
- 'n medisyne genaamd cholestiramien (gebruik om hoë cholesterol te verminder) of geaktiveerde houtskool aangesien hierdie medisyne die hoeveelheid LEFUNAR wat deur die liggaam geabsorbeer word, kan verminder
- rifampisien, vir tuberkulose aangesien dit die vlakke van LEFUNAR kan verhoog
- repaglinied of pioglitasoon, vir diabetes. LEFUNAR kan die effek van hierdie medisyne verhoog
- daunorubisien, doksorubisien, paclitaksel of topotelan vir kanker. LEFUNAR kan die effek van hierdie medisyne verhoog
- duloksetien vir depressie en angs aangesien LEFUNAR die effek van hierdie medisyne kan verminder
- teofillien vir asma, chroniese brongitis en ander longsiektes aangesien LEFUNAR die effek van hierdie medisyne kan verminder
- orale voorbehoedmiddels wat etinielestradiol en levonorgestrel bevat aangesien LEFUNAR die vlakke van hierdie medisyne kan verhoog
- sefaclor, bensielpenisillien, siprofloksasien vir infeksies aangesien LEFUNAR die vlakke van hierdie medisyne kan verhoog
- simetidien, vir maag- en dermsere aangesien LEFUNAR die vlakke van hierdie medisyne kan verhoog
- indometasien, ketoprofen vir pyn of inflammasie aangesien LEFUNAR die vlakke van hierdie medisyne kan verhoog
- furosemied, 'n diuretikum (waterpil) aangesien LEFUNAR die vlakke van hierdie medisyne kan verhoog
- sidovudien vir MIV-infeksie aangesien LEFUNAR die vlakke van hierdie medisyne kan verhoog
- rosuvastatien, simvastatien, atorvastatien, pravastatien vir hoë cholesterol. LEFUNAR kan die effek van hierdie medisyne verhoog
- sulfasalasien vir inflammatoriese dermsiekte of rumatoïede artritis. LEFUNAR kan die effek van hierdie medisyne verhoog.

Indien jy reeds 'n niesteroïdale anti-inflammatoriese middel (NSAID) en/ of kortikosteroïede neem, kan jy voortgaan om dit te neem nadat jy met LEFUNAR begin het.

Inentings:
Indien jy ingeënt moet word, vra jou dokter vir raad. Sekere inentings moet nie gegee word terwyl LEFUNAR geneem word nie, en vir 'n sekere tyd nadat behandeling gestaak is.

LEFUNAR saam met kos, drank en alkohol
Jy moet die gebruik van alkohol vermy terwyl jy met LEFUNAR behandel word, aangesien die risiko van newe-effekte verhoog word.

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy LEFUNAR neem.

LEFUNAR kan ernstige geboortedefekte veroorsaak wanneer dit tydens swangerskap geneem word. Moenie LEFUNAR neem indien jy swanger is nie. Indien jy swanger is of swanger word terwyl jy LEFUNAR neem, is die risiko om 'n baba met ernstige geboortedefekte te hê verhoog. Vroue van vrugbare potensiaal moet nie LEFUNAR neem sonder om betroubare voorbehoedmaatreëls te gebruik nie.
Vertel jou dokter as jy van plan is om swanger te raak nadat jy die behandeling met LEFUNAR gestaak het, aangesien jy moet verseker dat alle spore van LEFUNAR jou liggaam verlaat het voordat jy probeer om swanger te word. Dit kan tot 2 jaar neem. Dit kan tot 'n paar weke verminder word deur sekere medisyne te neem wat die verwydering van LEFUNAR uit jou liggaam bespoedig.
In beide gevalle moet dit deur 'n bloedtoets bevestig word dat LEFUNAR voldoende uit jou liggaam verwyder is en jy moet dan vir ten minste nog 'n maand wag voordat jy swanger word.
Kontak asseblief jou dokter vir verdere inligting oor die laboratoriumtoetse.

Indien jy vermoed dat jy swanger is terwyl jy LEFUNAR neem of in die twee jaar nadat jy die behandeling gestaak het, moet jy dadelik jou dokter kontak vir 'n swangerskapstoets.
LEFUNAR word in borsmelk uitgeskei. Vroue moet nie hul babas borsvoed terwyl hulle LEFUNAR neem nie.

Bestuur en gebruik van masjiene
LEFUNAR kan jou duiselig laat voel wat jou vermoë om te konsentreer en te reageer kan benadeel. As dit met jou gebeur, moenie bestuur of enige gereedskap of masjiene gebruik nie.
Dit is nie altyd moontlik om te voorspel tot watter mate LEFUNAR met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Jy moet seker maak dat jy nie 'n voertuig bestuur of masjiene gebruik totdat jy bewus is van die mate waarin LEFUNAR jou raak nie.

LEFUNAR bevat laktosemonohidraat en lesitien
Indien jou dokter jou vertel het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy LEFUNAR neem.

LEFUNAR bevat lesitien, afkomstig van sojabone. Indien jy allergies is vir grondboontjies of soja, moenie hierdie medisyne gebruik nie.

3. Hoe om LEFUNAR te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd LEFUNAR presies soos jou dokter of apteker jou voorgeskryf het. Gaan praat met jou dokter of apteker indien jy nie seker is nie.

Jou dokter sal jou vertel hoe lank jou behandeling met LEFUNAR sal duur. Moenie behandeling vroeg staak indien jou simptome opgeklaar het nie. Indien jy die indruk het dat die effek van LEFUNAR te sterk of te swak is, praat met jou dokter of apteker.

Die gewone aanvangsdosis van LEFUNAR is een 10 mg tablet een keer daagliks vir die eerste drie dae. Hierna is die onderhoudsdosis: 10 of 20 mg LEFUNAR een keer per dag.
Jou dokter sal jou vertel hoeveel tablette jy moet neem.
Dit kan ongeveer 4 weke of langer duur voordat jy 'n verbetering in jou toestand begin voel. Sommige pasiënte kan selfs verdere verbeterings voel na 4 tot 6 maande se terapie.

LEFUNAR moet slegs voorgeskryf word deur spesialiste wat ondervinding het in die behandeling van rumatoïede siektes.

Sluk die tablet heel met 'n glas water. Jy mag LEFUNAR met of sonder kos neem.

Indien jy meer LEFUNAR neem as wat jy moet
In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem altyd die boks, hierdie pamflet en enige tablette wat oorbly saam met jou, as jy kan. Tekens van 'n oordosis kan buikpyn, naarheid, diarree en uitslag insluit.

Indien jy vergeet om LEFUNAR te neem
Indien jy vergeet om jou tablette te neem, neem dit so gou as wat jy onthou. As dit amper tyd is vir die volgende dosis, neem die dosis soos gewoonlik. Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

Indien jy ophou om LEFUNAR te neem
Moenie ophou om LEFUNAR tablette te neem sonder om dit eers met jou dokter te bespreek nie.

Nadat behandeling met LEFUNAR gestaak is, sal spore van LEFUNAR vir tot 2 jaar in jou liggaam bly. Indien jy behandeling gestaak is as gevolg van ernstige newe-effekte of swangerskap, of beplande swangerskap (beide manlike en vroulike pasiënte), kan jou dokter die vlakke van LEFUNAR in jou liggaam binne 'n paar dae tot weke verminder deur vir jou sekere medisyne te gee wat die verwydering van LEFUNAR uit jou liggaam verspoedig. Praat met jou dokter of gesondheidsorgverskaffer indien dit op jou van toepassing is.

4. Moontlike newe-effekte
LEFUNAR kan newe-effekte hê.
Nie alle newe-effekte wat vir LEFUNAR aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy LEFUNAR neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om LEFUNAR te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal en flou te word
- erge uitslag of jeuk, kan blase en afskilfering van jou vel insluit, bloeding onder die vel, gepaardgaande met koors en gewrigstyfheid

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy dalk 'n ernstige allergiese reaksie op LEFUNAR gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel dadelik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- enige simptome van 'n infeksie soos koors, seer keel of hoes, aangesien hierdie medisyne die kans op 'n ernstige infeksie kan verhoog wat dodelik kan wees
- bleek vel, moegheid of kneusing, aangesien dit kan dui op bloedafwykings wat veroorsaak word deur 'n wanbalans in die verskillende tipes selle waaruit bloed bestaan
- ernstige toename in bloeddruk
- hoes- of asemhalingsprobleme aangesien dit probleme van die long kan aandui (interstisiële longsiekte of pulmonale hipertensie), wat dodelik kan wees
- vergeling van die vel en oë, ook genoem geelsug, gepaardgaande met koors, moegheid, verlies aan eetlus, naarheid, braking, buikpyn, donker uriene. Dit kan lewerskade aandui.

Hierdie is almal ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:
Gereelde newe-effekte:
- duiseligheid, hoofpyn
- abnormale velsensasies soos tinteling (parestesie)
- ongewone tinteling, swakheid of pyn in jou hande of voete aangesien dit probleme met jou senuwees kan aandui (perifere neuropatie)
- ligte verhoging in bloeddruk
- kolitis (inflammasie van die dikderm) – jy kan bloed in jou stoelgang, buikpyn en krampe opmerk
- diarree
- siek voel (naarheid)
- siek wees (braking)
- ontsteking van die mond of mondsere
- maagpyn
- verhoogde haarverlies
- ekseem, droë vel
- inflammasie van 'n sening – jy kan pyn, swelling en probleme ervaar om die aangetaste gewrig te\ beweeg
- verlies aan eetlus, gewigsverlies
- moegheid (astenie)

Minder gereelde newe-effekte:
- senuweeagtigheid, kommer
- smaakversteurings
- ontsteking van die pankreas – jy kan pyn in die boonste buik, naarheid en braking ervaar
- ernstige lewerbesering soos lewerversaking of nekrose wat dodelik kan wees
- korwe
- tendonbreuk, wat onmiddellike kneusing en erge pyn sal veroorsaak wat vererger met tendongebruik.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.-sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van LEFUNAR te verskaf.

5. Hoe om LEFUNAR te bewaar
Bewaar teen of benede 25 °C. Bewaar in die oorspronklike houer totdat dit benodig word vir gebruik.
Moet nie gebruik na die vervaldatum wat op die etiket/ karton gedruk is nie.
Gee alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

6. Inhoud van die pakkie en ander inligting
Wat LEFUNAR bevat
Die aktiewe bestanddeel is leflunomied.
Die ander bestanddele is:
Tabletkern: Lae-gesubstitueerde hidroksipropielsellulose, laktosemonohidraat, magnesiumstearaat, natriumlaurilsulfaat, wynsteensuur.
Filmbedekking: Opadry AMB wit wat bestaan uit lesitien, poli (vinielalkohol), talk, titaandioksied, xantangom.

Hoe LEFUNAR lyk en die inhoud van die verpakking
LEFUNAR 10 mg: Wit tot naaswit, ronde, bikonvekse filmbedekte tablette.
LEFUNAR 20 mg: Wit tot naaswit, ronde, bikonvekse filmbedekte tablette met eensydige breekmerk.

LEFUNAR 10 en LEFUNAR 20 word verpak in wit ronde of vierkantige HDPE-bottels wat toegemaak is met wit PP-sluitings met droogmiddel-insetsel.
Verpakkingsgrootte: 30 of 100 tablette.

Houer van Registrasiesertifikaat
Biotech Laboratories (Edms.) Bpk.
Blok K Wes, Central Park
400 16de Weg, Halfweghuis
Midrand, 1685
Tel: (011) 848 3050

Hierdie pamflet is laas hersien
19 Maart 2024

Registrasie-/Aansoeknommer
LEFUNAR 10: 56/3.1/0178.176
LEFUNAR 20: 56/3.1/0179.177

PIL 560178.176/79.177-1 MAT 51757392 · Code 338

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Rückseite/Backside

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