PATIENT INFORMATION LEAFLET

Information for the patient about

LEFLUNOMIDE 20 UNICORN

SCHEDULING STATUS:

Schedule 4.

LEFLUNOMIDE 20 UNICORN (20 mg leflunomide) film coated tablets.

Contains sugar (lactose monohydrate 72 mg/tablet).

Read all of this leaflet carefully before you start taking LEFLUNOMIDE 20 UNICORN. Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

LEFLUNOMIDE 20 UNICORN 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 LEFLUNOMIDE 20 UNICORN is and what it is used for
2. What you need to know before you take LEFLUNOMIDE 20 UNICORN
3. How to take LEFLUNOMIDE 20 UNICORN
4. Possible side effects
5. How to store LEFLUNOMIDE 20 UNICORN
6. Contents of the pack and other information

1. What LEFLUNOMIDE 20 UNICORN is and what it is used for

LEFLUNOMIDE 20 UNICORN is used to treat:

- Rheumatoid arthritis (inflammation of the joints) and to improve physical function.

2. What you need to know before you take LEFLUNOMIDE 20 UNICORN

Do not take LEFLUNOMIDE 20 UNICORN:

- If you are hypersensitive (allergic) to leflunomide, teriflunomide or any of the other ingredients of LEFLUNOMIDE 20 UNICORN.
- If you have liver function impairment.
- If you suffer from severe immunodeficiency state (compromised immune system) e.g. AIDS
- If you suffer from serious infection.
- If you suffer from kidney impairment.
- If you have low protein levels in your blood.
- If you are pregnant or if you are of child bearing age you should use reliable contraceptives.
- If you are breastfeeding.
- Reliable contraceptives in male patients should be guaranteed.
- If you are under 18 years of age.

Take special care with LEFLUNOMIDE 20 UNICORN:

- If you have recently been treated with hepatotoxic or haematotoxic DMARDs.
- If you suffer from liver impairment.
- If you have low levels of protein in your blood.
- If you have low iron levels, a reduced number of white blood cells and/or a low levels of platelets in the blood.

- If you have impaired bone marrow function or at risk of bone marrow suppression (a decrease in bone marrow activity resulting in reduced production of blood cells).
- If you have a history of blood disorders which primarily affect the blood and blood-forming organs.
- If you have a weak immune system.
- If you experience any skin reactions or ulcers, inform your healthcare practitioner immediately. You may need to discontinue your treatment with LEFLUNOMIDE 20 UNICORN.
- If you have problems with your lungs.
- If you experience symptoms of weakness, numbness and pain in the hands or feet, inform your healthcare practitioner.
- If you suffer from serious infections.
- If you are using antimalarial medicines.

Children

The safety and efficacy of LEFLUNOMIDE 20 UNICORN for use in children below 18 years have not been established.

Other medicines and LEFLUNOMIDE 20 UNICORN

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please discuss the use of the following medicines or substances in combination with LEFLUNOMIDE 20 UNICORN with your doctor or pharmacist:

- Other antirheumatoids medicines, such as methotrexate. Taking these medicines with LEFLUNOMIDE 20 UNICORN may lead to increased risk of blood or liver side effects
- Live attenuated vaccines (weakened)
- Anticoagulants (blood thinners) such as warfarin, as taking these medicines with LEFLUNOMIDE 20 UNICORN may affect the way your blood clots
- Anti-inflammatory medicines
- Oral contraceptives
- Corticosteroids.

The effectiveness of LEFLUNOMIDE 20 UNICORN may be reduced when taken with the following:

- Cholestyramine (used to treat high cholesterol)
- Activated charcoal.

The effects of LEFLUNOMIDE 20 UNICORN may be increased when taken with the following:

- Rifampicin (an antibiotic)
- Repaglinide, pioglitazone, or rosiglitazone (used to treat diabetes)
- Paclitaxel (used in chemotherapy).

The effectiveness of the following medicines may be reduced when taken with LEFLUNOMIDE 20 UNICORN:

- Duloxetine (an antidepressant)
- Alosetron (for treatment of irritable bowel syndrome)
- Theophylline (used to treat asthma and chronic obstructive pulmonary disease)
- Tizanidine (a muscle relaxant).

The effects of the following medicines may be increased when taken with LEFLUNOMIDE 20 UNICORN:

- Certain antibiotics, including cefaclor, benzylpenicillin and ciprofloxacin
- Certain anti-inflammatory medicines, including indomethacin and ketoprofen
- Furosemide (a diuretic, water pill)
- Cimetidine (used to treat gastric ulcers)
- Zidovudine (used in treatment of HIV)
- Certain medicines used to treat high cholesterol, such as rosuvastatin, simvastatin, atorvastatin, pravastatin
- Certain medicines used in chemotherapy such as topotecan and daunorubicin
- Sulfasalazine (used for treatment of gastrointestinal disorders)
- Nateglinide (used for treatment of diabetes)
- Certain oral contraceptives, including ethinyl estradiol and levonorgestrel.

LEFLUNOMIDE 20 UNICORN with food and drink:

LEFLUNOMIDE 20 UNICORN tablets should be swallowed whole, with sufficient amounts of liquid. LEFLUNOMIDE 20 UNICORN tablets can be taken with or without food.

It is not recommended to drink alcohol during treatment with LEFLUNOMIDE 20 UNICORN. Drinking alcohol while taking LEFLUNOMIDE 20 UNICORN may increase the chance of liver damage.

Pregnancy and breastfeeding:

Do not take LEFLUNOMIDE 20 UNICORN if you are or think you may be pregnant. If you are pregnant or become pregnant while taking LEFLUNOMIDE 20 UNICORN, the risk of having a

baby with serious birth defects is increased. Women of childbearing potential must not take LEFLUNOMIDE 20 UNICORN without using reliable contraceptive measures.

Pregnancy:

Tell your doctor if you plan to become pregnant after stopping treatment with LEFLUNOMIDE 20 UNICORN, as you need to ensure that all traces of LEFLUNOMIDE 20 UNICORN 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 LEFLUNOMIDE 20 UNICORN from your body (a “washout” procedure).

In either case it should be confirmed by a blood test that LEFLUNOMIDE 20 UNICORN has been sufficiently removed from your body and you should then wait for at least another month before you become pregnant.

Your doctor will advise you on the washout procedure as well as the laboratory tests required.

If you suspect that you are pregnant while taking LEFLUNOMIDE 20 UNICORN or in the two years after you have stopped treatment, you must contact your doctor immediately for a pregnancy test. If the test confirms that you are pregnant, your doctor may suggest treatment with certain medicines to remove LEFLUNOMIDE 20 UNICORN rapidly and sufficiently from your body, as this may decrease the risk to your baby.

Breastfeeding:

Do not use LEFLUNOMIDE 20 UNICORN if you are breastfeeding your baby as LEFLUNOMIDE 20 UNICORN is secreted in breast milk.

Fertility:

No effects of LEFLUNOMIDE 20 UNICORN on male and female fertility were observed.

Driving or using machinery:

LEFLUNOMIDE 20 UNICORN may cause dizziness. Therefore, you should not drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether LEFLUNOMIDE 20 UNICORN affects your ability to perform such activities.

It is not always possible to predict to what extent LEFLUNOMIDE 20 UNICORN may interfere with your daily activities. You should not engage in the above activities until you are aware of the measure to which LEFLUNOMIDE 20 UNICORN affects you.

LEFLUNOMIDE 20 UNICORN contains sugar (lactose monohydrate).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LEFLUNOMIDE 20 UNICORN.

3. HOW TO TAKE LEFLUNOMIDE 20 UNICORN:

LEFLUNOMIDE 20 UNICORN must be taken orally.

Do not share medicines prescribed for you with any other person.

Always take LEFLUNOMIDE 20 UNICORN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with LEFLUNOMIDE 20 UNICORN will last. Do not stop treatment early. If you have the impression that the effect of LEFLUNOMIDE 20 UNICORN is too strong or too weak, tell your doctor or pharmacist.

Adults:

Treatment of rheumatoid arthritis:

The usual starting dose of LEFLUNOMIDE 20 UNICORN is a loading dose of 100 mg (five tablets) once daily for 3 days.

The recommended maintenance dose is leflunomide 10 mg to 20 mg once daily.

A therapeutic effect usually starts after 4 to 6 weeks and may further improve up to 4 to 6 months.

No dose adjustment is needed if you have mild kidney impairment.

No dose adjustment is needed if you are over 65.

If you take more LEFLUNOMIDE 20 UNICORN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs and symptoms of overdose include abdominal pain, anaemia, diarrhoea, elevated liver enzymes, a low level of white blood cells in the blood, nausea, itching and rash.

If you forget to take LEFLUNOMIDE 20 UNICORN:

Always take LEFLUNOMIDE 20 UNICORN as prescribed (see **"HOW TO TAKE LEFLUNOMIDE 20 UNICORN"**). If you have missed a dose, take it as soon as you remember. Do not take a double dose of LEFLUNOMIDE 20 UNICORN to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

LEFLUNOMIDE 20 UNICORN can have side effects.

Not all side effects reported for LEFLUNOMIDE 20 UNICORN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LEFLUNOMIDE 20 UNICORN, please consult your health care provider for advice.

If any of the following happens, stop taking LEFLUNOMIDE 20 UNICORN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing

- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LEFLUNOMIDE 20 UNICORN. 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:

- The following symptoms of blood disorders which your doctor may determine with blood tests: getting infections more easily than normal, fever, sore throat, mouth ulcers or tiredness. This may be due to a low or abnormal number of white blood cells in your blood (leucopoenia or agranulocytosis)
- The following symptoms of blood disorders which your doctor may determine with blood tests:
  - bruising more easily than usual or you may have a rash of dark red spots under the skin (low number of blood platelets in your blood (thrombocytopenia))
  - chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine (low number of certain blood cells, e.g. red blood cells (anaemia) or decrease in the number of all blood cells (pancytopenia))
  - weight loss, night sweats and fever (eosinophilia)
- Severe infections and sepsis which may be life-threatening (infections may start with symptoms such as fever, sore throat or cough)
- Inflammation of the liver (hepatitis) which may be fatal. Symptoms may include tiredness, abdominal pain, yellow discolouration of the eyes or skin
- Jaundice (yellow discolouration of the eyes or skin)

- Cough or breathing problems as these may indicate problems of the lung, (e.g. interstitial lung disease) which may be fatal
- Unusual tingling, numbness, burning, weakness or pain in your hands or feet as these may indicate problems with your nerves (peripheral neuropathy)
- Problems with the nerves of the arms or legs (peripheral neuropathy)
- Severe increase in blood pressure
- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
- Kidney failure (symptoms may include decreased urine production and swelling of your arms and legs)
- Pulmonary hypertension (High blood pressure in the blood vessels that supply the lungs) Symptoms may include cough or breathing problems.

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:

- mild allergic reactions (e.g. rashes, itching)
- headache, dizziness
- abnormal skin sensations like tingling (paraesthesia)
- mild increase in blood pressure
- diarrhoea
- colitis (inflammation of the inner lining of the colon, leading to diarrhoea and pain)
- nausea, vomiting
- inflammation of the mouth or mouth ulcers
- abdominal pain

- loss of appetite
- weight loss
- an increase in some liver laboratory test results
- eczema, dry skin, rashes, itching
- increased hair loss
- tenosynovitis (inflammation of the fluid-filled sheath that surrounds a tendon, usually in the feet or hands)
- tiredness (asthenia).

Less frequent side effects:

- inflammation of your small blood vessels (may cause red sports on the skin, often the lower legs (vasculitis))
- The following symptoms of blood disorders which your doctor may determine with blood tests:
  - an increase in the amount of cholesterol in the blood
  - an increase of certain enzymes in the blood (lactate dehydrogenase)
  - a decrease in the levels of phosphates, potassium or uric acid in the blood
- anxiety
- taste disturbances
- urticaria (nettle rash)
- tendon rupture
- male infertility (which is reversible once treatment with this medicine is stopped).

Side effects of unknown frequency:

- skin ulcer (A round, open sore in the skin through which the underlying tissues can be seen)
- an increase of certain enzymes in the blood (creatine kinase (CK))
- an increase in the levels of fat in the blood (cholesterol and triglycerides)
- a decrease in the levels of phosphate and uric acid in the blood
- cutaneous lupus erythematosus (characterized by rash on skin areas that are exposed to light)
- pustular psoriasis (psoriasis with fluid-filled bumps) or worsening psoriasis (scaly red skin patches).

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.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of LEFLUNOMIDE 20 UNICORN.

5. How to store LEFLUNOMIDE 20 UNICORN:

This medicine does not require any special storage conditions.

Return all unused **LEFLUNOMIDE 20 UNICORN** to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LEFLUNOMIDE 20 UNICORN contains

The active substance is leflunomide.

The other ingredients are: Povidone K25, crospovidone, pregelatinized starch (corn), lactose monohydrate, colloidal silicon dioxide, magnesium stearate.

LEFLUNOMIDE 20 UNICORN contains sugar (lactose monohydrate).

What LEFLUNOMIDE 20 UNICORN looks like and contents of the pack

LEFLUNOMIDE 20 UNICORN 20: Round convex, yellow film-coated tablets, scored in one side.

Blister PVC 127 µm / PCTFE 51 µm / PVC 127 µm blister, sealed with an Aluminium 20 µm / PVDC 20 gm-2sheet.

Leflunomide 20 Unicorn film coated tablets are supplied in packs of 30 tablets.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Cape Town

8001

Application number

56/3.1/0001

This leaflet was last revised in:

Not applicable