

ARAVA[®] TABLETS

Leflunomide (10mg, 20mg)

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What Arava is used for

Arava is used to treat adult with:

- Active rheumatoid arthritis to improve physical function of the body -Arthritis symptoms include inflammation of joints, swelling, difficulty in moving and pain. Other symptoms that affect the entire body include loss of appetite, fever, loss of energy and anaemia (lack of red blood cells).

- Active psoriatic arthritis -Symptoms include patches of red, scaly skin (skin lesions).

How Arava works

Arava belongs to a group of medicines called anti-rheumatic medicines. It contains the active substance leflunomide. It works by reducing pain, inflammation, swelling and stiffness over a period of weeks or months by slowing down the disease and its effects on the joints.

Before you use Arava

- When you must not use it

Do not take Arava if:

- You are allergic (hypersensitive) to leflunomide (especially a serious skin reaction, often accompanied by fever, joint pain, red skin stains, or blisters e.g. Stevens-Johnson syndrome) or to any of the other ingredients of this medicine (listed in Ingredients below).
- You have any liver problems
- You have moderate to severe kidney problems

- You have severely low numbers of proteins in your blood (hypoproteinaemia)
- You suffer from any problem which affects your immune system (such as AIDS)
- You have any problems with your bone marrow, or if you have low numbers of red or white cells in your blood or a reduced number of platelets
- You are suffering from a serious infection
- You are pregnant, think you may be pregnant, or are breast-feeding.
- You are not using reliable birth control.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Arava.

- Before you start to use it

Check with your doctor before taking Arava if:

- You have ever suffered from tuberculosis or interstitial lung disease.
- You have problems related to your blood and bone marrow.
- You are taking other rheumatoid arthritis medicines (see 'Taking other medicines')
- You are having psoriasis and diabetes
- You are taking medicine that affect your immune system such as methotrexate.
- You have rare genetic problems such as galactose or lactose intolerance and glucose-galactose malabsorption.
- You are male and wish to father a child. Men should contact their doctor who may advise them to stop taking Arava and take certain medicines to remove Arava rapidly from their body. If both blood concentration measured are low, you should then wait for at least another 3 months before attempting to father a child.
- You will have or have had recent major surgery, or if you still have an unhealed wound following surgery. ARAVA may impair wound healing

Arava 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, or increase the chance of severe infection. (see 'side effects')

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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Arava.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as these combinations are inadvisable:

- Antimalarials (e.g. chloroquine and hydroxychloroquine)
- Intramuscular or oral gold,
- D-penicillamine
- Benzylpenicillin, Ciprofloxacin, rifampicin (antibiotic)
- Zidovudine (anti-virus)
- Azathioprine, methotrexate and other medicines that affect your immune system
- Activated charcoal.
- Warfarin (used to prevent blood clots)
- Caffeine
- Indomethacin and ketoprofen (use as painkiller or anti-inflammatory)
- Furosemide (reduce water retention in the body)
- Cimetidine (reduce stomach acid production)
- Theophylline (for asthma treatment)
- Simvastatin, atorvastatin, pravastatin, rosuvastatin and cholestyramine (cholesterol lowering agent).

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

Vaccinations

If you have to be vaccinated, ask your doctor for advice. Certain vaccinations such as live attenuated vaccines should not be given while taking Arava, and for a certain amount of time after stopping treatment.

How to use Arava

Always take Arava exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets orally in whole with plenty of water.
- You can take this medicine with or without food.

- How much to use

The usual starting dosage for Arava is one 100mg leflunomide once daily for the first three days. After this, most people need a dose of:

- For rheumatoid arthritis: 10mg or 20mg Arava once daily, depending on the severity of the disease.
- For psoriatic arthritis: 20mg Arava once daily.

Arava is not recommended for use in children and adolescents below 18 years of age.

- When to use it

Take Arava at about the same time each day unless your doctor tells you otherwise.

- How long to use it

It may take about 4 weeks or longer until you start to feel an improvement in your condition. Some people may even still feel further improvement after 4 to 6 months of therapy.

You will normally take Arava over long periods of time.

- If you forget to use it

- If you forget to take your tablet, take as soon as you remember. If it is nearing the time for next dose, leave out that dose completely and take the next tablet at the usual time.

- Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you take too many tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you.

While you are using it- Things you must do

Tell your doctor immediately if:

- You are pregnant or think you may be pregnant while taking Arava, as the risk of having a baby with serious birth defects increased. Women of

childbearing potential must not take Arava without using reliable contraceptive measures.

Tell your doctor if you plan to become pregnant after stopping Arava as this may take up to 2 years. This may be reduced to a few weeks by taking certain medicines (colestyramine or activated charcoal) which speed up removal of Arava from your body. In either case it should be confirmed by a blood test that Arava has been sufficiently removed from your body and you should then wait for at least another month before you become pregnant.

- You are breast-feeding as leflunomide passes into the breast milk.

Tell your doctor if you develop skin ulcer during treatment with Arava

- Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Arava, or change the dosage, without checking with your doctor.

- Things to be careful of

Driving and using machines
Arava can make you feel dizzy which may impair your ability to concentrate and react. If you are affected, do not drive, or do not use machines.

Consult doctor if you want to discontinue Arava and switch to another medicine regarding about the washout procedure.

Side Effect

Like all medicines, Arava can cause side effects, although not everyone gets them. Do not be alarmed by this list of possible side effects.

You may not experience any of them. Tell your doctor immediately and stop taking Arava:

- if you experience weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic reaction,
- if you develop a skin rash or ulcers in your mouth, as these may indicate

severe, sometimes life-threatening reactions (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS]), see section 2.

Tell your doctor immediately if you experience:

- pale skin, tiredness, or bruising, as these may indicate blood disorders caused by an imbalance in the different types of blood cells which make up blood,
- tiredness, abdominal pain, or jaundice (yellow discolouration of the eyes or skin), as these may indicate serious conditions such as liver failure, which may be fatal,
- 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 life-threatening,
- cough or breathing problems as these may indicate problems of the lung (interstitial lung disease or pulmonary hypertension or pulmonary nodule),
- unusual tingling, weakness or pain in your hands or feet as these may indicate problems with your nerves (peripheral neuropathy).

Common side effects (may affect up to 1 in 10 people)

- A decrease in the number of white blood cells
- Mild allergic reactions
- Loss of appetite, weight loss (usually insignificant)
- Tiredness
- Headache, dizziness
- Abnormal skin sensations like tingling
- Problems in the nerves of the arms or legs (peripheral neuropathy)
- Mild increase in blood pressure
- Diarrhoea
- Nausea, vomiting
- Inflammation of the mouth or mouth ulcers
- Abdominal pain
- An increase in some liver test results
- Increased hair loss
- Eczema, dry skin rash, itching
- Inflammation in the sheath that surrounds the tendons
- An increase of certain enzymes in the blood (creatinine)

Uncommon side effects (may affect up to 1 in 100 people)

- A decrease in the number of red

blood cells and a blood platelets.

- A decrease in the levels of potassium phosphate in the blood
- Anxiety
- Taste disturbances
- Nettle rash
- Tendon rupture
- An increase in the levels of fat in the blood (cholesterol and triglycerides)

Rare side effects (may affect up to 1 in 1000 people)

- An increase in the numbers of blood cells called eosinophiles (eosinophilia); decrease in the number of white blood cells or all blood cells.
- Severe increase in blood pressure
- Inflammation of the lung (interstitial lung disease)
- An increase in some liver results which may develop into serious conditions such as inflammation and yellowing of eyes and skin.
- Severe infections which may be fatal
- An increase of certain enzymes in the blood (lactate dehydrogenase).

Very rare side effects (may affect up to 1 in 10000 people)

- A marked decrease of some white blood cells
 - Severe and potentially severe allergic reactions
 - Inflammation of blood vessels
 - Inflammation of the pancreas
 - Severe liver injury such as liver failure or cell death which may be fatal
 - Severe sometimes life-threatening skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme).
- Other side effects such as kidney failure, a decrease in the levels of uric acid in your blood, pulmonary hypertension, male infertility (which is reversible once treatment with this medicine is stopped), cutaneous lupus (characterized by rash/erythema on skin areas that are exposed to light), psoriasis (new or worsening), and DRESS and Skin ulcer (Round, open sore in the skin through which the underlying tissues can be seen), may also occur with an unknown frequency.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the

website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Arava

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

- Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Arava after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store below 30°C. Keep the container tightly closed.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
 - Arava 10mg film-coated tablets are white to almost white and round with ZBN imprinted on one side.
 - Arava 20mg film-coated tablets are yellowish to ochre and triangular with ZBO imprinted on one side.

Both are packed in 100ml HDPE-bottle containing 30 film-coated tablets.

Ingredients:

Active ingredients:

- Arava 10mg contains 10mg of leflunomide.
- Arava 20mg contains 20mg of leflunomide.

Inactive ingredients:

- macrogol 8000, talc, colloidal anhydrous silica, magnesium stearate, methylhydroxypropylcellulose, polyvidone, maize starch, crospovidone, lactose monohydrate, titanium dioxide
- yellow ferric oxide (only for Arava 20mg).

MAL Numbers:

Arava 10mg tablets:
MAL20001528ARZ
Arava 20mg tablets:
MAL20001527AZ

Manufacturer

Opella Healthcare International SAS
56, route de Choisy
60200 Compiègne France.

Product Registration Holder Sanofi-aventis (Malaysia) Sdn. Bhd. Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

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