

AVEGESIC TABLET

Meloxicam (7.5 mg, 15 mg)

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What Avegesic Tablet is used for

Avegesic Tablet is used for:

- Symptomatic treatment of painful osteoarthritis (degenerative joint disease).
- Symptomatic treatment of rheumatoid arthritis (systemic inflammatory disorder that affects joints).
- Symptomatic treatment of ankylosing spondylitis (chronic inflammatory disease of the skeleton).

How Avegesic Tablet works

Avegesic Tablet contains a substance called meloxicam. It belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs) which are used to reduce inflammation, pain and fever.

Before you use Avegesic Tablet

- When you must not use it

- You are pregnant, planning to become pregnant or if you are breast feeding.
- You are allergic to meloxicam or to any of the other ingredients listed.
- You are allergic to aspirin or other anti-inflammatory medicines.
- You have ever suffered from wheezing, nasal polyps (nasal obstruction due to swellings in the lining in your nose) along with a runny nose, swelling of the skin, urticaria (nettle rash) when taking aspirin or other anti-inflammatory medicines.
- You have or have ever had a gastrointestinal ulcer or perforation (ulcer of the stomach or intestines).

- You have any kind of bleeding disorder or have ever suffered from gastrointestinal bleeding (bleeding in the stomach or intestines) or cerebrovascular bleeding (bleeding in the brain).
- You have serious liver disease.
- You have serious kidney disease and are not undergoing dialysis.
- You have severe heart failure.

- Before you start to use it

Inform your doctor if:

- You have high blood pressure.
- You are elderly.
- You have heart, liver or kidney disease.
- You have diabetes.
- You have heart failure, heart disease or stroke.
- Meloxicam may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Your doctor may monitor your progress whilst on treatment.

Pregnancy

This product should not be used during pregnancy or if you are planning to become pregnant. If you think or know you are pregnant you should talk to your doctor for advice.

Breast feeding

This product should not be given to breast feeding mothers.

Information about lactose

This product contains lactose. If you have been told by your doctor that you have an intolerant to some sugars, contact your doctor before taking this medicine.

- Taking other medicines

As Avegesic Tablet may affect or be affected by other medicines, please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, even those not prescribed.

In particular please tell your doctor or pharmacist if you are taking/have taken any of the following:

- Other anti-inflammatory drugs, including aspirin.
- Medicines which prevent blood clotting e.g. warfarin.
- Medicines which break down blood clots (thrombolytics).
- Medicines to treat high blood pressure.
- Corticosteroids
- Cyclosporin – a medicine often used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephritic syndrome.
- Any diuretic medicine ("water tablets"). Your doctor may monitor your kidney function if you are taking diuretics.
- Lithium – a medicine used to treat mood disorders.
- Selective Serotonin re-uptake inhibitors used in treatment of depression.
- Methotrexate – a medicine mainly used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis.
- Cholestyramine - mainly used to lower cholesterol levels.
- You are a woman who uses an intrauterine contraceptive device (IUD), usually known as a coil.

If in doubt, ask your doctor or pharmacist.

How to use Avegesic Tablet

- How much to use

Follow your doctor's instructions about when and how to take your medicine and always read the label. The usual recommended doses are given below:

- Osteoarthritis:
7.5 mg once a day. This may be increased to 15 mg once a day.
- Rheumatoid arthritis:
15 mg once a day. This may be reduced to 7.5 mg once a day.
- Ankylosing spondylitis:
15 mg once a day. This may be reduced to 7.5 mg once a day.
- Severe renal failure:
7.5 mg once a day.
- Elderly
7.5 mg once a day for long term treatment.

- Children (Under 15 years of age): Not recommended.

The tablet should be swallowed with water, or another drink, during a meal.

Only for 7.5 mg tablet:

If you need to take two tablets they must be taken together as one single dose.

Do not exceed the recommended maximum dose of 15 mg a day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Avegesic Tablet for as long as your doctor recommends.

- If you forget to use it

If you forget to take Avegesic Tablet do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you take more Avegesic Tablet than you should, talk to your doctor or pharmacist immediately.

Symptoms are:

- Lethargy, drowsiness, nausea, vomiting and epigastric pain, which are generally reversible with supportive care.
- Gastrointestinal bleeding
- Severe poisoning may result in hypertension (high blood pressure), acute renal failure (acute kidney failure), hepatic dysfunction (liver disease), respiratory depression (hard to breath), coma (deep sleep), convulsions (uncontrolled shaking of the body), cardiovascular collapse (failure of circulation) and cardiac arrest (sudden stop in effective blood circulation due to the failure of the heart to contract effectively).
- Anaphylactoid reactions (Serious allergic reaction which causes difficulty in breathing or dizziness)

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.

- Tell all the doctors, dentists and pharmacists treating you that you are taking Avegesic Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.
- If you feel that the effect of Avegesic Tablet is too strong or too weak, talk to your doctor or pharmacist.
- If after several days you do not feel any improvement in your condition then you should talk to your doctor or pharmacist.

- Things you must not do

- Avegesic Tablet should not be given to children under 15 years of age.
- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Avegesic Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machinery

Visual disturbances, drowsiness, vertigo (dizziness) may occur with this product. If affected do not drive or operate machinery.

Side Effects

All medicines can cause side effects. Medicines such as Avegesic Tablet may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. The side effects described below have been experienced by people taking meloxicam and they are listed as common, uncommon or rare. If a side effect is listed as

- Common: It has been experienced by between 1 in 10 and 1 in 100 people.
- Uncommon: It has been experienced by between 1 in 100 and 1 in 1000 people.
- Rare: It has been experienced by between 1 in 1000 and 1 in 10000 people.

Side effects associated with the digestive system (stomach and intestines)

- Common: indigestion, feeling sick or being sick, abdominal pain, constipation, flatulence, diarrhoea.
- Uncommon: gastrointestinal bleeding (causing offensive, tar-coloured stools), ulcers of the stomach or intestines, inflammation or soreness of the mouth or the gullet.
- Rare: gastrointestinal perforation (a hole in the wall of the bowel), inflammation or soreness of the stomach or the colon.
- Ulcers of the stomach or intestines, gastrointestinal bleeding and gastrointestinal perforation can occur at any time and can sometimes be severe, especially in the elderly and very rarely have been fatal.
- If you have a history of gastrointestinal symptoms whilst taking anti-inflammatory drugs, your doctor may monitor your progress whilst on treatment.

Side effects associated with the skin

- Common: itching, rash
- Uncommon: urticaria (nettle rash)
- Rare: severe blistering of the skin or peeling, swelling around the eyes, lips and face, rashes caused by exposure to sunlight.

Side effects associated with the central nervous system

- Common: lightheadedness, headache.
- Uncommon: vertigo (dizziness), tinnitus (noises in the ear), drowsiness.
- Rare: confusion, mood disorders, insomnia (inability to sleep), nightmares.

If affected by any of these side effects do not drive or operate machinery.

Side effects associated with the eye

- Rare: visual disturbances, for example blurred vision

If affected by visual disturbances do not drive or operate machinery.

Side effects associated with the cardiovascular system

- Common: swelling caused by fluid retention, including swollen ankles/legs.
- Uncommon: palpitations, increase in blood pressure, hot flushes

Side effects associated with the blood

- Common: anaemia
- Uncommon: abnormality of white blood cell or platelet numbers.

Side effects associated with the immune system and with the respiratory system

- Rare: severe allergic reactions which may include fainting, shortness of breath and skin reactions. Asthma attacks (seen in people who are allergic to aspirin or other non-steroidal anti-inflammatory drugs).

If you suffer from an allergic reaction or asthma attack after taking Avegesic Tablet seek medical advice immediately.

Side effects associated with the liver

- Uncommon: changes in tests of liver function.
- Rare: inflammation of the liver (hepatitis).

Side effects associated with the kidney

- Uncommon: salt and water retention, increased potassium levels in the blood, changes in tests of kidney function.
- Rare: kidney failure.

If you experience any of these side effects and they persist or become troublesome, consult your doctor.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Avegesic Tablet**- Storage**

- Keep them out of the reach of the children.
- Do not store in temperature over 25°C. Keep it at its original pack. Protect it from light and humidity.

- Do not use it after its expiring date, recorded on the packaging.

- 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**

- Avegesic Tablet 7.5 mg is yellow, round, flat tablet.
- Avegesic Tablet 15 mg is yellow, round, concave tablet.

- Ingredients**- Active Ingredient**

- Meloxicam

- Inactive Ingredients

- Lactose
- Microcrystalline cellulose
- Talc
- Magnesium stearate
- Sodium starch glycolate

- MAL number(s)

- Avegesic Tablet 7.5mg: MAL10033144AC
- Avegesic Tablet 15mg: MAL10033143AC

Manufacturer:

Delorbis Pharmaceuticals Ltd.
17 Athinon Street, Ergates Industrial Area, 2643 Ergates, 2081 Lefkosia, Cyprus, European Union.

Product Registration Holder

Apex Pharmacy Marketing Sdn Bhd
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