

Package leaflet: Information for the user

MAHADOL® Tablet

Aceclofenac / Paracetamol 100 / 325 mg Tablet IP

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What MAHADOL® is and what it is used for

MAHADOL® contains Aceclofenac and Paracetamol.

Aceclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). They have anti-inflammatory and painkiller properties causing a lowering of swelling, redness (inflammation) and pain. It works by blocking the production of hormone-like substances called prostaglandins. Prostaglandins have many functions in the body including an important role in both the way the body responds to inflammation and also the reabsorption of calcium in some diseases of the bone.

Paracetamol belongs to a group of medicines called Analgesics and Antipyretic. It is used for the treatment of mild to moderate pain including headache, migraine, neuralgia (severe pain in nerves), toothache, period pains and the symptomatic relief of sprain, strain and rheumatic

pains. They also reduce temperature and used for the symptomatic relief of feverishness, feverish colds and influenza.

MAHADOL® is used to relieve pain and reduce redness and swelling (inflammation) in patients

suffering from:

- Arthritis of the joints (osteoarthritis). This commonly occurs in patients over the age of 50 and causes the loss of the cartilage and bone tissue next to the joint.
- Autoimmune disease that causes chronic inflammation of the joints (rheumatoid arthritis).
- Arthritis of the spine which can lead to the fusion of the vertebrae (ankylosing spondylitis).

2. What you need to know before you take MAHADOL®

Do not take MAHADOL®, if

- If you are allergic to aceclofenac, paracetamol, or any of the other ingredients of this medicine. If you are allergic to aspirin or any other NSAIDs (such as ibuprofen, naproxen or diclofenac).
- If you are taking any other medicines that contain Paracetamol.
- If you have taken aspirin or any other NSAIDs and experienced one of the following:
 - Asthma attack causing tightness in the chest wheezing and difficulty breathing.
 - Runny nose, itching and/or sneezing (irritation of the nose).
 - Raised red circular patchy rash on the skin which may have felt itchy or like a sting or burn.
 - A severe allergic reaction known as anaphylactic shock. The symptoms may be life threatening and include difficulty breathing, wheezing, abdominal pain and vomiting.
- If you have a history of, suffer from, or suspect that you have a stomach ulcer or have vomited blood or passed blood in your faeces (black tarry stools).
- If you have severe kidney disease.
- If you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages.
- If you have or have had problems with your blood circulation (peripheral arterial disease).

- If you suffer from, or suspect that you have severe liver failure.
- If you suffer from bleeding or any type of blood clotting disorders.
- If you are pregnant (unless your doctor considers it essential for you to continue to take this medicine)

MAHADOL® is not recommended for use in children.

Warnings and precautions

Before you start taking MAHADOL®, tell your doctor:

- If you suffer from any other form of kidney or liver disease.
- If you have any of the following disorders, as they may worsen:
 - Disorders of the stomach or gut/bowel
 - Inflammatory bowel disease (ulcerative colitis)
 - Chronic inflammatory bowel disease (Crohn's disease)
 - Ulceration, bleeding or perforation of the stomach or bowel
- If you have, or have ever had problems with the circulation of the blood to your brain.
- If you suffer from asthma or any other breathing problems.
- If you suffer from a rare inherited disorder known as porphyria.
- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or other raised body fats such as triglycerides
- If you suffer from an autoimmune condition known as systemic lupus erythematosus or other connective tissue disorders.
- If you are infected with chicken pox, the use of this medicine should be avoided because a rare serious infection of the skin may develop.
- If you are recovering from major surgery.
- If you are elderly (your doctor will prescribe you the lowest effective dose over the shortest duration).

Hypersensitivity reactions can occur and very rarely, very serious allergic reactions are appearing. The risk is higher in the first month of treatment. MAHADOL® should be stopped immediately at the first onset of symptoms such as tightness of the chest, breathing difficulties, fever, skin rashes, soreness of the skin lining the mouth and other mucous membranes causing ulcers, or any signs of hypersensitivity.

Medicines such as MAHADOL® may be associated with a small increased risk of heart attack ("myocardial infarction"). Any risk is more likely with high doses and prolonged treatment.

Do not exceed the recommended dose or duration of treatment.

Other medicines and MAHADOL®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Please tell your doctor if you are taking:

- Medicines used to treat mental health problems like depression (selective serotonin-reuptake inhibitors (SSRIs) such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline) or manic depression (lithium)
- Medicines used to treat heart failure and irregular heartbeats (cardiac glycosides such as digoxin)
- Medicines used to treat high blood pressure (antihypertensives: ACE inhibitors such as enalopril, lisinopril; angiotensin II receptor antagonists such as losartan, candesartan; also hydralazine, methyldopa, clonidine, moxonidine, propranolol)
- Medicines to treat infection (quinolone antibiotics such as ciprofloxacin, ofloxacin, levofloxacin moxifloxacin)
- Drugs used to increase the rate of urine excretion (diuretics such as thiazides, furosemide, amiloride hydrochloride)
- Medicines that stop blood clotting (anticoagulants) such as warfarin, heparin
- Medicines to control nausea and vomiting e.g. Metoclopramide or domperidone
- Medicines to control high lipid levels e.g. Colestyramine
- Methotrexate which is used to treat cancer and autoimmune disorders such as arthritis and skin conditions
- Chloramphenicol (an antibiotic): paracetamol may increase the levels of chloramphenicol in the blood.
- Mifepristone
- Any steroids for the treatment of swelling and inflammation (glucocorticoids such as hydrocortisone, prednisolone)
- Medicines used to suppress the immune system after organ transplant (ciclosporin or tacrolimus)
- Medicines used to treat HIV (zidovudine)
- Medicines used to lower blood sugar levels in diabetes (antidiabetics such as glibenclamide, glicazide, tolbutamide)
- Any other painkiller NSAID drugs (aspirin, ibuprofen, naproxen, COX-2 inhibitors such as celecoxib and etoricoxib)

- Antiplatelet drugs such as clopidogrel.

MAHADOL® with food and drink

MAHADOL® must be taken preferably with or after food

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should inform your doctor if you have problems becoming pregnant. NSAIDs may make it more difficult to become pregnant.

Do not take MAHADOL® if you are pregnant or think you are pregnant. The safety of this medicine for use during pregnancy is not known. It is not recommended for use in pregnancy unless considered essential by your doctor. (it must not be used during the last three months of

pregnancy).

MAHADOL® should not be used if you are breast-feeding. It is not known if this medicine passes into breast milk. It is not recommended for use during breast-feeding unless considered essential by your doctor.

Driving and using machines

If you are taking MAHADOL® and you experience dizziness, drowsiness, vertigo, tiredness or any difficulty with your eyesight, you must not drive or use machinery.

3. How to use MAHADOL®

Always take this medicine exactly as your doctor or pharmacist has told you. You will be prescribed the lowest effective dose over the shortest duration to reduce side effects. Check with your doctor or pharmacist if you are not sure.

The recommended dose in adults is 1 tablet twice a day. One tablet should be taken in the morning and one in the evening.

Children

MAHADOL® is not recommended for use in children under the age of 18.

Elderly

If you are elderly, you are more likely to experience serious side effects. If your doctor prescribes MAHADOL® for you, you will be given the medicine over the shortest duration of treatment.

Method and route of administration:

Tablets should be swallowed whole with a glass of water and should be taken with or after food.

Do not crush or chew the tablets.

Do not exceed the stated daily dose.

Continue to take your tablets for as long as your doctor recommends.

If you use more MAHADOL® than you should

If you accidentally take too many MAHADOL® Tablets, contact your doctor immediately or go to your nearest hospital casualty department. Please take this leaflet or the box the MAHADOL® Tablets came in, with you to the hospital so that they will know what you have taken.

If you forget to use MAHADOL®

If you miss a dose, do not worry, just take the next dose at the usual times. Do not take a double dose to make up for a forgotten dose.

If you stop using MAHADOL®

Do not stop having MAHADOL® until your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Aceclofenac

Stop taking the medicine and seek medical advice IMMEDIATELY, if you experience any of the following side effects,

- Severe allergic reaction (anaphylactic shock). Symptoms may develop quickly and can be life-threatening if not immediately treated and include fever, difficulty breathing, wheezing, abdominal pain, vomiting, swelling of the face and throat.
- Severe skin rashes such as Stevens-Johnnson Syndrome and Toxic Epidermal Necrolysis. These are potentially life-threatening and develop quickly forming large blisters and the skin to peel away. The rash can also appear in the mouth, throat or eyes. Fever, headache and aching of the joints usually occur at the same time.
- Meningitis. The symptoms include high fever, headache, vomiting, blotchy red rashes, neck stiffness, sensitivity and intolerance to light.
- Passing blood in your faeces (stools/motions).
- Passing black tarry stools. Vomit any blood or dark particles that look like coffee grounds.
- Kidney failure.

Stop taking the medicine and seek medical advice if you experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
- Blood disorders such as reduced production of blood cells, abnormal breakdown of red blood cells known as haemolytic anaemia, low content of iron in the blood, low level of white blood cells, low number of platelet cells, increased blood potassium levels which can irritate the blood vessels causing inflammation known as vasculitis. These disorders can cause you to feel extremely tired, breathless, aching of the joints and be prone to repeated infections and bruising.

If any of the below side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common (may affect up to 1 in 10 people)

- Dizziness
- Nausea (feeling sick)
- Diarrhoea
- Increased liver enzymes in the blood

Uncommon (may affect up to 1 in 100 people)

- Wind
- Inflammation or irritation of the lining of the stomach
- Constipation
- Vomiting
- Mouth ulcers
- Itching
- Rash
- Inflammation of the skin
- Raised circular red itchy, stinging or burning patches on the skin (hives)
- Increase in blood urea levels
- Increase in blood creatinine levels

Rare (may affect up to 1 in 1,000 people)

- Hypersensitivity (allergic reaction)
- Problems with eyesight
- Heart failure
- High blood pressure shortness of breath
- Bleeding from the stomach or bowel

- Stomach or bowel ulceration

Very Rare (may affect up to 1 in 10,000 people)

- Depression
- Strange dreams
- Inability to sleep
- Tingling, pricking or numbness of skin
- Uncontrollable shaking
- Drowsiness
- Headaches
- Abnormal taste in the mouth
- Sensation of spinning when standing still
- Ringing in the ears
- Heart pounding or racing hot flushes
- Difficulty breathing
- High pitched noise when breathing
- Inflammation of the mouth
- Perforation of either the stomach, large intestine or bowel wall
- Worsening of colitis and Crohn's disease
- Inflammation of the pancreas injury of the liver (including hepatitis)
- Yellowing of the skin (jaundice)
- Spontaneous bleeding into the skin (appears as a rash)
- Nephrotic syndrome: a condition which indicates kidney damage and includes large amounts of protein in the urine, low blood albumin levels, high blood cholesterol levels and swelling of the legs, feet or ankles
- Water retention and swelling
- Tiredness
- Leg cramps
- Increased blood alkaline phosphatase levels
- Weight gain

Other side effects that have been reported with this type of drug (NSAIDs) are

- Hallucinations
- Confusion
- Blurred, partial or complete loss of vision

- Painful movement of the eye
- Worsening of asthma
- Skin reaction to sunlight
- Inflammation of the kidneys
- Generally feeling unwell

Serious skin infections may occur in association with chickenpox

Paracetamol

Severe allergic reactions include

- Difficulty in breathing
- Skin rash and itching
- Swelling of the face and throat
- Runny nose

Rare cases of serious skin reactions have been reported with symptoms like skin reddening, blisters or rash.

Other possible side effects

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist:

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.
- Nausea, sudden weight loss, loss of appetite, abdominal pain and swelling, dark colored urine or stools and yellowing of skin and eyes.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top right end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

5. How to store MAHADOL®

Keep this medicine out of the sight and reach of children

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

MAHADOL®

Each film coated tablet contains:

Aceclofenac IP 100mg

Paracetamol IP 325 mg

Excipients q.s.

Colour: Titanium Di Oxide IP.

Marketing Authorisation Holder

Manufacturer