

MILLISPIRIN

Acetyl Salicylic Acid Soluble Tablet 300 mg (Aspirin)

Aspirin (300mg)

WHAT IS IN THE LEAFLET?

1. What MILLISPIRIN is used for
2. How MILLISPIRIN works
3. Before you use MILLISPIRIN
4. How to use MILLISPIRIN
5. While you are using it
6. Side effects
7. Store and Disposal of MILLISPIRIN
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of Revision

1. WHAT MILLISPIRIN IS USED FOR

MILLISPIRIN can be used for:

- Relief of mild to moderate pain such as joint pain, period pain, muscle pain, nerve pain and headache
- Reduce or relief of inflammation
- Relief of fever

Under advice by a doctor, MILLISPIRIN can also be used to prevent blood clots especially after a heart attack or in patients with unstable angina (chest pain) or reduced blood flow in the brain.

2. HOW MILLISPIRIN WORKS

Aspirin belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDS) which have analgesic (pain relieving), anti-inflammatory (inflammation reducing) and antipyretic (temperature reducing) properties.

Aspirin can also be used to reduce the chances of blood clots and help to prevent blocking of blood vessel which can lead to events such as stroke, heart attack or death.

3. BEFORE YOU USE

MILLISPIRIN

When you must not use it

Do not use MILLISPIRIN if you:

- Are allergic (hypersensitive) to aspirin, salicylates or NSAIDs or other ingredients in the product
- Are prone to indigestion or known to have a stomach or small intestine ulcer
- Have severe kidney, heart or liver problem
- Are receiving anticoagulant (medicine used to prevent blood clot)
- Are a patient with haemophilia or other bleeding disorders
- Are a patient with gout

Pregnancy and breast-feeding

Do not use MILLISPIRIN if you are pregnant or trying for a baby unless directed by your doctor. MILLISPIRIN can prolong labour and affect blood clotting in the mother or baby.

If you are breastfeeding, you should not take MILLISPIRIN because it passes into the breast milk and could harm your baby.

Use in children under 16 years of age

There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome typically occurs after a viral

infection such as chickenpox or influenza.

For this reason aspirin should not be given to children under 16 years, unless on the advice of a doctor.

Using aspirin to stop blood clotting

The optimal dose to stop blood clotting in humans is not known. Hence, do not use aspirin for indications related to

stop blood clotting unless directed by a doctor.

If you are not sure whether you should start taking this medicine, consult your doctor.

Before you start to use it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- You are planning to have an operation (including dental surgery) in the next two weeks. Your doctor will decide whether or not you need to stop MILLISPIRIN prior to surgery.
- If you have or have had any medical conditions, especially the following:
 - bleeding disorders or blood clotting problems
 - any illness or disability that was caused by bleeding, for example impaired sight or vision because of bleeding within the eye
 - recent serious injury
 - recent surgery (including dental surgery)
 - any form of liver disease
 - any recent history of stroke
 - any form of kidney disease
 - history of stomach ulcers or other problems with your digestive system
 - inherited diseases causing galactose intolerance
 - gout
 - asthma or allergies

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking MILLISPIRIN.

Taking other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and MILLISPIRIN may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Warfarin and heparin -medicines used to prevent blood clot.
- Acetazolamide - can lead to high serum concentrations of acetazolamide (and toxicity).
- Phenytoin and valproic acid, (for treatment of epilepsy) .Aspirin can cause decrease in the total concentration of phenytoin and an increase in valproic acid levels.
- Methotrexate which can cause bone marrow toxicity, especially in the elderly or renal impaired.
- Drugs for treatment of diabetes – aspirin may increase effect of low blood sugar.
- The concurrent use of aspirin with other NSAIDs should be avoided because this may increase bleeding or lead to decreased renal function

4. HOW TO USE MILLISPIRIN

MILLISPIRIN can be used for:

- Relief of mild to moderate pain such as joint pain, period pain, muscle pain, nerve pain and headache
- Reduce or relief of inflammation
- Relief of fever

Under advice by a doctor, MILLISPIRIN can also be used to prevent blood clots especially after a heart attack or in patients with unstable angina (chest pain) or reduced blood flow in the brain.

How much to use

The dose given by your doctor may differ from this leaflet.

The recommended dose for adults and elderly:

Adults

For mild to moderate pain i.e., headache, muscle pain, joint pain and fever. 300 - 900 mg (1 to 3 tablets) every 4 to 8 hours. Up to a maximum of 12 tablets daily (per 24 hours).

For coronary bypass, transluminal angioplasty, strokes, transient ischaemic attack, unstable angina. 150 (1/2 tablet) to be taken every day, preferably at the same time each day.

The advice of a doctor should be sought before commencing therapy for the first time. In some circumstances a higher dose may be appropriate, and up to 300 mg a day may be used on the advice of a doctor.

Elderly

In general, aspirin should be used with caution in elderly patients who are more prone to adverse events. The usual adult dose is recommended in the absence of severe renal or hepatic insufficiency. Treatment should be reviewed at regular intervals.

When to use it

Take MILLISPIRIN at about the same time each day. Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take it.

Taking with or without food

MILLISPIRIN may be taken with or without food. If stomach upset occurs, take with or after food to reduce stomach irritation.

How long to use it

Continue to take your medicines as long as your doctor tells you.

Do not use MILLISPIRIN continuously for more than 10 days for pain or more than 3 days for fever without consulting a doctor.

If you forget to use it

Take MILLISPIRIN as soon as you remember if you forget to take it. However, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed.

If you use too much (overdose)

If you (or someone else) accidentally take too many tablets, talk to your doctor or pharmacist immediately. Show this leaflet or any packaging to your doctor to alert what you have taken.

Symptoms of an overdose include:-

- Mild to moderate toxicity (overdose)
 - dizziness,
 - tinnitus (ringing in your ears),
 - deafness,
 - sweating,
 - nausea and vomiting,
 - headache and
 - mental confusion
- Severe toxicity (overdose)
 - hyperventilation,
 - fever,
 - restlessness,
 - ketosis
 - respiratory alkalosis
 - metabolic acidosis
 - Depression of the central nervous system may lead to coma; cardiovascular collapse and respiratory failure may occur.

5. WHILE YOU ARE USING IT

Things you must do

If you become pregnant while taking MILLISPIRIN tell your doctor immediately.

If you are about to start taking any new medicine tell your doctor and

pharmacist that you are taking MILLISPIRIN.

Tell all of the doctors, dentists, and pharmacists that are treating that you are taking/using MILLISPIRIN.

If you are going to have surgery, tell your doctor you are taking MILLISPIRIN.

Things you must not do

Do not give MILLISPIRIN to anyone else, even if they have the same condition as you.

Do not take MILLISPIRIN to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how MILLISPIRIN affects you.

MILLISPIRIN may cause dizziness or light-headedness in some people. Make sure you know how you react to MILLISPIRIN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or lightheaded.

If this occurs, do not drive. If you drink alcohol, dizziness or lightheadedness may be worse.

6. SIDE EFFECTS

Like all medicines, MILLISPIRIN can cause side-effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects and they worry you:

- **Central Nervous System:** Agitation, accumulation of water in the brain, coma, confusion, dizziness, headache, bleeding in the brain, tiredness and fits.
- **Cardiovascular:** Irregular heartbeat (Dysrhythmia), low blood

pressure, fast heart rate (tachycardia).

- **Fluid and Electrolyte:** Dehydration, high calcium in the blood, too much acid in the body fluid (metabolic acidosis), low level of carbon dioxide in the blood (respiratory alkalosis).
- **Gastrointestinal:** Indigestion, GI bleeding, ulceration and perforation, nausea, vomiting, transient increase in liver enzymes, hepatitis, Reye's syndrome, (acute brain damage and liver function problems), inflammation of the pancreas.
- **Respiratory:** Deep breathing (Hyperpnea), pulmonary edema, rapid breathing (tachypnea).
- **Urogenital:** kidney problem and disorder (Interstitial nephritis and papillary necrosis), high protein in the urine, problems and damage to the kidney..
- **Hematologic:** Prolongation of clotting, clotting and bleeding disorder (coagulopathy) and decrease in blood platelets (thrombocytopenia).
- **Hypersensitivity:** Acute anaphylaxis, swelling of the epidermis and larynx (angioedema and laryngeal edema), asthma, bronchospasm, rashes of the skin.
- **Musculoskeletal:** Damaged skeletal muscle tissue (Rhabdomyolysis).
- **Metabolism:** low blood sugar (in children), high blood sugar.
- **Reproductive:** Prolonged pregnancy and labor, stillbirths, lower birth weight infants, bleeding before or after delivery.
- **Special Senses:** Hearing loss, ringing in the ear.

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of side effects. Most people do not experience any of them.

Compulsory statement:

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. STORAGE AND DISPOSAL OF MILLISPIRIN

Store below 30°C.

Protect from light and moisture.

Do not store MILLISPIRIN or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach and sight of children.

Disposal

Do not use MILLISPIRIN after the expiry date which is stated on the carton and blister.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

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

8. PRODUCT DESCRIPTION

What it looks like

MILLISPIRIN: White circular biconvex uncoated tablets with break line.

Packing

Tablets are packed in Alu-Alu blister Pack. Each strip contains 10 tablets.

Ingredients

Each tablet contains aspirin (acetyl salicylic acid) 300 mg.

The other ingredients are:

Colloidal anhydrous silica, sodium lauryl sulphate, purified talcum, stearic acid and maize starch.

Registration Number

MAL13115223XZ

9. MANUFACTURER**Manufactured by:**

KCK Pharmaceutical Industries Sdn. Bhd.

Plot 61, Bayan Lepas Industrial Park
Phase 4, Lintang Bayan Lepas 1, 11900
Bayan Lepas, Pulau Pinang, Malaysia.

**10. PRODUCT REGISTRATION
HOLDER****Product Registration Holder:**

UNIMED SDN BHD

53, Jalan Tembaga SD 5/2B, Bandar
Sri Damansara, 52200 Kuala Lumpur,
Malaysia.

11. DATE OF REVISION

10th November 2022

12. SERIAL NUMBER

NPRA(R2/1)221110/974