

AETOS IBUPROFEN FILM COATED TABLET

400 MG

Ibuprofen (400 mg)

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What Aetos Ibuprofen Film Coated Tablet is used for

To relief pain such as:

- Headache
- Dental pain
- Period pain
- Rheumatic pain (inflammation)
- Muscular pain
- backache

Also to relief fever such as fever associated with cold and flu.

It also relieves inflammation of muscles and joints in rheumatic disease including juvenile arthritis and other muscular skeletal disorder.

How Aetos Ibuprofen Film Coated Tablet works

This medicine belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

NSAIDs stop the production of chemicals called prostaglandins. These chemicals are released in your body in response to illness and injury. In humans, ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

Before you use Aetos Ibuprofen Film Coated Tablet

- When you must not use it

Do not take this medicine if:

- you are allergic to Ibuprofen or any of the other ingredients of this product.
- you are allergic to aspirin or any other NSAIDs medicine
- you are pregnant, or intend to become pregnant.
- you have a peptic ulcer (stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.
- you have severe heart failure
- you have severe liver failure
- you have severe kidney disease

- Before you start to use it

Tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives.
- you are pregnant or plan to become pregnant
- you are breastfeeding or wish to breastfeed
- you plan to have surgery
- you have the following medical condition:
 - heart disease or high blood pressure
 - severe skin reactions such as Stevens-Johnson syndrome
 - asthma
 - vision problems
 - liver or kidney disease
 - tendency to bleed or other blood problems
 - bowel or intestinal problems such as ulcerative colitis
 - heart failure
 - swelling of ankles or feet
 - diarrhea
- you currently have an infection

- Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.

This medicine should not be taken together with the following:

- Acetylsalicylic acid (aspirin – pain killer medicine)
- Other NSAIDs including cyclooxygenase -2-selective inhibitors

This medicine should be used with caution in combination of the following:

- Anticoagulant such as warfarin (medicine to treat blood clot)
- Antihypertensive and diuretics (medicine to treat hypertension)
- Corticosteroid (allergic medicines)
- Anti-platelet agents and SSRI (medicine to treat myocardial infarction and depression)
- Cardiac glycosides (medicine to treat heart condition)
- Lithium which is used to treat anti-psychotic disorder
- Cyclosporine
- Mifepristone
- Tacrolimus
- Zidovudine
- Quinolone antibiotics

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

Do not use this medicine if any of the above conditions apply to you. If you are not sure, get advice from your doctor pharmacist.

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How to use Aetos Ibuprofen Film Coated Tablet

- How much to use

Your doctor will determine the amount of medicine you should take based on the severity of your condition. Take this medicine in the dose prescribed by your doctor.

Adults and children over 12 years:
Initial dose 1 tablet, then if necessary, 1 tablet every 4 hours.

Swallow the tablet(s) with a full glass of water.

- When to use it

To be taken during or immediately after a meal. This will lessen the chance of a stomach upset.

- How long to use it

You are advised to take it as long as your doctor tells you to.

- If you forget to use it

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

If you forget to take your dose, take it as soon as you remember. Skip the missed dose if it is almost time for your next dose.

- If you use too much (overdose)

Contact your doctor immediately as soon as you realise you have taken too much.

Overdose symptoms may include:

- Nausea
- Vomiting
- Discomfort below ribs
- Diarrhea

Noise or ringing in ear, headache and gastrointestinal (stomach) bleeding are also possible.

In more serious poisoning, the following symptoms may occur:

- Drowsiness
- Dizziness
- Excitation of muscle
- Nystagmus (involuntary eye movement)
- Disorientation or coma
- Convulsions
- Fainting
- Hypothermia (heat lost from body)
- Apnoea (breathing stop)
- Respiratory or CNS depression such as hypotension (low blood pressure), bradycardia (low heart rate) or tachycardia (high heart rate)

In serious poisoning metabolic acidosis may occur.

Exacerbation of asthma is possible in asthmatics.

While you are using Aetos Ibuprofen Film Coated Tablet

- Things you must do

- Tell your doctor immediately if you become pregnant.
- If you are going to have surgery, make sure the surgeon and anaesthetist know you are taking Ibuprofen Tablet.
- Tell your doctor if you get an infection while using Ibuprofen Tablet.
- Tell your doctor if you get any visual disturbances such as blurred vision.
- Before starting any new medicine, tell your doctor or pharmacist that you are taking Ibuprofen tablet.

- Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not take any other medicines to relieve pain and reduce inflammation while you are taking

Ibuprofen Tablet without first telling your doctor. This includes:

- Aspirin (also called acetylsalicylic acid)
- Other medicine containing ibuprofen
- any other NSAID medicine
- Take your medicine to treat any other complaints unless you are told by your doctor or pharmacist.
- Stop taking the medicine or change the dosage on your own before asking your doctor.

- Things to be careful of

Drinking alcohol will make it worse. Watch your intake.

Be careful while driving or operating machinery as Ibuprofen Tablet may cause dizziness and affect your eyesight.

Side effects

All medicines can cause unwanted side effects. These effects can be serious but most of the time, they are mild and temporary.

Tell your doctor if you notice any of the following and they worry you:

- Gastrointestinal bleeding
- Peptic ulceration
- Abdominal or stomach cramp
- Pain or discomfort
- Heartburn or indigestion
- Nausea
- Diarrhea
- Constipation
- Decreased or Loss of appetite
- Skin rash

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- Headache
- Dizziness
- Nervousness
- Pruritus (skin itchiness)
- Tinnitus (ringing in ear)
- Depression
- Oedema (water retention in body)

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- Drowsiness
- Insomnia (difficulty in sleeping)
- Eye problems such as blurred vision, sore red eyes, itching
- Anxious or worrying
- Hypersensitivity reactions
- Abnormalities of liver function test
- Impairment of renal function

These may be serious side effects of Ibuprofen 400mg Tablet. You may need urgent medical attention. Serious side effects are rare.

Be careful when operating machines or driving while taking ibuprofen, as there is increase in reaction time.

Other unwanted side effects not listed may occur. Tell your doctor immediately.

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)]

Storage and Disposal of Aetos Ibuprofen Film Coated Tablet

- Storage

Keep out of reach of children. Protect from light and moisture.

Store Aetos Ibuprofen Film Coated Tablet below 30°C. Protect from light and moisture.

- Disposal

Medicines should not be disposed of via waste water 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

Round, 13.0mm in diameter, pink coated tablet with shallow convex faces, bevel-edged and “HD” embossed on one face.

- Ingredients

Active ingredients

Each tablet contains Ibuprofen 400 mg.

Inactive ingredients

Ponceau 4R Lake
Titanium Dioxide
Propylene Glycol
Talc
Colloidal Silicon Dioxide
Crosscarmellose Sodium
Hydroxypropyl Methylcellulose
Isopropyl Alcohol
Magnesium Stearate

- MAL Number:

MALXXXXXXXXXA

- Pack size:

Blister of 10 x 10 film coated tablets

Manufacturer

HOVID Berhad
Lot 56442, 71/2 Miles, Jalan Ipoh /
Chemor, 31200 Chemor, Perak,
Malaysia.

Product Registration Holder

Abiotide Sdn. Bhd.
121, Jalan Tunku Abdul Rahman,
30010 Ipoh, Perak, Malaysia.

Date of revision

25/05/2022

Serial number

NPRA (R2) 22/014