INFLAFEN TABLETS

Ibuprofen (200mg)

What is in this leaflet

- 1. What Inflafen Tablets is used for
- 2. How Inflafen Tablets works
- 3. Before you use Inflafen Tablets
- 4. How to use Inflafen Tablets
- While you are using Inflafen Tablets
- 6. Side effects
- 7. Storage and Disposal of Inflafen Tablets
- 8. Product description
- 9. Manufacturer and Product Registration holder
- 10. Date of Revision

What Inflafen Tablets is used for

Ibuprofen is the active ingredient of Inflafen Tablets.

is Ibuprofen used in the management of mild to moderate conditions such pain in as menstrual cramps, migraine, postoperative pain, osteoarthritis (degenerative joint disease), rheumatoid arthritis (systemic inflammatory disorder that affects ankylosing spondylitis joints), (chronic inflammatory disease of skeleton), and in other musculoskeletal and joint disorders such as sprain and strain.

How Inflafen Tablets works

Ibuprofen is a non-steroidal antiinflammatory drug (NSAID). It works by reducing hormone-like substance called prostaglandin that cause inflammation and pain in the body. It helps the human body reduce a fever, decrease pain and decrease inflammation.

Before you use Inflafen Tablets

- When you must not use it
 - If you have known hypersensitivity to ibuprofen or any other ingredients of Inflafen Tablets.

- If you have sensitivity to aspirin or other NSAID drugs i.e. in patients who develop bronchospasm (an abnormal contraction of the smooth muscle of the bronchi), angiodema (swelling below surface of the skin), nasal polyps (growths in the nose) or urticaria (hives) with those medicines or with history a bronchial asthma.
- If you have active gastrointestinal bleeding or in the presence of peptic ulceration (stomach ulcer).
- If you are pregnant or a nursing mother.
- Before you start to use it
 You must tell your doctor if:
 - You have bleeding disorder.
 - You have heart disease or stroke.
 - You have kidney or liver disease.
 - You have or have had ulceration, bleeding and perforation of the stomach and intestinal.
 - You are receiving any blood thinning agent such as coumarin anticoagulant.
 - You have vision problem.
 - You have allergies to any medicine which you have taken previously to treat your current condition.
 - You are pregnant, trying to get pregnant or think you may be pregnant.
 - You are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of these medicines:

- ACE inhibitors, medicines for high blood pressure.
- Cyclosporin, medicine used for organ transplant.
- Lithium, medicine for depression.
- Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancers.
- 4-Quinolone antibacterial, medicines for infection.
- Sulphonylureas, medicines for diabetes.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

How to use Inflafen Tablets

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

- How much to use

Adults: 1.2-1.8g daily in divided dose.

Maintenance dose: 0.6-1.2g daily

If you have kidney problem, your doctor might prescribes a lower dose for you.

Ibuprofen should not be used as self medication in children younger than 12 years old unless advise by your doctor.

When to use it
Use as directed by your doctor or pharmacist.

Inflafen Tablets may be taken with food or milk to reduce stomach and intestinal disturbances.

How long to use it Continue Inflafen taking Tablets for as long as your doctor recommends.

If you forget to use it

- If you forget a dose, take it as soon as remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.
- If you use too much (overdose) Contact vour doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause drowsiness, nystagmus rapid involuntary (a movement of the eyeballs), breathing), apnea (stop cyanosis (blue skin due to lack of oxygen in blood) and response to painful only stimuli.

While you are using it

Things you must do Contact your doctor if your symptoms does not improve.

> If you do become pregnant whilst taking Inflafen Tablets, tell your doctor.

Things you must not do

Do not give Inflafen Tablets to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Inflafen Tablets for you and your condition.

Things to be careful of

Be careful driving or operating machinery until you know how Inflafen Tablets affects

Side effects

Like all medicines. Inflafen Tablets can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Most frequent: Upset stomach.
- Others: headache, dizziness, nervousness, mild itching or rash, hearing changes (such as ringing in the ears), swelling the ankle/feet/hands, of depression, drowsiness, insomnia and blurred vision and other ocular reactions.
- Hypersensitivity reactions, abnormalities of liver function test, impairment of renal function, agranulocytosis (decrease of white blood cell) and thrombocytopenia (low blood platelet count) have occasionally been observed.
- of Stomach Risk and Intestinal Ulceration, Bleeding and Perforation with NSAID.

Serious stomach and intestinal toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet.

please tell doctor your orpharmacist.

Consult your doctor or pharmacist if you are in doubt or for any further information.

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

(Consumers→Reporting)

Storage and Disposal of Inflafen Tablets

Storage

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not store above 30°C. Protect from heat and moisture.

Keep out of the reach and sight of children.

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

The tablets are a white, scored, convex of diameter 9mm round tablet with 'MPI' marking.

Ingredients

Active ingredient - Each tablet contains 200mg of Ibuprofen.

- Inactive ingredient The other ingredients are microcrystalline cellulose pH101, potato starch, sodium starch glycolate, stearic acid powder, colloidal silicone dioxide and talc.
- <u>MAL number:</u> MAL19900497AZ

Manufacturer and Product Registration Holder

Malaysian Pharmaceutical Industries Sdn. Bhd. Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Penang, Malaysia.

Date of Revision

30/10/2015

Serial Number: BPFK(R4/1)211015/00380