BIFEN SUSPENSION

Ibuprofen (100mg/5ml)

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What Bifen Suspension is used for

It can be used for:

- Children: Symptomatic relief of pain and fever associated with colds, influenza, toothache, bronchitis (inflammation of the airway) and other bacterial and viral infections.
- Adults: Management of mild to moderate pain in conditions such as dysmenorrhoea (period pain), migraine, after operation pain, ankylosing spondylitis (chronic inflammatory disease of the skeleton), osteoarthritis (degenerative joint disease), and rheumatoid arthritis (systemic inflammatory disorder that affects joints) and in other musculoskeletal and ioint disorders.

How Bifen Suspension works

This medicine contains Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which act to relieve pain, swelling (inflammation) and reduce fever.

Before you use Bifen Suspension

- When you must not take it

Do not take Bifen Suspension if:

- -If you have active stomach and intestinal bleeding.
- -If you have had asthma, rhinitis (Inflammation of the nasal mucous membrane), urticaria

(itching or hives) or the symptoms become worsen caused by Aspirin or NSAIDs.

-If you are allergic to ibuprofen or any other ingredients in the product, aspirin or other nonsteroidal anti-inflammatory medicines

- Before you start to take it

Always take Bifen Suspension exactly as your doctor or Pharmacist has told you. You should check with your doctor or pharmacist if:

- you are allergic to any other medicines
- you are allergic to any other orally consumed substances
- -you have bleeding disorder -you have heart problem or
- stroke -you have kidney or liver
- problem
 -you are receiving coumarin
- -you are receiving coumarin anticoagulants (blood thinning agent)
- -you have vision problem
- -you have collagen disease
- -you have or have had ulceration, bleeding and perforation of the stomach or intestinal.

Ibuprofen may cause severe skin reactions. 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.

Please consult your doctor before start to use Bifen suspension if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Bifen suspension against the benefits they expect it will have for you.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Bifen Suspension may increase or decrease the effect of some drugs. These include:

- Lithium (for bipolar disorder)
- Methotrexate (for cancer, psoriasis or rheumatism)
- Medicines to thin the blood (e.g. warfarin)
- Water tablets (diuretics, beta blockers), medicines to treat high blood pressure, medicines for heart problems
- Phenytoin (to treat seizures)
- Sulphonylureas, a class of antidiabetic drugs

How to use Bifen Suspension

- How much to use

Shake well before administration.

<u>Children:</u> 1 ml/kg body weight daily given in divided doses.

- 6 months to 1 year as per above guide.
- 1 5 years old, 5 ml 3 times a day or 1 ml/kg body weight daily in divided doses.
- 5 12 years old, 10 ml 3 times a day or 1 ml/kg body weight daily in divided doses.
- Up to 2 ml/kg body weight daily in divided doses may be given in cases of juvenile rheumatoid arthritis.

Adults:

20ml, 4 to 6 hourly (maximum 120 ml a day)

- When to use it

Read the label on the carton or follow what your doctor has told you.

- How long to use it

Take Bifen Suspension for as long as your doctor recommends. If the symptom still persists or not lighten after a few days, please consult your doctor.

- If you forget to use it

If you forget to take Bifen Suspension take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you take more Bifen Suspension than you should, tell a doctor or go to a hospital straight away.

Depression of the center nervous system and respiration may occur.

Take the medicine pack with you. This is so the doctor knows what you have taken.

While you are using it

- Things you must do

Tell your doctors who are treating you that you are taking Bifen Suspension.

If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking Bifen Suspension.

Talk to your pharmacist or doctor if your symptoms do not improve.

- Things you must not do

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

Do not take Bifen Suspension to treat any other complaints unless your pharmacist or doctor tells you to.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

- Things to be careful of

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

Side Effects

Like all medicines, Bifen Suspension may cause side effects, although not everybody gets them.

Consult doctor or pharmacist for further information if you notice any of the following and they worry you:

- -stomach and intestinal disturbances, stomach ulceration, stomach and intestinal bleeding.
- -headache
- -dizziness or drowsiness
- -insomnia
- -skin rashes
- -blurred vision
- -ringing in the ears

- -kidney problems
- -edema
- -thrombocytopenia (low platelet count in blood)
- -nervousness, pruritus, depression, hypersensitivity

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 Bifen Suspension

- Storage

Keep all medicines out of the reach of children. Store below 25°C.

- Disposal

Do not take this medicine after the expiry date stamped on the pack/bottle.

Return any unused suspension to your pharmacist to be disposed of. Only keep the suspension if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

Product Description

- What it looks like

Orange suspension with orange flavor and sweet taste.

-Ingredients

Active Ingredient

Each 5ml contains Ibuprofen BP 100mg.

Inactive ingredients

Citric acid monohydrate, Sugar granulated, Sodium benzoate, Sodium saccharin, Glycerin, Xanthan gum, Tween 80, Tuttifrutti flavor 74805-71, orange flavor 78970-51, Sunset yellow No 6 aluminium lake 38-42%, Purified water.

- MAL Number MAL19990569AZ

Manufacturer

Drug Houses of Australia Pte. Ltd.

#09-01/02 Haw Par Tiger Balm Building,

No. 2, Chia Ping Road, Singapore 619968

Product Registration Holder

Actavis Sdn Bhd

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