

IBUGESIC

Ibuprofen tablets 200mg

What is in this leaflet

Please read this leaflet carefully before you start using IBUGESIC.

This leaflet answers some common questions about IBUGESIC. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using IBUGESIC against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What IBUGESIC is used for

IBUGESIC is used to treat:

- Headaches
- Migraines
- Pain and swelling associated with arthritis
- Muscular pain
- Pain and swelling associated with sprains and strains
- Backache
- Period pain
- Dental pain
- Neuralgia
- Fevers
- Cold and flu symptoms
- Sinus pain

IBUGESIC is a non-steroidal anti-inflammatory drug (NSAID) that is thought to prevent the synthesis of prostaglandins, which are responsible for inflammation, fever and inflammatory-related pain.

Your doctor may have prescribed IBUGESIC for another reason. Ask your doctor if you have any questions about why IBUGESIC has been prescribed for you.

IBUPROFEN is not for use in children aged younger than 6 years or if you are over 65 years of age unless on doctor's advice.

Before you use IBUGESIC

When you must not use IBUGESIC

Do not use IBUGESIC if you:

- are allergic (hypersensitive) to ibuprofen, aspirin or other NSAIDs (including getting asthma, a runny nose or itching when you have previously had aspirin or an NSAID)
- are allergic (hypersensitive) to any other ingredient in the tablet (listed at the end of this leaflet)
- had bleeding in your stomach or perforation of your stomach when you previously used an NSAID (you may vomited up blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- have Crohn's disease, recurrent stomach or duodenal ulcers or recurrent bleeding from your intestine
- have an increased tendency to bleeding
- have severe heart failure
- have severe liver failure
- have severe renal failure
- are in the last three months of pregnancy

If you are not sure whether you should start using IBUGESIC, talk to your doctor or pharmacist.

Before you start to use IBUGESIC

Tell your doctor or pharmacist if you:

- are pregnant, trying to get pregnant or breastfeeding
- are aged older than 65 years
- have asthma
- have systemic lupus erythematosus
- have heart, liver or kidney problems
- have high blood pressure
- have fluid accumulation in your feet or hands
- have had a stroke
- have diabetes, high cholesterol or smoke
- have ever had an allergic reaction to another medicines, foods, preservatives or dyes.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using IBUGESIC.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking IBUGESIC.

Some medicines may interfere with IBUGESIC. These include:

- Aspirin
- Other pain killers (including other NSAIDs or coxibs)
- Medicines to control blood pressure or heart problems, including ACE inhibitors, beta-blockers, diuretics, frusemide or digoxin
- Lithium, a drug used to treat mental health disorders
- Blood thinning drugs (such as warfarin) or drugs used to prevent blood clotting
- Selective serotonin reuptake inhibitors, drugs used to treat depression and other mental health disorders
- Steroids
- Cholestyramine, a drug used to lower cholesterol
- Ginko biloba, a herbal preparation
- Cyclosporin or tacrolimus, drugs used to suppress the immune system (given after transplant surgery or to treat arthritis or psoriasis)
- Mifepristone, a drug used to induce miscarriage or abortion
- Quinolone antibiotics
- Sulphonylureas, drugs used to manage diabetes
- Zidovudine, a drug used to manage HIV
- Methotrexate
- Drugs used to treat fungal infections, such as voriconazole or fluconazole.

These medicines may be affected by IBUGESIC, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking IBUGESIC.

Pregnancy and breast-feeding

IBUGESIC should not be used if you are pregnant, planning to become pregnant or breast-feeding, unless you are advised to do so by your doctor. IBUGESIC should not be used at all during the last three months of pregnancy.

How to use IBUGESIC

How much IBUGESIC to take and how to take it

Adults and children aged 12 years or older: 2 tablets then 1 or 2 tablets every 4 to 6 hours, as necessary. Do not take more than 6 tablets in 24 hours.

Children aged 6 to 12 years: 1 tablet every 6 to 8 hours, as necessary. Do not take more than 3 tablets in 24 hours.

Take the lowest amount for the shortest possible time to relieve your symptoms.

Swallow IBUGESIC with a glass of water. Do not crush, chew or suck the tablets.

How long to take IBUGESIC

Do not take IBUGESIC for more than a few days at a time, except on your doctor's advice.

While you are using IBUGESIC

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking IBUGESIC.

Contact your doctor immediately if you become pregnant while taking IBUGESIC.

Tell any doctors, dentists or pharmacists treating you that you are taking IBUGESIC.

Tell your doctor or pharmacist if your symptoms do not improve. Your doctor or pharmacist will assess your condition and advise you as to whether you should continue using IBUGESIC.

Things you must not do

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

Do not start taking any other medicines, including medicines obtained without a prescription or herbal medicines, without first talking to your doctor or pharmacist.

Things to be careful of

Take care when driving or using machines until you know how IBUGESIC affects you. If you do experience a delayed reaction time while taking IBUGESIC, you should not drive or operate machinery.

In case of overdose

If you take too much IBUGESIC (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much IBUGESIC.

Do this even if there are no signs of discomfort or poisoning.

Signs and symptoms of an overdose may include:

- Nausea or vomiting
 - Stomach pain
 - Dizziness
 - Seizures
 - Loss of consciousness
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Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using IBUGESIC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

If you experience any of the following side effects while taking IBUGESIC, seek immediate medical attention:

- Itching, rash or reddened skin
- Swelling of the mouth or tongue
- Shortness of breath or wheezing
- Sudden or severe skin reaction or rash
- Symptoms of sunburn (such as redness, itching, swelling or blistering) that occur more quickly than normal
- Chest pain or tightness in the chest
- Swelling in your ankles or legs
- Vomiting up blood or dark particles that look like coffee grounds

- Blood in your stools or black tarry stools
- Difficulty breathing, asthma, wheeziness
- Eye problems, such as blurred vision, sore red eyes, itching eyes
- Yellowing of eyes or skin.
- Sensitivity to light
- Severe or persistent headache
- Severe pain or tenderness in the stomach

If you experience any of the following side effects and they worry you, tell your doctor or pharmacist:

Common side effects (affecting more than 1% of IBUGESIC) users:

- Nausea or vomiting
- Stomach pain or cramps or an upset stomach
- Diarrhoea
- Constipation
- Indigestion
- Heartburn
- Bloating or flatulence
- Ringing in your ears or difficulty hearing
- Dizziness
- Headache
- Nervousness
- Rash
- Lack of appetite
- Tiredness

If you are aged 65 years or older, you may be more likely to experience side effects. Report any events to your doctor.

If you have high blood pressure, your blood pressure medication may not work as well when using IBUGESIC. It is recommended that you get your blood pressure regularly checked if using IBUGESIC for extended periods of time.

If you have liver problems, it is recommended that you have liver tests performed at regular intervals if using IBUGESIC for extended periods of time.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using IBUGESIC

Storage

Keep your IBUGESIC tablets in their packet until it is time to take them.

Store IBUGESIC tablets in a cool dry place where the temperature stays below 25°C.

Keep IBUGESIC out of reach of children.

Disposal

Do not use IBUGESIC after the expiry date shown on the label. The unused medicine should be returned to your pharmacist so that it may be disposed of safely.

Product description

What IBUGESIC looks like

IBUGESIC is the brand name of your medicine.

IBUGESIC is a white, circular, biconvex, film-coated tablet and comes in blister packs of 120 tablets.

Ingredients

Active ingredient: each IBUGESIC tablet contains 200mg ibuprofen.

Inactive ingredients: colloidal silicon dioxide, hypromellose-E15, magnesium stearate, maize starch, propylene glycol, purified talc, purified water, sodium laurilsulfate, titanium dioxide.

Sponsor Details

IBUGESIC is supplied in New Zealand by:

REX Medical Ltd
67L Elizabeth Knox Place
Mt Wellington
AUCKLAND.
Ph (09) 574 6060
Fax (09) 574 6070

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