

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

IBUTRIN 100 mg/5 mL oral suspension

Ibuprofen

Preservative: sodium benzoate 10 mg per 5 mL

Contains sugar: sucrose 1 500 mg per 5 mL

Read all of this leaflet carefully because it contains important information for you

IBUTRIN is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use IBUTRIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share IBUTRIN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What IBUTRIN is and what it is used for
2. What you need to know before you or your child use IBUTRIN
3. How to use IBUTRIN
4. Possible side effects
5. How to store IBUTRIN
6. Contents of the pack and other information

1. What IBUTRIN is and what it is used for

The active ingredient (which makes this medicine work) is ibuprofen which is a

non-steroidal-anti-inflammatory (NSAID) painkiller. Ibuprofen relieves pain and reduces fever and inflammation.

IBUTRIN is used for the relief of symptoms of fever, pain and inflammation, associated with cold and flu, a sore throat, earache, headache, dental pain and minor aches and sprains.

2. What you need to know before you or your child use IBUTRIN

Do not use IBUTRIN:

- If you or your child is hypersensitive (allergic) to ibuprofen or any of the other ingredients of IBUTRIN (listed in section 6).
- If you or your child has ever had a reaction (e.g. asthma, runny nose, rash, swelling of the face, tongue, lips or throat) after taking ibuprofen, aspirin or other non-steroidal anti-inflammatory (NSAID) medicines.
- If you or your child has (or have had two or more episodes of) a stomach ulcer, perforation or bleeding.
- If you or your child has severe kidney, heart or liver failure.
- If you or your child has a history of stomach bleeding or perforation after taking ibuprofen or other NSAIDs.
- If you or your child is pregnant or breastfeeding.
- If you or your child has nasal polyps caused by taking aspirin and it's linked to difficulty breathing,
- If you or your child has asthma that is not well controlled,
- If your child is less than 12 months old.
- If you or your child has porphyria (a rare genetic disorder that affects the nerves and skin, resulting in symptoms such as stomach pain, sensitivity to sunlight, and problems with the nervous system).

- If you or your child is using lithium (medicine commonly used to manage mood disorders) or digoxin (digoxin is medicine use to manage heart diseases)

Warnings and precautions

Talk to your doctor or pharmacist if:

- you or your child has or has had high blood pressure, heart problems or a stroke because there is a small increased risk of heart problems with IBUTRIN.
- you think that you or your child might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- you or your child has asthma or any allergic disease of the lungs.
- you or your child has, or has had liver, kidney, heart or bowel problems.
- you or your child is dehydrated as there is a risk of kidney problems.
- you or your child has SLE (Systemic Lupus Erythematosus, a condition of the immune system) or any similar disease.
- you or your child suffers from chronic inflammatory bowel disease such as Crohn's disease or ulcerative colitis as IBUTRIN may worsen the condition.
- you or your child has chicken pox (varicella). It is advisable to avoid use of IBUTRIN during chicken pox.

Any risk is more likely with high doses and prolonged treatment.

Do not exceed the recommended dose or duration of treatment.

If you are elderly talk to your doctor before using IBUTRIN.

Other medicines and IBUTRIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may affect how IBUTRIN works, or IBUTRIN may affect how you or your child's other medicines work.

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines, especially:

- any other non-steroidal anti-inflammatory medicines or aspirin (even if low dose up to 75 mg a day) as these may increase the risk of experiencing side effects.
- diuretics (to help you pass water) as it can make IBUTRIN more likely to harm the kidneys.
- anticoagulants (blood thinning medicines e.g. warfarin) as the effects of warfarin may be increased.
- medicines for high blood pressure (e.g. captopril, atenolol, losartan) as IBUTRIN might make these medicines less effective.
- lithium (for mood disorders) as there are evidence that the amount of lithium in the liquid part of the blood (plasma) might go up.
- methotrexate (for psoriasis, arthritis and types of cancer) as there are evidence that the amount of methotrexate in the liquid part of the blood (plasma) might go up.
- zidovudine (for HIV) as it might cause blood-related issues (such as haematological toxicity), particularly in HIV-positive individuals with haemophilia (a disorder that affects blood clotting).
- corticosteroids (an anti-inflammatory medicine) as these may increase the risk of experiencing side effects such as stomach ulcers and bleeding.
- cardiac glycosides (for heart problems, such as digoxin), as it could make heart problems (such as heart failure) worse, affect how well the kidneys are working, and increase the concentration of the heart medication in the blood.
- ciclosporin or tacrolimus (to prevent organ rejection after transplant) as the combination with IBUTRIN has the potential to damage or be harmful to the kidney.
- mifepristone (for termination of pregnancy). IBUTRIN should not be used for 8-12

days after mifepristone, as it can reduce the effect of mifepristone.

- quinolone antibiotics (for infections). This might increase the risk of convulsions (fits) associated with quinolone antibiotics.
- SSRI antidepressant medicines (such as fluoxetine, sertraline), as it may increase the risk of stomach and intestinal bleeding.
- antiplatelet medicines (e.g. dipyridamole, clopidogrel) as it may increase the risk of stomach and intestinal bleeding.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

Do not use IBUTRIN if you are pregnant or breastfeeding.

Fertility

IBUTRIN belongs to a group of medicines which may impair fertility in women. This is reversible on stopping IBUTRIN. Tell your doctor before taking IBUTRIN if you have problems becoming pregnant.

Driving and using machines

It is not always possible to predict to what extent IBUTRIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which IBUTRIN affects them.

IBUTRIN might make you feel dizzy or drowsy. This could impact your ability to drive or use machinery.

IBUTRIN contains sucrose

IBUTRIN contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking or giving IBUTRIN.

3. How to use IBUTRIN

Do not share medicines prescribed for you or your child with any other person.

Always use IBUTRIN exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Age	Body weight	Daily dosage
1 - 2 years	7 – 12 kg	2,5 mL up to 3 – 4 times daily
3 – 7 years	14 – 23 kg	2,5 – 5 mL up to 3 – 4 times daily
8 – 12 years	25 – 40 kg	10 mL up to 3 – 4 times daily
Adults & children Aged 12 or older	Above 40 kg	10 mL to 20 mL (two to four teaspoons) 3 to 4 times a day

A measuring cup is provided in the package. Use this measuring cup to give the amount mentioned in the table above.

Doses should be given every 6 – 8 hours. Leave at least 4 hours between doses.

Do not take more than the recommended dose in 24 hours.

IBUTRIN is for short-term use only.

Do not give to children 12 months of age.

If symptoms of pain or fever persists for more than 3 days, consult your doctor.

If you use more IBUTRIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement.

At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to give IBUTRIN

If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 4 hours ago. Do not give a double dose to make up for forgotten individual doses.

4. Possible side effects

IBUTRIN can have side effects.

Not all side effects reported for IBUTRIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBUTRIN, please consult your health care provider for advice.

If any of the following happens, stop giving IBUTRIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to IBUTRIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- blood in the stools (faeces/motions), black tarry stools, or vomiting blood or dark particles that look like coffee grounds,
- unexplained wheezing, asthma, shortness of breath, skin rash (which may be severe with blistering or peeling of the skin), itching or bruising, severe skin reactions including Stevens-Johnson syndrome, racing heart, fluid retention (swollen ankles or decreased levels of passing urine),
- stiff neck, headache, nausea, vomiting, fever and disorientation,
- a severe skin reaction known as DRESS (Drug reaction with eosinophilia and systemic symptoms) syndrome can occur. Symptoms of DRESS include skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells),
- unexplained stomach pain, indigestion, heartburn, nausea or vomiting,
- yellowing of the eyes, pale stools and dark urine (these can be signs of kidney or liver problems),
- severe sore throat with high fever,
- unexplained bruising or bleeding, tiredness, getting more infections than normal, such as mouth ulcers, colds, sore throat, fever. (These can be signs of anaemia or other blood disorders.)
- stroke (symptoms vary but often include sudden numbness or weakness in the face, arm, or leg, especially on one side of the body; confusion; trouble speaking or understanding speech; difficulty walking; and severe headache) or heart problems (such as heart attack, with symptoms that can include chest pain or discomfort, shortness of breath, light-headedness, nausea, and pain or discomfort in the arms,

back, neck, jaw, or stomach). This is unlikely at the dose level given to children, These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent

- headache, dizziness, ringing in ears, feeling depressed, drowsy
- difficulty sleeping
- diarrhoea, wind or constipation,
- worsening of colitis and Crohn's disease,
- high blood pressure,
- stomach ulcer (symptoms can include burning pain, indigestion, nausea and vomiting, loss of appetite, weight loss, and dark or tarry stools), bleeding of the stomach with symptoms including black or tarry stools, vomiting blood, weakness and fatigue, abdominal pain, dizziness, shortness of breath, and rapid heart rate),
- inflammation of the stomach lining (also known as gastritis), including symptoms such as abdominal pain, nausea and vomiting, loss of appetite, bloating, indigestion, blood in stool or vomit, and heartburn.

Frequency not known

- serious infections of the skin and soft tissues have occurred during chicken pox (varicella).
- Decreased appetite

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem252reporting-form/>.

By reporting side effects, you can help provide more information on the safety of IBUTRIN.

5. How to store IBUTRIN

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep the container in the outer carton
- Keep the container tightly closed
- Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IBUTRIN contains

- The active substance is ibuprofen.

Each 5 mL contains ibuprofen 100 mg.

Preservative: sodium benzoate 10 mg per 5 mL

Contains sugar: sucrose 1 500 mg per 5 mL

- The other ingredients are acesulfame potassium, anhydrous citric acid, D & C yellow 10, FD & C red 40, glycerol/glycerin, hypromellose, mix berry flavour B1600948, polysorbate 80, purified water, sodium benzoate, sucrose and xanthan gum.

What IBUTRIN looks like and contents of the pack

IBUTRIN contains an orange colour suspension.

IBUTRIN is packed in a transparent HDPE bottle with a white opaque child resistant polypropylene closure and clear polypropylene measuring cup.

Pack size is one 120 mL bottle packed in an outer cardboard carton.

Holder of Certificate of Registration**Strides Pharma (SA) Pty Ltd**

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Registration numbers

IBUTRIN Suspension: 55/2.7/0276

FEVATRIN Suspension: 55/2.7/0277.276

Access to the corresponding Professional Information

The PI is available with the packaging of IBUTRIN Suspension.