

SCHEDULING STATUS

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GO PAIN IBUPROFEN 200 and GO PAIN IBUPROFEN 400

200 mg and 400 mg, film-coated

Ibuprofen

Sugar free

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

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

Nevertheless, you still need to use GO PAIN IBUPROFEN carefully to get the best results from it.

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

What is in this leaflet

1. What GO PAIN IBUPROFEN is and what it is used for
2. What you need to know before you take GO PAIN IBUPROFEN
3. How to take GO PAIN IBUPROFEN
4. Possible side effects
5. How to store GO PAIN IBUPROFEN
6. Contents of the pack and other information

1. What GO PAIN IBUPROFEN is and what it is used for

GO PAIN IBUPROFEN contains ibuprofen. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines provide relief by changing the body's response to pain, inflammation and fever.

GO PAIN IBUPROFEN is used for the relief of headache and back pain of muscular origin, feverishness, muscular aches and pain, menstrual pain, dental pain and for the relief of pain associated with migraine.

2. What you need to know before you take GO PAIN IBUPROFEN

Do not take GO PAIN IBUPROFEN

- If you are hypersensitive (allergic) to ibuprofen or any of the other ingredients of GO PAIN IBUPROFEN (listed in section 6).
- If you previously experienced asthma, skin rash or any allergic-type reaction after taking aspirin or other non-steroidal anti-inflammatory drugs (NSAID).
- If you have heart failure.
- If you have kidney failure or liver failure.
- If you have a history of ulcers (sores) in your stomach or bowel or bleeding from the stomach or bowel after you have taken a NSAID, including GO PAIN IBUPROFEN.
- If you have or had a history of stomach or bowel ulcers or bleeding.
- If you are pregnant in the last three months of pregnancy (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with GO PAIN IBUPROFEN. You should talk to your doctor first before you take GO PAIN IBUPROFEN

- If you have problems with bleeding easily, have heart problems, or have asthma.

- If you have asthma or allergies, as you may experience bronchospasm (tightness of the chest and difficulty breathing) when you take GO PAIN IBUPROFEN.
- If you are sensitive/allergic to aspirin, you should not take GO PAIN IBUPROFEN.
- If you are taking other NSAID as you might experience more severe side-effects.
- If you have joint pain, skin disorders (systemic lupus erythematosus and mixed connective tissue disease) as you have a higher risk for meningitis (an inflammation (swelling) of the protective membranes covering the brain and spinal cord).
- If you have problems with your kidneys, as GO PAIN IBUPROFEN may make this worse.
- If your child is dehydrated, e.g. after vomiting or diarrhoea, GO PAIN IBUPROFEN may cause damage to their kidneys.
- If you have high blood pressure or heart problems as GO PAIN IBUPROFEN may increase your risk of having heart failure.
- GO PAIN IBUPROFEN may affect your ability to fall pregnant (see Pregnancy, breastfeeding and fertility).
- GO PAIN IBUPROFEN may cover/disguise symptoms of an infection. If your symptoms stay or becomes worse, you should speak to your doctor.
- If you are elderly, you might have an increased risk to experience side-effects, especially problems with your stomach or gut. Speak to your doctor before taking this medicine.

You may experience side-effects while taking GO PAIN IBUPROFEN, e.g. an allergic reaction, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome, or severe skin reactions. See section 4. POSSIBLE SIDE EFFECTS, for a list of serious side effects which you might experience and how to address those.

Children and adolescents

GO PAIN IBUPROFEN should not be used in children under 12 years of age.

Other medicines and GO PAIN IBUPROFEN

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

- Aspirin or other NSAIDs painkillers as it may increase your risk of side effects.
- Corticosteroids (medicines for treating severe allergies and skin problems) as it may increase your risk of stomach problems.
- Medicines for high blood pressure and water tablets as GO PAIN IBUPROFEN may reduce their effect.
- Medicines for treating blood clots (e.g. warfarin) as it may increase your risk of bleeding.
- Antidepressants known as selective serotonin reuptake inhibitors (SSRIs) as it may increase your risk of stomach bleeding.
- Medicines for treating heart failure, called cardiac glycosides, as it may worsen your heart condition.
- Lithium (for depression) as it may increase the levels of lithium in your blood.
- Methotrexate (for treating rheumatoid arthritis and some cancers) as it may increase the levels of methotrexate.
- Ciclosporin and tacrolimus (used for prevention of organ transplant) as this may lead to kidney impairment.
- Mifepristone (for terminating pregnancy) because GO PAIN IBUPROFEN can make mifepristone ineffective.
- Zidovudine (for treatment of HIV infection) as it may increase your risk of joint bleeds and/or swelling.
- Quinolone antibiotics (e.g. levofloxacin used in the treatment of bacterial infections like pneumonia and other respiratory and urinary infections) as this may lead to seizures.

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 you take GO PAIN IBUPROFEN.

GO PAIN IBUPROFEN should not be used during pregnancy or while you are breastfeeding.

You should not take GO PAIN IBUPROFEN if you are planning to have a baby. GO PAIN IBUPROFEN may make it more difficult to become pregnant. However, this is reversible once you stop taking GO PAIN IBUPROFEN.

Driving and using machines

It is not always possible to predict to what extent GO PAIN IBUPROFEN may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which GO PAIN IBUPROFEN affects you.

3. How to take GO PAIN IBUPROFEN

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

Always take GO PAIN IBUPROFEN exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dosage for adults and children over 12 years

The initial dose is 400 mg ibuprofen (two GO PAIN IBUPROFEN 200 tablets or one GO PAIN IBUPROFEN 400 tablet) taken with water, then if necessary, 200 mg ibuprofen (one GO PAIN IBUPROFEN 200 tablet) or 400 mg ibuprofen (two GO PAIN IBUPROFEN 200 tablets or one GO PAIN IBUPROFEN 400 tablet) every four hours.

Migraine

Take 400 mg ibuprofen (two GO PAIN IBUPROFEN 200 tablets or one GO PAIN IBUPROFEN 400 tablet) three times a day.

Period pain

Take 400 mg ibuprofen (two GO PAIN IBUPROFEN 200 tablets or one GO PAIN IBUPROFEN 400 tablet) three times a day.

Do not take more than 1200 mg ibuprofen (six GO PAIN IBUPROFEN 200 tablets or three GO PAIN IBUPROFEN 400 tablets) in any 24 hours.

If symptoms persist for more than 7 days or worsen or new symptoms occur, consult your doctor.

Use the lowest effective dose for the shortest possible duration of treatment.

Taking GO PAIN IBUPROFEN tablets

GO PAIN IBUPROFEN tablets should be taken with enough liquid (e.g. a glass of water) with meals.

If you take more GO PAIN IBUPROFEN than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of GO PAIN IBUPROFEN

If you forget a dose, take it as soon as you remember. 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.

4. Possible side effects

GO PAIN IBUPROFEN can have side effects.

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

If any of the following happens, stop taking GO PAIN IBUPROFEN and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Feeling tired, pale skin, shortness of breath, light-headedness, dizziness or a fast heartbeat, increase in nose bleeds or unusual bleeding.
- Hypersensitivity reactions, including facial, tongue and throat swelling, a skin rash, itching, difficulty breathing, changes to your heartbeats, dizziness or light-headedness.
- Heart disease: You may experience chest pain, fatigue, leg swelling and/or shortness of breath.
- Fever, neck pain or stiffness, sensitive to light, headache.
- Tightening of your chest, asthma or worsening of your asthma.
- Skin reactions which cause severe blistering of the skin, skin peeling, fever, weakness
- A life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat.

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

Tell your doctor if you notice any of the following

Less frequent side effects

- Headache
- Decreased appetite

- High blood pressure: You may experience severe headaches, dizziness, chest pain, difficulty breathing
- Diarrhoea, nausea, vomiting
- Constipation, heartburn
- Vomiting blood, bleeding from the gut (your stools might be black)
- Ulcers in the stomach or bowels: You may experience a dull or burning pain in your abdomen, heartburn, nausea or feeling bloated
- Liver disease: You may experience tummy pain and yellowing of the eyes and skin
- Skin rash, severe skin reaction to the sun
- Kidney problems: It may cause blood in your urine, cloudy urine, change in how frequent you want to urinate, and swelling of feet/legs and ankles.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GO PAIN IBUPROFEN.

In addition, side-effects can also be reported to info@pharmacorp.co.za.

5. How to store GO PAIN IBUPROFEN

Store all medicines out of reach of children.

- Store at or below 25 °C
- Do not use after the expiry date stated on the blister or carton

6. Contents of the pack and other information

What GO PAIN IBUPROFEN contains

The active substance is ibuprofen

GO PAIN IBUPROFEN 200: Each tablet contains ibuprofen 200 mg.

GO PAIN IBUPROFEN 400: Each tablet contains ibuprofen 400 mg

The other ingredients are

Tablet core: cellulose, microcrystalline; colloidal silicon dioxide; croscarmellose sodium; magnesium stearate; povidone (K-90); starch, pregelatinised (maize); sodium lauryl sulphate.

Film coating: Aquarius® BKP18066 Cool Vanilla (hypromellose 2910 3 cPS; hydroxy propyl cellulose EF; hypromellose HPMC, 2910 6 cPS; hypromellose HPMC, 2910 50 cPS; polyethylene glycol 400; titanium dioxide).

What GO PAIN IBUPROFEN looks like and contents of the pack

GO PAIN IBUPROFEN 200: White to off-white round shape, film- coated tablets with "G 2" debossing on one side and plain on the other side.

GO PAIN IBUPROFEN 200 are packed in blister packs of 24 tablets.

GO PAIN IBUPROFEN 400: White to off-white oval shape, film-coated tablets with "I 6" debossing on one side & plain on the other side.

GO PAIN IBUPROFEN 400 are packed in blister packs of 12 tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

(and the translated Patient Information Leaflet)

www.pharmacorp.co.za