

1.3.3.2 English Leaflet

Information for the user

Sapofen 200 mg, 400 mg and 600 mg.

Ibuprofen

Film-Coated Tablets

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

- This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.
- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice.

In this leaflet:

- 1. What Sapofen is and what it is used for?**
- 2. What should you know before taking Sapofen Tablets?**
- 3. How to take Sapofen?**
- 4. Possible side effects.**
- 5. How to store Sapofen?**
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1. What sapofen is and what it is used for?

Sapofen Tablets belongs to a group of medicines called anti-inflammatory pain killers. They can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine, ankylosing spondylitis, swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

Sapofen Tablets can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

The active ingredient in Sapofen Tablets is ibuprofen and each tablet contains either 200, 400 or 600 mg.

2. What should you know before taking Sapofen Tablets?

- If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist BEFORE taking any Sapofen Tablets:
- Are you pregnant or planning to become pregnant, or are you breast-feeding? Sapofen tablets may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.
- Are you sensitive (allergic) to any of the ingredients in the tablets? These are listed in Section 6.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint?

- Do not take Sapofen Tablets if you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past.
- Do you have a condition which increases your tendency to bleeding?
- Do you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- Do you suffer from swelling and irritation inside the nose?
- Do you suffer from liver or kidney disease?
- Do you suffer from heart disease?

Medicines such as Sapofen Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. You should discuss your treatment with your doctor or pharmacist before taking Sapofen Tablets if you:

- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries).
- have any kind of stroke or think that you might be at risk of these conditions (e.g., if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).
- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Do you have chicken pox or shingles?
- Are you or your child dehydrated? As there is a risk of kidney damage in dehydrated children, adolescents and the elderly.

Skin reactions

- Serious skin reactions have been reported in association with Sapofen Tablets treatment. You should stop taking Sapofen Tablets and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Can you take Sapofen with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen.

You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines.

In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

- Diuretics (water tablets)

- Cardiac glycosides, such as digoxin, used to treat heart conditions
- Lithium
- Zidovudine (an anti-viral drug)
- Steroids (used in the treatment of inflammatory conditions)
- Methotrexate (used to treat certain cancers and rheumatoid arthritis)
- Medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- Medicines known as selective serotonin reuptake inhibitors (ssris), used for the treatment of depression
- Antibiotics called quinolones such as ciprofloxacin
- Aminoglycosides (a type of antibiotic)
- Mifepristone
- Any other ibuprofen, such as those you can buy without a prescription
- Any other anti-inflammatory pain killer, including aspirin
- Cholestyramine (a drug used to lower cholesterol)
- Medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- Voriconazole or fluconazole (type of anti-fungal drugs)
- Gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Alcohol: Sapofen may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with Sapofen might make these side effects worse.

Pregnancy and breast-feeding: The use of Sapofen whilst pregnant or breast feeding should be avoided. Sapofen should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and Using Machines: Sapofen may make you feel dizzy or drowsy. If the tablets affect you in this way, do not drive, operate machinery or do anything that requires you to be alert.

3. How to take Sapofen.

ALWAYS take Sapofen exactly as your doctor has told you. If you are not sure refer to the label on the carton or check with your doctor or pharmacist.

Take your Sapofen Tablets with or after food, with a glass of water. Sapofen Tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

DOSAGE:

- **Adults and children over 12 years**
 - The usual dosage is 600 to 1800 mg spread throughout the day. Your doctor may choose to increase this depending on what you are being treated for; but no more than 2400 mg should be taken in one day.
- **Children**
 - The usual daily dose is 20 mg per kg of bodyweight each day, given in divided doses.

- Sapofen Tablets should NOT be taken by children weighing less than 7 kg. The 600 mg tablets should not be given to children under the age of 12 years.
- In cases of severe juvenile arthritis your doctor may increase the dosage up to 40 mg/kg in divided doses.

You should avoid excessive use of painkillers. If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys, tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine. This risk may be increased if you are dehydrated.

The use of painkillers for a long period of time has in some patients been linked to headaches, a condition called medication overuse headache (MOH). Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of Sapofen. Tell your doctor if you have been having headaches while taking this medicine.

If you take more Sapofen than you should

If you have taken more Sapofen than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

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 take your Sapofen tablets

take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

4. Possible side effects

As with all medicines, Sapofen Tablets may cause side effects, although they are usually mild and not everyone will suffer from them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

STOP TAKING Sapofen Tablets and seek immediate medical help if you experience:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
- Signs of intestinal bleeding such as
 - Passing blood in your faeces (stools/motions)
 - Passing black tarry stools
 - Vomiting any blood or dark particles that look like coffee grounds

TELL YOUR DOCTOR AND STOP TAKING SAPOFEN TABLETS IF YOU EXPERIENCE:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).
- Loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Severe spreading skin rash ('Stevens-Johnson Syndrome', 'toxic epidermal necrolysis' and 'erythema multiforme', symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness)
- A severe skin reaction known as DRESS 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).
- Medicines such as Sapofen Tablets have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.
- Medicines such as Sapofen Tablets have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles.
- Blood disorders such as reduction in blood cells and platelet counts – the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin.
- Kidney problems such as reduced kidney function, fluid retention (oedema), inflammation of the kidney and kidney failure.
- Liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen.
- Sapofen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

Other side effects

Common (affects up to 1 in 10 people):

- Feeling dizzy or tired
- Diarrhoea, wind, constipation
- Headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

Uncommon (affects up to 1 in 100 people):

- Feeling drowsy
- Feeling anxious
- Feeling a tingling sensation or 'pins and needles'
- Difficulty sleeping
- Hives

- Skin becomes sensitive to light
- Hearing problems
- Sneezing, blocked, itchy or runny nose (rhinitis)
- Stomach or gut ulcer, hole in the wall of the digestive tract
- Inflammation of your stomach lining
- Ringing in ears (tinnitus)
- Sensation of spinning (vertigo)
- Mouth ulcers

Rare (affects up to 1 in a 1000 people):

- Feeling depressed or confused

Very rare (affects up to 1 in 10,000 people):

- inflammation of the pancreas

Not known (cannot be estimated from the available data):

- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Sapofen Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Sapofen.

Do not store above 30°C.

Store in the original package.

Keep out of the reach and sight of children, preferably in a locked cupboard.

Do not use this medicine after the expiry date that is printed on the pack. The expiry date refers to the last day of that month.

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

6. Further information.

What this medicine contains:

- Sapofen 200 mg. Film-coated tablets: Each film-coated tablet contains Ibuprofen 200 mg, which is the active ingredient.
- Sapofen 400 mg. Film-coated tablets: Each film-coated tablet contains Ibuprofen 400 mg, which is the active ingredient.
- Sapofen 600 mg. Film-coated tablets: Each film-coated tablet contains Ibuprofen 600 mg, which is the active ingredient.

Other ingredients:

- **Sapofen 200mg Film-Coated Tablet:**

Core: Hydroxypropyl Cellulose, Colloidal Silicon Dioxide, Avicel PH 101, Sodium Lauryl Sulphate, Croscarmellose Sodium Type A, Avicel PH 102, Purified Talc,

Coating Material: Purified Talc, Polysorbate 80, Titanium Dioxide, Polyethylene Glycol, Hydroxypropyl Methylcellulose and Purified Water.

- **Sapofen 400mg Film-Coated Tablet:**

Core: Hydroxypropyl Cellulose, Colloidal Silicon Dioxide, Avicel PH 101, Sodium Lauryl Sulphate, Croscarmellose Sodium Type A, Avicel PH 102, Purified Talc

Coating Material: Opadry OY-S-1188 and Purified Water.

- **Sapofen 600mg Film-Coated Tablet:**

Core: Hydroxypropyl Cellulose, Colloidal Silicon Dioxide, Avicel PH 101, Sodium Lauryl Sulphate, Croscarmellose Sodium Type A, Avicel PH 102, Purified Talc,

Coating Material: Opadry OY-L-33025 Dark Orange and Purified Water.

What this medicine looks like:

Sapofen 200mg FC Tablets	A white to off white, round, biconvex, film coated tablet with "177" on one side and plain on the other side.
Sapofen 400mg FC Tablets	Dark pink film coated-circular tablet; engraved on one face with a crescent logo and on the other face with the letters "SP" and the number "113".
Sapofen 600mg FC Tablets	Orange to light orange, oblong, biconvex, film coated tablet with a breakline on one side and "SP 153" on the other side.

Contents of the pack:

Sapofen 200 mg. film-coated tablets: each pack contains 30 tablets in 3 blisters.

Sapofen 400 mg. film-coated tablets: each pack contains 20 tablets in 2 blisters.

Sapofen 600 mg. film-coated tablets: each pack contains 30 tablets in 3 blisters.

Marketing Authorisation Holder and Manufacturer**SPIMACO**

AlQassim pharmaceutical plant
Saudi Pharmaceutical Industries &
Medical Appliance Corporation

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To report any side effect(s):

For Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2340.
- Reporting hotline: 19999.
- E-mail: npc.drug@sfda.gov.sa
- Website: <https://ade.sfda.gov.sa>

For UAE

- Pharmacovigilance & Medical Device section
P.O.Box: 1853
- Tel: 80011111
- Email: pv@moh.gov.ae
- Drug Department
Ministry of Health & Prevention
Dubai

For Oman

- Department of Pharmacovigilance & Drug Information
- Directorate General of Pharmaceutical Affairs & Drug Control
- Ministry of Health, Sultanate of Oman
- Phone Nos. 22357687 / 22357686
- Fax: 22358489
- Email: dg-padc@moh.gov.om
- Website: www.moh.gov.om

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists