

Sapofen®

Information for the user
Sapofen- Junior
Suspension
Ibuprofen 100 mg/5 ml

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

- Keep this leaflet as you may need to read it again.
- This leaflet provides a summary of the information currently available about SAPOFEN - JUNIOR Suspension.
- For further information or advice ask your doctor or pharmacist.
- This medicine is for you only and should never be given to anyone else, even if they appear to have the same symptoms as you.
- Tell your doctor or pharmacist if you experience any side effects.

In this leaflet:

1. WHAT SAPOFEN- JUNIOR IS AND WHAT IT IS USED FOR.
2. BEFORE YOU GIVE SAPOFEN- JUNIOR.
3. HOW TO GIVE SAPOFEN- JUNIOR.
4. POSSIBLE SIDE EFFECTS.
5. HOW TO STORE SAPOFEN- JUNIOR.
6. FURTHER INFORMATION.

1. WHAT SAPOFEN- JUNIOR IS AND WHAT IT IS USED FOR

SAPOFEN - JUNIOR Suspension belongs to a group of medicines called anti-inflammatory pain killers. It 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, tendonitis, tenosynovitis, lower back pain, sprains and strains.

SAPOFEN - JUNIOR Suspension can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine. It can also be used for the short term treatment of fever in children over the age of 1 year.

The active ingredient in SAPOFEN - JUNIOR Suspension is ibuprofen. Each 5ml spoonful of SAPOFEN - JUNIOR Suspension contains 100mg ibuprofen.

2. BEFORE YOU GIVE SAPOFEN- JUNIOR

If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist BEFORE taking any SAPOFEN - JUNIOR Suspension:

- Are you pregnant or planning to become pregnant, or are you breast-feeding? SAPOFEN - JUNIOR Suspension 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 Suspension? These are listed in Section 6. If you develop an unexpected rash, sore eyes, sore mouth or difficulty breathing whilst taking the medicine stop taking it and contact your doctor for advice.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint? Do not take SAPOFEN - JUNIOR Suspension 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 - JUNIOR Suspension 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 - JUNIOR Suspension 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?
- Have you been told by your doctor that you have an intolerance to some sugars? Due to the content of sorbitol and sucrose, it is not recommended for those with hereditary fructose intolerance, glucose malabsorption syndrome or sucraseisomaltase deficiency.
- Is your child dehydrated? As there is a risk of kidney damage in dehydrated children and adolescents.

Can you take SAPOFEN - JUNIOR with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine), 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. Patient should therefore always seek the advice of doctor or pharmacist before using ibuprofen with other medicines.

In addition to those mentioned above the following medicines can interact with ibuprofen:

- 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),
- Medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down patient 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 preparations, 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 (types of anti-fungal drugs),
- Ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for your child, including herbal and homeopathic remedies.

Other important information

The Suspension contains small amounts of glycerin (glycerol). In high doses, glycerin may sometimes cause headache, stomach upset and diarrhoea. As such, you should not take more than the stated dose unless your doctor advises you to. The Suspension contains sucrose and therefore may be harmful to your teeth.

Pregnancy and breast-feeding: The use of SAPOFEN - JUNIOR Suspension whilst pregnant or breast feeding should be avoided. SAPOFEN - JUNIOR Suspension 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 - JUNIOR Suspension may make you feel dizzy or drowsy, if it affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. HOW TO GIVE SAPOFEN- JUNIOR

ALWAYS take SAPOFEN - JUNIOR Suspension 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. Ensure the bottle is thoroughly shaken before use. Take with or after food.

DOSSAGE:

Adults and children over 12 years -The usual dosage is 4 to 6 spoonfuls (5 ml) taken three times a day. Your doctor may choose to increase or decrease this depending on what you are being treated for; but no more than 24 spoonfuls (120 ml/2400 mg) should be taken in one day.

Children - SAPOFEN - JUNIOR Suspension should NOT be taken by children weighing less than 7 kg. When used to treat fever, the Suspension should not be used long term or given to children under the age of 1 year.

The usual dose in children is 20 mg per kg of bodyweight each day, in divided doses. This can be given as follows:

1-2 years: One 2.5 ml (50 mg) dose three/four times a day

3-7 years: One 5 ml (100 mg) dose three/four times a day

8-12 years: Two 5 ml (200 mg) doses three/four times a day

The doctor may choose to increase this dose in children with juvenile rheumatoid arthritis. This dose should not exceed 40mg/kg bodyweight daily 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.

IF YOU TAKE MORE SAPOFEN - JUNIOR SUSPENSION THAN PRESCRIBED (AN OVERDOSE) you should contact a doctor or go to the nearest hospital casualty department IMMEDIATELY taking your Suspension with you.

IF YOU FORGET TO TAKE YOUR SAPOFEN - JUNIOR SUSPENSION take it 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 - JUNIOR Suspension 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 minimize the risk of side effects by taking the least amount of Suspension for the shortest amount of time necessary to control your symptoms.

STOP TAKING SAPOFEN - JUNIOR Suspension 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 - JUNIOR SUSPENSION 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).
- Yellowing of the eyes and/or skin (jaundice).
- Severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis).
- Blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Fluid retention e.g. swollen ankles (this may be a sign of kidney problems).
- Severe spreading skin rash (Stevens-Johnson Syndrome and erythema multiforme, symptoms include severe skin rash, blistering inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness).

Medicines such as SAPOFEN - JUNIOR Suspension have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Medicines such as SAPOFEN - JUNIOR Suspension have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen

Very rarely SAPOFEN - JUNIOR Suspension may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

SAPOFEN - JUNIOR has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

A burning feeling in the throat or mouth may happen briefly after taking this medicine.

Other side effects

Common (affects up to 1 in 10 people):

- Rash,
- Feeling dizzy or tired.
- Stomach pain, indigestion, diarrhoea, feeling sick, being sick, 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.
- Passing black tarry stools.
- Passing blood in your faeces (stools/motions).
- Vomiting any blood.

Uncommon (affects up to 1 in a 100 people):

- Feeling drowsy.
- Feeling anxious.
- Feeling a tingling sensation or 'pins and needles'.
- Difficulty sleeping.
- Hives, itching.
- Skin becomes sensitive to light.
- Visual disturbances, hearing problems.
- Hepatitis, yellowing of your skin or eyes, reduced liver function.
- Reduced kidney function, inflammation of the kidneys, kidney failure.
- Sneezing, blocked, itchy or runny nose (rhinitis).
- Stomach or gut ulcer, hole in the wall of the digestive tract.
- Inflammation of your stomach lining.
- Small bruises on your skin or inside your mouth, nose or ears.
- Difficulty breathing, wheezing or coughing, asthma or worsening of asthma.
- Ringing in ears (tinnitus).
- Sensation of feeling dizzy or spinning (vertigo).
- Mouth ulcers.
- Serious allergic reaction which causes swelling of the face or throat.

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

- Feeling depressed or confused.
- Fluid retention (oedema).
- A brain infection called 'non-bacterial meningitis'.
- Loss of vision.
- Changes in blood count - the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, feeling very tired, bleeding from the nose and the skin.
- Reduction in blood cells (anaemia).
- Serious allergic reaction which causes difficulty in breathing or dizziness.
- Severe sore throat with high fever (agranulocytosis).

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

- Liver failure.
- Heart failure.
- Heart attack.
- Inflammation of the pancreas.
- Skin problems (which can also affect inside your mouth, nose or ears) such as 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis' or 'erythema multiforme'.
- High blood pressure.

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

- Worsening of ulcerative colitis or Crohn's Disease (inflammation of the colon).

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. You can also report side effects directly via the National reporting systems.

5. HOW TO STORE SAPOFEN- JUNIOR

- Do not store above 30°C.
- Keep this medicine in a safe place out of the sight and reach 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.
- This medicine will be expired after 30 days from the first opening.
- 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:

Each 5 ml of oral suspension contains ibuprofen 100 mg, which is the active ingredient.

Other ingredients: Polysorbate 80, Sucrose Granular, Sorbitol Solution 70% Non-Cryst, Glycerol, Sodium Benzoate, Disodium Edetate, Citric Acid Anhydrous, Avicel RC, Keltrol Xanthan Gum PF, Sunset Yellow, Orange Flavour Juiy, Pineapple Flavour, Sodium Citrate Anhydrous and Purified Water.

What Sapofen Junior looks like:

An orange coloured thick suspension with pleasant odour and taste.

Marketing Authorization Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant

Saudi Pharmaceutical Industries &

Medical Appliances Corporation

Saudi Arabia

This leaflet is last revised in December 2016.

Sapofen is a trade mark
34SA707

To report any side effects(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222. Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

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