

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

Under the age of 6 months use according to a doctor's prescription only.
Over the age of 6 months this medicine is dispensed without a doctor's prescription.

Children's Advil Grape Flavor Suspension

100 mg/5 mL

Children's Advil Fruit Flavor Suspension

100 mg/5 mL

Active ingredient and its concentration:

Each 5 mL contains: Ibuprofen 100mg

For the list of inactive ingredients and allergens: see section 6 "Additional information" and section 2 "Before using the medicine" – under subsection "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in section 3 – "How should you use the medicine?" in this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 24 hours in infants aged 3-6 months or after 3 days in children aged 6 months and older.

This medicine is suitable for most infants over 3 months of age, children and adults.

In infants aged 3-6 months use according to a doctor's prescription.

Refer to the doctor if your child is taking aspirin at a dosage above 75 mg per day, or if your child develops a rash, difficulty breathing, diarrhea or increased fatigue.

1. What is the medicine intended for?

For the reduction of fever and relief of mild to moderate pain, in infants and children from 3 months to 12 years of age.

Therapeutic class: Non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before using the medicine

This medicine is suitable for most people, but some people should avoid using it. Consult the pharmacist or the doctor if you are uncertain.

Do not use this medicine if:

- You or your child are sensitive (allergic) to ibuprofen, or to any of the additional ingredients the medicine contains (see section 6).
- You or your child have had allergic reactions (such as asthma, inflammation of the nose (rhinitis), subcutaneous swelling (angioedema), or

urticaria) as a result of taking ibuprofen, acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).

- You or your child have (or you or your child have had) stomach ulcers/bleeding (two or more distinct episodes of proven perforation or bleeding).
- You or your child have suffered in the past from gastrointestinal bleeding or perforation associated with prior treatment with non-steroidal anti-inflammatory drugs (NSAIDs).
- You or your child have severe liver failure, kidney failure or heart failure.
- You are in the last three months of pregnancy.

Special warnings regarding the use of the medicine

Before treatment with Children's Advil, inform the doctor if:

- You or your child have or have had **high blood pressure, heart problems or stroke**, as there is a small increase in the risk of heart problems when using ibuprofen.
- You or your child have a risk factor for **heart problems**, such as **diabetes or high cholesterol**.
- You or your child have **asthma or any allergic lung disease**.
- You or your child have or have had **liver, kidney, heart or intestinal problems**.
- You or your child are dehydrated, as there is a risk of kidney problems.
- You or your child have **systemic lupus erythematosus (SLE, an autoimmune disease)** or another similar disease.
- You or your child have a **chronic inflammatory bowel disease** such as Crohn's disease or ulcerated inflammation of the large intestine (Ulcerative Colitis).
- It is recommended to avoid using the medicine during the period of time the patient has **chickenpox**.
- **The patient has an infection** – as Children's Advil may mask signs of infections such as fever and pain. Therefore, this medicine may delay the appropriate treatment of the infection, which may lead to an increased risk of complications. Such cases have been observed in pneumonia caused by a bacterial infection and in bacterial skin infections associated with chickenpox. If you or your child are taking this medicine while having an infection and the symptoms of your infection persist or worsen, consult the doctor without delay.

Skin reactions – severe skin reactions have been reported in association with treatment with this medicine. Stop taking/giving the medicine and seek medical attention immediately if you or your child develop a skin rash, mucosal tissue lesions, blisters or other signs of allergy, as this may be the first sign of a very severe skin reaction. See section 4.

Additional warnings

The following warnings apply primarily to adults. In any case, consider these carefully before giving or taking this medicine:

- Medicines such as Advil may be associated with a small increase in the risk of heart attack (myocardial infarction) or stroke. The likelihood of any risk will increase when taking high dosages and with prolonged treatment. Do not exceed the recommended dosage or duration of treatment.
- If you have heart problems, have had a stroke or if you think you are at risk for these conditions (for example if you have high blood pressure, diabetes or

high cholesterol, or if you smoke), you should talk to your doctor or pharmacist about the treatment.

If you are an elderly person, consult the doctor before using the medicine.

Tell the doctor immediately if:

- **Your child's symptoms do not disappear quickly or if they get worse.**
- **You are not sure what your child's illness is or if the illness is accompanied by a rash, difficulty breathing, diarrhea or increased fatigue.**

Drug interactions

If you or your child are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you or your child are taking:

- **Other medicines containing ibuprofen or other non-steroidal anti-inflammatory drugs**, including those you can buy without a prescription.
- **Low-dosage aspirin** (up to 75 mg per day).
- **Diuretic medicines** (help with urination).
- **Anticoagulants** (blood-thinning medicines such as warfarin).
- **Medicines for the treatment of high blood pressure** (such as captopril, atenolol, losartan).
- **Lithium** (for mood disorders).
- **Methotrexate** (for psoriasis, arthritis and types of cancer).
- **Zidovudine** (for HIV, human immunodeficiency virus).
- **Corticosteroids** (anti-inflammatory medicine).
- **Cardiac glycosides** (for heart problems).
- **Cyclosporine or tacrolimus** (to prevent organ rejection after transplantation).
- **Mifepristone** (for termination of pregnancy).
- **Quinolone antibiotics** (for infections).
- **Antidepressant medicines from the class of SSRI.**
- **Antiplatelet agents** such as dipyridamole, clopidogrel.

If you are not sure what type of medicines your child is taking, show the medicine to the doctor or pharmacist.

Use of the medicine and food

In patients with a sensitive stomach, the medicine can be used with or after a meal.

Pregnancy, breastfeeding and fertility:

Pregnancy

This medicine has a possible side effect of kidney impairment in the fetus and deficiency of amniotic fluid starting from the 20th week of pregnancy. It is recommended to avoid using medicines from the NSAIDs family starting from the 20th week of pregnancy.

Consult the doctor before taking this medicine during the first 6 months of pregnancy.

Do not use Children's Advil during the last 3 months of pregnancy.

Breastfeeding

In a few studies, very low concentrations of ibuprofen have been found in breast milk, however it is unlikely that these amounts will have an effect on the breastfed baby.

Fertility

Ibuprofen belongs to a class of medicines, which may impair fertility in women. This is reversible once the medicine is discontinued.

It is unlikely that occasional use of this medicine will affect your chances of becoming pregnant, however, tell the doctor before using the medicine if you are having difficulties becoming pregnant.

Driving and operating machinery

No effects are expected on the ability to drive and operate machinery at the recommended dosages and duration of treatment.

Important information about some of the ingredients of the medicine

- This medicine contains sucrose at a concentration of 2.5 g/5 mL. This should be taken into account in patients with diabetes.
- This medicine contains less than 1 mmol sodium (23 mg) per 15 mL, and is therefore considered sodium-free.
- This medicine contains sorbitol. Sorbitol may cause gastrointestinal discomfort and has a mild laxative effect.
- This medicine contains 12.5 mg sodium benzoate in each 5 mL.
- Children's Advil Grape Flavor Suspension contains 1.9 mg propylene glycol per mL.
- Children's Advil Fruit Flavor Suspension contains a maximum of 0.4 mg benzyl alcohol per mL. Benzyl alcohol may cause allergic reactions.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The generally accepted dosage is:

Dosage table by weight

Weight (kg)	Dosage		Number of times in 24 hours
	In tsp, as marked on the measuring cup	In mL, for use with a syringe or measuring spoon	
Under 5 kg	According to a doctor's prescription		
5-5.4	-	2 mL	3-4
5.5-8.1	-	2.5 mL	3-4
8.2-10.9	-	3.75 mL	3-4
11-15	1 tsp	5 mL	3-4
16-21	1.5 tsp	7.5 mL	3-4
22-26	2 tsp	10 mL	3-4
27-32	2.5 tsp	12.5 mL	3-4
33-43	3 tsp	15 mL	3-4
Be sure to shake well before use.			

Dosage table by age

Age (years)	Dosage		Number of times in 24 hours
	In tsp, as marked on the measuring cup	In mL, for use with a syringe or measuring spoon	
3-6 months	According to a doctor's prescription		
6-11 months	-	2.5 mL	3-4
12-23 months	-	3.75 mL	3-4
2-3	1 tsp	5 mL	3-4
4-5	1.5 tsp	7.5 mL	3-4
6-8	2 tsp	10 mL	3-4
9-10	2.5 tsp	12.5 mL	3-4
11-12	3 tsp	15 mL	3-4
Be sure to shake well before use.			

Children of the same age may have significantly different weights. Therefore, an effort must be made to find out the child's weight and determine the dosage according to the weight table. Only if it is impossible to find out the child's weight, the dosage can be determined according to this table.

Do not give this medicine to infants under 3 months of age (unless the doctor instructs this) or to infants weighing less than 5 kg without a doctor's instruction.

Doses should be given every 6-8 hours, at intervals of at least 4 hours between doses. Do not take more than the recommended dosage in 24 hours. For infants aged 3-6 months, use according to a doctor's prescription. From the age of 6 months and older the medicine can be used without a doctor's prescription.

If you know the child's weight – give the dosage as it appears in the weight table indicating the dosage by weight.

Only in case the weight of the child is not known – the dosage will be determined according to age as it appears in the age table indicating the dosage according to the child's age.

Warning: do not exceed the recommended dose.

Duration of treatment

For short term use only.

Do not use this medicine for more than 24 hours in infants aged 3-6 months. If symptoms persist for more than 24 hours or worsen, consult the doctor. Do not use this medicine for more than 3 days in children aged 6 months and older. If symptoms persist for more than 3 days or worsen, consult the doctor. Take the lowest dose and for the shortest period of time to relieve the symptoms. Consult the doctor without delay if your child is taking this medicine while having an infection and his symptoms persist or worsen.

How to take the medicine

Always shake the bottle well before use.

Instructions for opening

To remove the cap, press it downwards, and turn it counterclockwise. Child-proof safety caps have significantly reduced the number of poisoning incidents caused by medicines each year. However, if you find it difficult to open the package,

you can refer to a pharmacist to ask to have the safety mechanism of the cap removed and to turn the cap into a regular, easy-to-open cap.

Use a syringe or a cup intended for measuring the correct amount of the medicine. If a measuring device is not included in the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in size and it is likely you will not receive the correct amount of medicine. Do not use this medicine when the plastic ring attached to the bottle cap is broken or disconnected.

If you have used or given your child a higher dosage

If you have taken or your child has taken a larger dose than necessary or if a child has accidentally swallowed the medicine, refer to a doctor or go to the nearest hospital immediately to get an opinion about the risk, and to consult about the action to be taken. Bring the medicine package with you.

The symptoms may include nausea, abdominal pain, vomiting (may be a small amount of blood), headache, ringing in the ears, confusion and jumpy eye movement.

In high dosages there have been reports of drowsiness, chest pain, strong heartbeats, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in the urine, cold body feeling and breathing problems.

If you forget to use the medicine

If you forget to give or take a dose, give or take the next dose as needed, provided that at least 4 hours have passed since taking the previous dose. **Do not give or take a double dose.**

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Children's Advil may cause side effects in some users. Do not be alarmed when reading the list of side effects. You or your child may not experience any of them.

The most common side effect is irritation of the stomach which may cause problems such as indigestion and heartburn.

Stop giving your child the medicine and tell your doctor immediately in the case of:

- Blood in the stool
- Black tarry stools
- Vomiting blood or dark particles that look like coffee grounds
- Unexplained wheezing, asthma, shortness of breath, skin rash (which may be severe and accompanied by blisters or peeling of the skin), itching or bruising, severe skin reactions including Stevens-Johnson syndrome, rapid heartbeat, fluid retention (swollen ankles or decreased urine output)
- Stiff neck, headache, nausea, vomiting, fever and disorientation

- Swelling of the face, tongue or throat (these can be signs of a severe allergic reaction)
- Severe skin reaction known as DRESS syndrome (drug reaction with eosinophilia and systemic symptoms). DRESS symptoms include: skin rash, fever, swelling of lymph nodes and an increase in the number of eosinophils (a type of white blood cells)

Stop giving your child the medicine and tell the doctor in the case of:

- Unexplained abdominal 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 accompanied by high fever
- Unexplained bruising or bleeding, tiredness, contracting more infections than usual such as mouth ulcers, colds, sore throat, fever (these can be signs of anemia or other blood disorders)

Additional side effects

Uncommon side effects:

- Headache

Rare side effects:

- Diarrhea, flatulence or constipation. Tell the doctor if these effects last for more than a few days or if they bother you

Very rare side effects:

- Kidney or liver problems may occur with ibuprofen use
- Stroke or heart problems may occur with ibuprofen use. The likelihood of this is low at the dosage level given to children
- Exacerbation of inflammation of the large intestine (Colitis) and Crohn's disease
- High blood pressure
- Stomach ulcer, stomach bleeding, inflammation of the lining of the stomach

Side effects with unknown frequency

- In exceptional cases, severe infections of the skin and soft tissues have occurred during chickenpox (varicella)
- The skin becomes sensitive to light

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid

poisoning. Do not induce vomiting without an explicit instruction from the doctor!

- Do not use the medicine after the expiry date (exp. date) appearing on the package and the bottle. The expiry date refers to the last day of that month.
- **Storage conditions:**
Store at a temperature of up to 25°C.
The expiry date after opening the medicine is identical to the expiry date stamped on the package.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Grape flavored suspension – inactive ingredients:

Sucrose, Sorbitol Solution, Glycerin, Microcrystalline cellulose, Polysorbate 80, Sodium Benzoate, Citric Acid Hydrous, Grape Flavor Art. # 6175, Xanthan Gum, Carboxymethylcellulose Sodium, Disodium Edetate, FD&C Red # 40, FD&C Blue # 1, Purified Water.

Fruit flavored suspension – inactive ingredients:

Sucrose, Sorbitol Solution, Glycerin, Microcrystalline cellulose, Polysorbate 80, Sodium Benzoate, Citric Acid Hydrous, Xanthan Gum, Carboxymethylcellulose Sodium, Tutti Frutti Art. Flavor 51880A, Disodium Edetate, FD&C Red # 40, Purified Water.

What does the medicine look like and what are the contents of the package:

Grape flavored suspension: a translucent, purple liquid packed in a 120 mL plastic bottle with a child resistant cap.

Fruit flavored suspension: a translucent, red suspension packed in a 60 mL or 120 mL plastic bottle with a child resistant cap.

Not all package sizes may be marketed.

Manufacturer and address:

Fareva Richmond Inc. Virginia, USA.

Marketing authorization holder and address:

GSK Consumer Healthcare Israel Ltd., P.O.box 3256, Petach Tikva.

Registration numbers of the medicine in the national drug registry of the Ministry of Health:

Grape flavored suspension: 122.43.30111

Fruit flavored suspension: 122.42.30110

Revised in January 2022 in accordance with the Ministry of Health guidelines.

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