

This medicine is dispensed without a doctor's prescription

Advil Liqui-Gels 200

Liquid Filled Capsules

Active ingredient – each capsule contains: Ibuprofen 200 mg

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.

Take the preparation according to the instructions in the dosage section of 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 within 10 days in adults and within 3 days in adolescents (12-18 years).

1. What is the medicine intended for?

For the relief of pain associated with headache, toothache, back pain, muscle pain and menstrual pain.

For the reduction of fever.

Anti-inflammatory in rheumatic diseases.

For the treatment of migraine-related pain.

Therapeutic class: Ibuprofen belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAID), that work by relieving pain and reducing inflammation, swelling and fever.

2. Before using the medicine

X Do not use this medicine if:

- You are sensitive (allergic) to ibuprofen, or to any of the other ingredients this medicine contains (see section 6).
- You are sensitive (allergic) to aspirin, or have narrowing of the airways, asthma, rhinitis, angioedema or urticaria associated with the use of medicines from the class of non-steroidal anti-inflammatory drugs (NSAIDs).
- You have a stomach ulcer or stomach bleeding or you have had two or more incidents of stomach ulcers or bleeding in the past. You have suffered in the past from intestinal bleeding or perforation because of treatment with this medicine or with medicines from the class of non-steroidal anti-inflammatory drugs (NSAIDs).
- You suffer from conditions of cerebral hemorrhage, other active bleeding or blood disease.
- You suffer from severe liver, kidney or heart failure.
- You are in the last trimester of pregnancy.

! Special warnings regarding the use of the medicine

Talk to the pharmacist or doctor if you:

- Are asthmatic or suffer from hay fever.
- Suffer from liver or kidney problems.
- Suffer from autoimmune diseases, including systemic lupus erythematosus (SLE) – a condition of the immune system which affects the connective tissue, causing joint pain, skin changes and disorders in other organs.
- Suffer or have suffered in the past from gastrointestinal disorders, such as ulcerated inflammation of the large intestine (Ulcerative Colitis) or Crohn's disease, because medicines such as ibuprofen may make these conditions worse.
- Are in the first 6 months of pregnancy.
- You are 12-18 years old, as there is a risk of renal impairment. Therefore, ask the doctor before use if a child or adolescent aged 12-18 years has not been drinking fluids or has lost fluids due to continuous vomiting or diarrhea.
- Have heart problems including heart failure, angina (chest pain) or if you have had a heart attack, bypass surgery, peripheral artery disease (a problem with blood circulation in the legs or feet due to narrowing or blockage of arteries) or any kind of stroke (including “mini-stroke” or transient ischemic attack – “TIA”).

- Have high blood pressure, diabetes, high cholesterol, a family history of heart disease or stroke, or if you are a smoker.
- Have an infection – please see subsection “Infections” in this section.

Medicines such as Advil Liqui-Gels 200 capsules may be associated with a small increase in the risk of heart attack (myocardial infarction) or stroke. The likelihood of any risk increases with high dosages and prolonged treatment. Do not exceed the recommended dose or duration of treatment. See section 3.

! Skin reactions

Serious skin reactions have been reported in association with taking this medicine. Stop taking this medicine and seek medical advice immediately if you develop any type of skin rash, lesions in the mucous membranes, blisters, or any other sign of allergy, as these can be the first signs of very serious skin reactions (see section 4).

! Infections

Advil Liqui-Gels 200 may mask signs of infection such as fever and pain. Therefore, Advil Liqui-Gels 200 may delay appropriate treatment of infections, which may lead to a higher chance of complications. Such cases have been observed in pneumonia caused by a bacterial infection and in bacterial skin infections associated with chickenpox. If you are taking this medicine while you have an infection and the symptoms of the infection persist or worsen, you should seek medical advice immediately.

! Drug interactions

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

Do not use this medicine if you are taking aspirin/acetylsalicylic acid at a daily dosage higher than 75 mg, or other non-steroidal anti-inflammatory drugs.

In particular, tell the doctor or pharmacist if you are taking:

- Anticoagulant medicines (i.e. blood thinners/medicines that prevent clotting, such as aspirin/acetylsalicylic acid, warfarin, ticlopidine), diuretic medicines (water tablets – increase the amount of urine your body produces).
- Medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan), or other medicines, as these may affect or be affected by treatment with ibuprofen.
- Other medicines such as corticosteroids (used in the management of asthma and to treat skin diseases and other conditions), anti-platelet preparations (commonly used to help prevent stroke or heart problems), cardiac glycosides (used in patients with heart problems), selective serotonin reuptake inhibitors (SSRIs) or lithium (used to treat depression), methotrexate (used to treat certain types of cancers, and to treat psoriasis or rheumatoid arthritis), ciclosporin or tacrolimus (used in patients undergoing organ transplants, and to treat certain skin disorders), zidovudine (used to treat HIV infection), quinolone antibiotic medicines (a class of antibiotic medicines used to treat certain infections), phenytoin (used to treat epilepsy), or antacids (used to treat indigestion).

Some other medicines may also affect or be affected by the treatment with Advil Liqui-Gels 200. Therefore, you should always consult a doctor or pharmacist before taking Advil Liqui-Gels 200 along with other medicines.

! Fertility, pregnancy and breastfeeding

Ibuprofen belongs to a class of medicines called NSAIDs, which may impair fertility in women. This effect is reversible after stopping the medicine. It is unlikely that occasional use of ibuprofen will affect your chances of becoming pregnant. However, if you have difficulty becoming pregnant or are trying to become pregnant, consult the doctor before using this medicine.

Consult the doctor before using ibuprofen if you are in the first 6 months of 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 and to consult a healthcare professional if necessary.

Do not use ibuprofen during the last 3 months of pregnancy.

Ibuprofen appears in breast milk in very low concentrations, but it is unlikely that the medicine will adversely affect the breastfed baby.

If you are breastfeeding, pregnant, think that you might be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

! Important information about some of the ingredients of the medicine

This medicine contains 50.1 mg of sorbitol in each liquid filled capsule. Sorbitol is a source of fructose. If you have been told by your doctor that you (or your child) have an intolerance to certain sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Advil Liqui-Gels 200 capsules contain soy lecithin. If you have an allergy to peanuts or soy, do not use this medicine.

3. How should you use the medicine?

This medicine is intended for short-term use only. You should always take the lowest dosage for the shortest period necessary to relieve your symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever or pain) persist or worsen (see section 2).

If you are 12 to 18 years old and the medicine is needed for more than 3 days or if the symptoms worsen, you should refer to a doctor.

If you are 18 years of age or older, do not take this medicine for more than 10 days unless your doctor tells you to. If the symptoms persist or worsen, consult your doctor.

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

The generally accepted dosage is:

For adults, the elderly and children and adolescents aged 12-18: one or two capsules, up to 3 times a day as required. The recommended interval between doses of the medicine is approximately 6 to 8 hours, and you must wait at least 4 hours between doses. Do not take more than 6 capsules (1,200 mg of ibuprofen) during any 24-hour period.

Swallow the capsules with water.

Do not halve, crush or chew the capsule. The capsule should be swallowed whole because it contains liquid.

Do not exceed the recommended dose.

If you have taken an excessive amount of Advil Liqui-Gels 200 or if a child has accidentally swallowed the medicine, refer to a doctor or go to the nearest hospital to get an opinion about the risk, and advice on the action required. Bring the medicine package which includes the remaining capsules with you to show the doctor.

The symptoms may include nausea, abdominal pain, vomiting (may include blood spots), headache, ringing in the ears, confusion and shaky eye movement. When taking large doses, there have been reports of sleepiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in the urine, cold body feeling and breathing problems.

If you have forgotten to take Advil Liqui-Gels 200

Do not take a double dose in order to compensate for a forgotten 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 Advil Liqui-Gels 200 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The following effects are very rare (frequency of less than 1:10,000), but if you experience any of these, stop taking this medicine immediately and refer to a doctor or pharmacist:

- Stomach ulceration or perforation: the symptoms may include severe abdominal pain, bloody vomit (granulated coffee-like liquid), blood in the stool or black stool.
- Inflammation of the membranes surrounding the brain (meningitis): the symptoms may include stiff neck, headache, nausea, vomiting, fever or a sense of confusion.
- Severe allergic reactions (which may be life-threatening). The symptoms may include sudden allergy

symptoms such as rash, itch or hives, fainting, hypotension, accelerated heart rate, swelling of the face, tongue and throat, shortness of breath, wheezing or breathing difficulties.

- Asthma/worsening of asthma and other breathing difficulties.
- Severe skin conditions that can appear in the mouth and other parts of the body. These may develop into a severe skin reaction that begins with painful red areas, followed by large blisters, and eventually peeling of skin layers around the mouth, nose, eyes or genitals. This condition can be accompanied by fever and chills, muscle pain and a general feeling of being unwell.
- Liver problems. The symptoms may include yellowing of the skin or of the whites of the eyes.

Medicines such as ibuprofen may be associated with a small increase in the risk of heart attack (“myocardial infarction”) or stroke.

Additional side effects

Less than one in 100 people may experience the following uncommon side effects:

- Allergic reactions such as hives, rash and itchy skin (or systemic lupus erythematosus – SLE).
- Abdominal pain, indigestion, heartburn and nausea.
- Headache or dizziness.

Less than one in 1,000 people may experience the following rare side effects:

- Diarrhea, flatulence, constipation and vomiting.

Less than one in 10,000 people may experience the following very rare side effects:

- Reduction in blood cells, which can cause pale or yellow skin, increased temperature, sore throat, superficial mouth ulcers, flu-like symptoms, fatigue or weakness, tendency to bruise or bleeding from the skin or nose.
- High blood pressure, heart failure or chest pain.
- Nervousness, visual disturbance, ringing in the ears and dizziness.
- Kidney problems: the symptoms may include swelling of the ankles.
- Severe skin reactions: the symptoms may include blisters.
- Blood in the urine, or foamy appearance of the urine.

Other very rare side effects with unknown frequency:

- Worsening of symptoms of inflammation of the large intestine and Crohn’s disease.
- A severe skin reaction known as DRESS syndrome can occur. The symptoms of DRESS include: Skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A widespread red and scaly rash with bumps under the skin and blisters located mainly in the skin folds, trunk and upper extremities, accompanied by fever at the beginning of treatment. Stop taking this medicine if you develop these symptoms and seek medical assistance immediately (see section 2).

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 your 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 through the following link: <https://sideeffects.health.gov.il>

In addition, you can report to GSK Israel by email to: il.safety@gsk.com

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. The expiry date refers to the last day of that month.

Store at a temperature below 25°C.

Do not discard medicines via wastewater or household waste. Consult the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients the medicine also contains:

Polyethylene glycol 600, Gelatin (Type 150), Sorbitan Sorbitol Solution (contains purified water, Sorbitan, D-sorbitol), Potassium hydroxide, Purified water, FD&C Green no.3, Ink [White Opacode (WB): Ammonium Hydroxide, Isopropyl alcohol, Purified water, Polyvinyl acetate phthalate, Propylene glycol, SDA 35A alcohol, Macrogol 400, Titanium dioxide], Lecithin blend/fractionated coconut oil.

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

A green, elliptical, soft gel capsule, with the word Advil printed in white ink on one side.

Advil Liqui-Gels 200 capsules are packed in:

White, round and opaque containers, containing: 16, 20, 40, 80 capsules.

Not all types of packages may be marketed.

Marketing authorization holder:

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

Manufacturer:

PF Consumer Healthcare Canada ULC, Quebec, Canada
for Pfizer Consumer Healthcare, a division of Pfizer Canada Inc., Canada.
or
Fareva Richmond Inc., Virginia, USA
for Pfizer, USA.

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

115-33-29761-21

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