

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

This medicine is dispensed without a doctor's prescription

Advil Forte 400

Liquid Filled Capsules

Active ingredient – each capsule contains: Ibuprofen 400mg (present as the free acid and potassium salt)

Inactive ingredients and allergens: see section 6 "Additional information" and section 2 "Before using the medicine" – sub-section "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 section 3 ("How should you use the medicine") 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).

Do not give to children under 12 years of age, except on the advice of the doctor.

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

1. What is the medicine intended for?

The medicine is intended for the relief of mild to moderate pain, such as: headache, treatment of headache associated with migraine, toothache, menstrual pain, back pain, muscle pain, anti-inflammatory in rheumatic diseases, reduction of fever.

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 preparation contains (see section 6 "Additional information"), to aspirin or to other NSAID pain relievers.
- You have or have had two or more separate occurrences of stomach ulcers or bleeding.
- You have suffered in the past from intestinal bleeding or perforation because of treatment with this medicine or other NSAIDs.
- You suffer from other bleeding conditions or blood disease.
- You suffer from severe liver, kidney or heart failure.
- You are in the last 3 months 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.
- You suffer from liver or kidney problems.
- You 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.
- You suffer or have suffered in the past from gastrointestinal disorders, such as ulcerative colitis or Crohn's disease, because medicines such as ibuprofen may make these conditions worse.
- You 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.

- You 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”).
- You have high blood pressure, diabetes, high cholesterol, a family history of heart disease or stroke, or if you are a smoker.
- You have an infection – please see the sub-section “Infections” below.

Medicines such as Advil Forte 400 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

Severe skin reactions have been reported in association with taking Advil Forte 400 capsules. Stop taking Advil Forte 400 capsules and seek immediate medical advice if you develop any type of skin rash, lesions in the mucous membranes, blisters or any other sign of allergy, as these may be the first signs of severe skin reactions (see section 4).

! Infections

Advil Forte 400 may mask signs of infection such as fever and pain. Therefore, Advil Forte 400 may delay proper treatment of infections, which may lead to a higher chance of complications. This has been observed in cases of pneumonia caused by a bacterial infection and in cases of bacterial skin infections associated with chickenpox. If you take this preparation while you have an infection and the symptoms of the infection persist or worsen, seek medical advice immediately.

! Smoking

Talk to the pharmacist or your doctor before taking Advil Forte 400 if you smoke.

Careful consideration should be exercised before initiating long-term treatment in patients with risk factors for cardiac event (e.g. smokers).

! Children and adolescents

Talk to the pharmacist or your doctor if 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 suffers from fluid loss due to continuous vomiting and diarrhea.

! Drug interactions

Do not use this medicine if you are taking aspirin/acetylsalicylic acid at a daily dosage higher than 75 mg, or other NSAIDs.

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

- Anticoagulants (i.e. blood thinners/medicines that prevent clotting, such as aspirin/ acetylsalicylic acid, warfarin, ticlopidine), diuretics (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 blockers 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 receiving organ transplants, and to treat certain skin disorders), zidovudine (used to treat HIV infection), quinolone antibiotics (a class of antibiotics 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 Forte 400. Therefore, you should always consult a doctor or pharmacist before taking Advil Forte 400 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 preparation has a possible side effect of kidney impairment in the fetus and low amniotic fluid volume 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 pregnant, breastfeeding, think that you might be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

! Driving and operating machinery

Effects on driving or operating machinery have not been examined.

At the recommended dosage and duration of treatment, no effects on driving or operating machinery are expected.

! Important information about some of the ingredients of the medicine

Advil Forte 400 capsules contain soy lecithin. If you are allergic to peanuts or soy, do not use this medicine.

Advil Forte 400 capsules contain 79.9 mg sorbitol (E-420) per 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.

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 the doctor without delay if symptoms (such as fever and 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 method of use.

The generally accepted dosage is:

For adults, the elderly and children and adolescents aged 12-18: one capsule, 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 3 capsules (1,200 mg of ibuprofen) during a 24-hour period.

Take 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 too much Advil Forte 400 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 remaining capsules with you to show to 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 somnolence, 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 Forte 400

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 Forte 400 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 in 10,000 people), 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 (may be life-threatening). The symptoms may include sudden allergy symptoms such as rash, itching or hives on the skin, fainting, hypotension, faster 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 itching on the 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 colitis 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 (acute generalized exanthematous pustulosis). Stop taking Advil Forte 400 if you develop these symptoms and seek immediate medical attention. 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 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. The expiry date refers to the last day of that month.

Even under the recommended packaging/storage conditions, medicines may be kept for a limited period only. Please note the expiry date of this medicine! In case of a doubt, consult the pharmacist who dispensed the medicine to you.

Store at room temperature, at a temperature below 25°C.

Do not discard medicines via wastewater or household waste. Consult the pharmacist on how to dispose of the medicine. These measures will help protect the environment.

6. Additional information

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

Macrogol 600, Gelatin, Purified Water, Sorbitol, Potassium Hydroxide, Opacode Black Ink, Phosal in Ethanol solution, Lecithin in triglycerides (medium chain), Triglycerides.

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

A colorless elliptical capsule, made of translucent gelatin with the number "400" printed in black ink. Contains clear liquid.

The capsules are packed in a tray with an aluminum cover inside a box.

The registered packages are: 4, 6, 8, 10, 12, 16, 20, 24, 30, 32, 36, 48, 50, 60, 96 or 100 capsules.

Not all package sizes may be marketed.

Marketing authorization holder: GSK Consumer Healthcare Israel Ltd., P.O.box 3256, Petach Tikva.

Manufacturer: Pfizer Consumer Manufacturing Italy S.R.L., Via Nettunense 90, Aprilia, Italy.

The leaflet was revised in June 2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 145
20 32014

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AdvFor PT v0.1