

Patient package insert according to Pharmacists' Regulations (Preparations), 1986

This medicine can be sold without a physician's prescription

IBUPRO 200/ IBUPRO FORTE 400, Caplets

Each caplet of **Ibupro 200** contains ibuprofen at a dose of 200 mg. Each caplet of **Ibupro Forte 400** contains ibuprofen at a dose of 400 mg.

Inactive ingredients: see section 6 "Additional Information".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

The medicine is intended for adults, children and adolescents over 12 years of age.

Take this medicine according to the instructions in section 3 "how to use this medicine" in this leaflet.

Consult your pharmacist if you need further information.

Contact a doctor if your symptoms worsen, or do not improve after 10 days for adults and 3 days for children and adolescents between 12 and 18 years.

1. What is the medicine used for?

Ibupro 200 / Ibupro Forte 400 are preparations intended for the treatment of headaches associated with migraine; for the relief of mild to moderate pain, such as: headache, toothache, menstrual pain, backache, muscle ache and anti-inflammatory for rheumatoid diseases. **Ibupro 200** is also intended for fever reduction.

Therapeutic group: Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before using the medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (ibuprofen), or to any of the other ingredients of this medicine (see section 6).
- You have had in the past an allergic reaction (such as asthma attacks, facial swelling, runny nose or hives [skin rash]) after taking aspirin or a similar pain reliever from the NSAID group.
- You suffer or have suffered in the past (two or more episodes) from a gastrointestinal ulcer or bleeding.
- You have suffered in the past from a gastrointestinal bleeding or perforation due to previous use of NSAIDs.
- You suffer from severe liver failure, severe kidney failure or severe heart failure.
- You are in the last three months of pregnancy.

Special warnings regarding the use of the medicine:

- **Before treatment with Ibupro 200 / Ibupro Forte 400, tell your doctor if:**
 - You suffer or have suffered in the past from asthma.
 - You suffer from kidney, liver or bowel problems.
 - You suffer from heart problems (such as heart failure, angina), have had a heart attack, bypass surgery, have suffered from peripheral arterial disease (poor circulation to the legs or feet due to constricted or blocked arteries), or have had any kind of stroke (including mini-stroke or transient ischaemic attack - TIA).
 - You suffer or have suffered in the past from high blood pressure, suffer from diabetes, high cholesterol, or if your family has a history of heart disease or stroke.
 - You have a history of gastrointestinal disease (such as ulcerative colitis or Crohn's disease).
 - You suffer from connective tissue diseases or from systemic lupus erythematosus (autoimmune condition causing joint pain, skin changes and other organ disorders).
 - You are about to undergo surgery (including dental surgery) since the medicine may increase the risk of bleeding.
 - You smoke.
 - You are in the first 6 months of pregnancy.
- **Additional warnings:**
 - Ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine.

Used occasionally, it is unlikely that this medicine will affect your chances of becoming pregnant; however, if you have problems becoming pregnant, consult your doctor before taking this medicine.

- Anti-inflammatory and pain-reliever medicines such as ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.
- There is a risk of renal impairment in dehydrated children and adolescents.

Elderly

Elderly patients have an increased tendency to develop side effects after taking medicines from the NSAID group, e.g. ibuprofen, and especially gastrointestinal bleeding or perforation, which may be fatal.

Drug Interactions:

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

- Other medicines containing NSAIDs (such as aspirin, ibuprofen). Do not take these medicines with **Ibupro 200 / Ibupro Forte 400** to reduce the risk of side effects. Low dose aspirin (up to 75 mg daily) may be taken only as recommended by a doctor.
- Steroids (to treat inflammatory conditions). Concomitant use may increase the risk of an ulcer or bleeding in the digestive system.
- Quinolone antibiotics.
- Anticoagulants (blood thinners/coagulation inhibitors e.g. aspirin/acet/salicylic acid, warfarin, ticlopidine).
- Medicines that stimulate the heart (e.g. cardiac glycosides - digoxin).
- Medicines for the treatment of high blood pressure (e.g. ACE inhibitors such as captopril, beta-blockers such as atenolol or angiotensin-II receptor antagonists such as losartan). Ibuprofen may reduce the effect of these medicines.
- Diuretics (ibuprofen may reduce the diuretic's effect).
- Medicines for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, tacrolimus).
- Medicines to treat mania or depression (e.g. lithium – used concomitantly, there is evidence for potential increase in plasma levels of lithium, or e.g. SSRIs- concomitant use may increase the risk of gastrointestinal bleeding).
- Medicines for pregnancy termination (e.g. mifepristone).
- Medicines to treat HIV (e.g. zidovudine).

Use of this medicine and food

Swallow the medicine with a glass of water. It can be taken with or without food.

Pregnancy, breastfeeding and fertility:

Tell your doctor if you become pregnant while taking **Ibupro 200 / Ibupro Forte 400**.

Do not take **Ibupro 200 / Ibupro Forte 400** during the last three months of pregnancy.

Consult a doctor before using the medicine if you are in the first 6 months of pregnancy.

If you are breastfeeding, consult a doctor or pharmacist before taking the medicine.

See section 2 - "Additional warnings" regarding the influence of the medicine on fertility.

Driving and using machines:

If used at recommended dose and therapy duration, effects that may influence these actions are not expected.

3. How to use this medicine

Ibupro 200 / Ibupro Forte 400 are intended for short term use only. You should take the lowest dose, for the shortest time necessary to relieve the symptoms. You should check with a doctor

or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual dosage is:

Adults and children over 12 years of age:

Ibupro 200: 1-2 caplets, up to 3 times a day. Leave at least 4 hours between doses. Do not take more than 6 caplets in 24 hours.

Ibupro Forte 400: One caplet up to 3 times a day. Leave at least 4 hours between doses. Do not take more than 3 caplets in 24 hours.

Do not exceed the recommended dose.

Dosage for children: Do not use the medicine in children under 12 years of age.

Treatment Duration

Consult a doctor if treatment is required for more than 3 days in children and adolescents between 12 and 18 years or if the symptoms worsen.

In adults, do not take the medicine for longer than 10 continuous days unless your doctor tells you to.

Consult your doctor or pharmacist if symptoms persist, if the pain or fever worsen, or if any new symptoms occur.

Method of administration: The medicine can be halved. Do not crush or chew the medicine to avoid its bitter taste. Swallow the medicine with a glass of water with or without food.

If you accidentally took a higher dose

If you accidentally took a higher dose, symptoms such as drowsiness or nausea, vomiting, abdominal pain, diarrhea, ringing in the ears, headache, gastrointestinal bleeding may appear.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or hospital emergency room, and bring the medicine package with you.

In cases of serious poisoning, there may be effects such as: disorientation, excitation or coma and occasionally convulsions. Exacerbation of asthma is possible in asthmatics.

If you forget to take the medicine

If you forget to take this medicine at the designated time, continue taking the medicine according to the above specified instructions. Do not take more than the usual dosage.

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

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

4. Side effects

Like all medicines, the use of **Ibupro 200 / Ibupro Forte 400** can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

The risk of side effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Stop taking the medicine and seek immediate medical help (hospital emergency room or a doctor) if the following side effects appear:

- Signs of gastrointestinal bleeding such as: bloody or black tarry feces, vomiting blood or dark particles that look like coffee grounds.
- Signs of serious allergic reaction, such as:
 - Difficulty breathing or unexplained wheezing.
 - Dizziness or fast heartbeat.
 - Severe skin reaction such as itchiness, rash, skin peeling or blistering (such as Stevens-Johnson syndrome).
 - Swelling of the face, tongue or throat.
- Signs of blood disorders: unexplained or unusual bleeding or bruising, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion.
- Signs of liver problems: such as stomach pain, jaundice (yellowing of skin and whites of the eyes) or passing dark brown urine.

Refer to the doctor if the following side effects appear:

- Fever, headache, a stiff neck, vomiting.
- Indigestion, abdominal pain, constipation, diarrhea, flatulence, nausea.
- Chest pain, fast or irregular heartbeat.
- Liver or kidney problems, associated with swelling of the arms and legs.

Medicines such as **Ibupro 200 / Ibupro Forte 400** may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. See section 2 "Additional warnings".

If a side effect appears, if any of the side effects worsen or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "דיווח על תופעות לוואי עקב תרופות" that can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects, or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

• **Storage conditions:** Store at a dry place, do not store at a temperature above 25°C.

6. Additional information

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

Ibupro 200:

Microcrystalline cellulose, Maize starch, Croscarmellose sodium, Magnesium stearate, Hypromellose, Carmellose sodium, Silica colloidal anhydrous, Talc, Stearic acid, Titanium dioxide E-171, Erythrosine aluminum lake E-127, Macrogol, Carnauba wax, Quinoline yellow aluminum lake E-104, Brilliant blue FCF aluminum lake E-133.

Ibupro Forte 400:

Microcrystalline cellulose, Maize starch, Croscarmellose sodium, Magnesium stearate, Carmellose sodium, Silica colloidal anhydrous, Hypromellose, Stearic acid, Titanium dioxide E-171, Talc, Macrogol, Carnauba wax.

What the medicine looks like and contents of the package:

Ibupro 200: Pink caplets scored on one side.

Ibupro Forte 400: White caplets scored on both sides.

Approved pack sizes:

Ibupro 200: 10, 16, 20, 30, 50, 100, 1000 caplets.

Ibupro Forte 400: 10, 20, 30, 50, 100, 1000 caplets.

Not all pack sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health in: May 2018.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Ibupro 200: 127-98-30762-00

Ibupro Forte 400: 127-97-30763-00

Manufacturer and registration holder:

Dexcel Ltd., 1 Dexcel St., Or-Akiva 3060000, Israel

Manufactured for and marketed by: Super-Pharm (Israel) Ltd., P.O.B. 2171, Herzliya 4672516

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