**Patient package insert according to Pharmacists' Regulations (Preparations) - 1986.**
This medicine can be sold without a physician's prescription.

# ADEX® 200 / ADEX® FORTE 400, Caplets

Each caplet of **Adex 200** contains Ibuprofen 200 mg.
Each caplet of **Adex Forte 400** contains Ibuprofen 400 mg.
Inactive ingredients and allergens in the medicine - see section 6 "Additional Information" and in section 2 "Important information about some of the ingredients of the medicine".
**Read this entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine is intended for adults, children and adolescents over the age of 12. Under this age, refer to a doctor.
Take this medicine according to the instructions in section 3 "How to use the medicine?" in this leaflet.
Consult the pharmacist if you need additional information.
Refer to the doctor if the symptoms worsen or do not improve within 10 days in adults and within 3 days in adolescents (12-18 years old).

## 1. What is the medicine intended for?

**Adex 200** / **Adex Forte 400** are intended for the treatment of headaches associated with migraine; for the relief of mild to moderate pain, such as headache, toothache, menstrual pain, backache, muscular pain and anti-inflammatory for rheumatic diseases. **Adex 200** is also intended for the reduction of fever.
**Therapeutic group:** Ibuprofen belongs to a group of medicines called Non–Steroidal Anti–Inflammatory Drugs (NSAIDs). These medicines act by changing the body's response to pain, swelling and high temperature.

## 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 this medicine contains (see section 6) or to aspirin or to other non–steroidal anti–inflammatory drugs (NSAIDs).
- You have suffered from gastrointestinal bleeding or perforation following the use of NSAID group medicines.
- You suffer or have suffered in the past from recurrent gastrointestinal ulcer (2 or more different cases of verified gastrointestinal ulcer or bleeding or other disorders in the digestive system).
- You have previously experienced hypersensitivity (such as bronchospasm, asthma, rhinitis, angioedema or urticaria) when taking ibuprofen, aspirin or other anti–inflammatory drug (of the NSAID group).
- You are under 12 years of age.
- You suffer from severe liver failure or severe renal failure or severe heart failure.
- You are in the last three months of pregnancy (see "Pregnancy, breastfeeding and fertility" section).

**Special warnings regarding the use of the medicine**
**Before treatment with Adex 200 / Adex Forte 400, tell the doctor if:**
- You suffer or have suffered in the past from asthma.
- You suffer from kidney or liver problems.
- You suffer from heart problems including heart failure, angina pectoris, or if you have previously had a heart attack, coronary artery bypass surgery, peripheral artery disease (impaired blood circulation from legs or feet as a result of narrowed or blocked arteries), or any kind of a stroke (including a “mini–stroke” or transient ischemic attack “TIA”).
- You suffer from gastrointestinal problems (such as Crohn's disease or ulcerative colitis).
- You suffer from high blood pressure, diabetes, high cholesterol, or if you have a history of heart disease or stroke or if you are a smoker.
- You suffer from a head injury, an unexplained bleeding or an increase in intracranial pressure.
- You suffer from connective tissue diseases such as systemic lupus erythematosus (lupus).
- You are above 65 years of age, since the elderly have a higher risk of suffering from side effects, such as stomach bleeding and perforation, which may be fatal.
- You are receiving medicinal treatment regularly.
- It is recommended to avoid the use of this medicine while you have chickenpox (Varicella).
- You suffer from infection, because ibuprofen may mask signs of infections such as fever and pain. It is therefore possible that this medicine will delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor immediately.
- You are an adolescent suffering from dehydration. In this case, there is a risk of renal damage.

**Additional warnings:**
- Anti-inflammatory/pain relief medicines such as ibuprofen, may be associated with a slight increase in the risk of a heart attack or stroke, especially when used at high doses. Do not exceed the recommended dose or duration of treatment.
- Serious skin reactions have been reported in association with ibuprofen treatment. You should stop taking this medicine and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy, these can be the first signs of a very serious skin reaction. See section 4.

**Drug Interactions:**

**If you are taking or have recently taken, other medicines including non-prescription drugs and nutritional supplements, tell the doctor or pharmacist.** Especially, if you are taking:
- Aspirin or other NSAID medicines (for example: COX–2 inhibitors).
- Corticosteroids (such as prednisolone) since they may increase the risk of an ulcer and gastrointestinal bleeding.
- Medicines for the treatment of heart failure such as digoxin.
- Medicines of the selective serotonin reuptake inhibitors group used to treat depression (SSRIs), since they may increase the risk of gastrointestinal side effects.
- Diuretics medicines, since medicines of the NSAID group may diminish their impact.

- Lithium (used to treat mania or depression) since a possible increase of lithium levels in the blood has been reported.
- Methotrexate (for cancer and rheumatism) since a possible increase of methotrexate levels in the blood has been reported.
- Hypoglycaemic medicines (oral medicines for the treatment of diabetes).
- Aminoglycosides (antibiotics).
- Probenecid (for the treatment of gout).
- Ciclosporin or Tacrolimus (immunosuppressive medicines) since there is a risk of nephrotoxicity increase.
- Zidovudine: there is an increased risk of hematoma and hemarthrosis in HIV(+) haemophilia patients being treated concurrently with zidovudine and ibuprofen.
- Quinolones (antibiotics) – since there is a risk of convulsions in patients treated with medicines of the NSAID group and antibiotics of the quinolone group.
- Anticoagulant medicines (for example blood thinners, such as aspirin, warfarin, ticlopidine).
- Antihypertensive medicines, such as beta–blockers (such as atenolol), ACE inhibitors (such as captopril) and angiotensin II antagonists (such as losartan).
- Mifepristone (used for termination of pregnancy).

**A number of other medicines may also affect or be affected by ibuprofen treatment. Therefore, always consult a doctor or pharmacist before taking this medicine with other drugs.**

**Use of the medicine and food**
The medicine can be taken with or without food.

**Pregnancy, breastfeeding and fertility**
- This medicine belongs to a group of medicines which may impair fertility in women. This is reversible upon discontinuing the medicine. The medicine may affect the chances of becoming pregnant. If you are planning to become pregnant or have had difficulties becoming pregnant, consult the doctor before using this medicine.
- This medicine has a possible side effect of renal injury in the foetus and low levels of amniotic fluid after the 20th week of pregnancy. It is recommended to avoid using NSAID group medicines from the 20th week of pregnancy.
- Consult the doctor if you are in the first 6 months of your pregnancy. Do not use this medicine if you are in the last 3 months of pregnancy.
- Ibuprofen may pass into breast milk in very low concentrations, it is unlikely that the medicine will affect your infant. There is no need to avoid breastfeeding during short-term treatment at the recommended dose.

**Driving and using machines**
There is no known effect of the medicine on driving and using machines.

**Use of the medicine in adolescents**
There is a risk of impaired renal function in adolescents suffering from dehydration.

**Important information about some of the ingredients of the medicine**
This medicine contains less than 1 mmol sodium (23 mg) per caplet, that is to say essentially ‘sodium free’.

## 3. How to use the medicine?

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

**The usual recommended dosage is:**

Adults and children over 12 years of age:
**Adex 200:** 1-2 caplets, up to 3 times a day. Wait at least 4 hours between doses. Do not take more than 6 caplets within 24 hours.
**Adex Forte 400:** One caplet up to 3 times a day. Wait at least 4 hours between doses. Do not take more than 3 caplets within 24 hours.
The medicine is not intended for children under 12 years old.
**Do not exceed the recommended dose.**

Adolescents (12–18 years old) – do not take the medicine for more than 3 days.
Adults – do not take the medicine for more than 10 days unless explicitly instructed by the doctor.
Take the lowest dose for the shortest time to relieve symptoms.
If the signs of your illness do not pass or worsen, or if new signs of illness (symptoms) appear, consult the doctor or pharmacist. If you suffer from infection and the symptoms (such as fever and pain) do not pass or become worse - refer to the doctor immediately (see section 2).

**Method of administration:** The caplets 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 taken a higher dosage** or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. The symptoms may include nausea, abdominal pain, vomiting (may be bloody), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, strong heartbeat, loss of consciousness, convulsions (especially in children), weakness and dizziness, blood in the urine, feeling cold in the body and breathing problems have been reported.

**If you forgot to take the medicine** at the set time, do not take a double dose. Take the next dose at the usual time and do not exceed the recommended dose.

**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 this medicine, consult a doctor or pharmacist.**

## 4. Side effects

Like any medicine, the use of **Adex 200** / **Adex Forte 400** may 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.

**Stop taking the medicine and refer to the doctor immediately at the occurrence of:**
• Signs of stomach or intestinal bleeding (bloody vomiting and/or black stools).

- Severe skin reaction such as skin peeling, for example Stevens-Johnson syndrome.
- Severe skin reaction known as DRESS syndrome (Drug Rash with Eosinophilia and Systemic Symptoms). DRESS symptoms include skin rash, fever, swelling of the lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities, accompanied by fever at the initiation of treatment (Acute Generalised Exanthematous Pustulosis, AGEP). Stop taking this medicine if you develop these symptoms and seek immediate medical help. See also section 2.

**Refer to a doctor if you suffer from:**
- Stomach problems, such as unexplained stomach pain, indigestion, nausea or vomiting, constipation, diarrhea, flatulence.
- Worsening of colitis and Crohn's disease.
- Stomach ulcers.
- Liver or Kidney problems.
- Severe sore throat accompanied by fever and flu–like symptoms, extreme exhaustion, bleeding from the nose or skin, mouth ulcers.
- Severe headache, stiff neck, nausea, vomiting, fever, confusion.
- Allergic reaction, such as unexplained wheezing, shortness of breath, swelling of the face, tongue or throat, palpitations, skin rash or itching (hives).
- Asthma, exacerbation of asthma or wheezing.
- Blood disorders, swelling (edema), high blood pressure, heart failure, blurred vision.
- Tendency to bruising or bleeding (thrombocytopenia – low platelet level).
- Severe skin infections and soft tissue complications during chicken pox (varicella).
- The skin becomes sensitive to light.

Side effects may be minimized by using low doses for a short time.
- Medicines such as **Adex 200** / **Adex Forte 400** may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.
- The elderly are at an increased risk of side effects.
- If you have a history of an allergic disease, you may suffer from shortness of breath.

Serious skin reactions (such as Stevens–Johnson syndrome) have been reported very rarely in association with the use of NSAIDs. Stop taking the medicine immediately at the first appearance of a rash, mouth ulcers or any other symptom of allergic reactions.
There is an increased risk of stomach bleeding, ulcers and perforation with increasing doses of NSAIDs in patients with a history of ulcers and the elderly. It is recommended to start treatment at the lowest dose. Consult the doctor regarding adding a medicine to protect the stomach.

**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.**

Side effects can be reported to the Ministry of Health by clicking the link " דיווח על תופעות לוואי עקב טיפול תרופתי" 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 link: https://sideeffects.health.gov.il

## 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored 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 (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at a dry place, below 25°C.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Additional information

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

**Adex 200:**

Microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium stearate, hypromellose, carmellose sodium, silica colloidal anhydrous, talc, stearic acid, titanium dioxide (E-171), erythrosine aluminium lake (E-127), macrogol 400, carnauba wax, quinoline yellow aluminium lake (E-104), brilliant blue FCF aluminium lake (E-133).

**Adex Forte 400:**

Microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium stearate, carmellose sodium, silica colloidal anhydrous, hypromellose, stearic acid, titanium dioxide (E-171), talc, macrogol 400, carnauba wax.

**What the medicine looks like and what the package contains:**

**Adex 200:** Pink caplets scored on one side.

**Adex Forte 400:** White caplets scored on both sides.

**Approved package sizes:**

**Adex 200:** 10, 16, 20, 30, 40, 50, 100, 1000 caplets.
**Adex Forte 400:** 10, 20, 30, 40, 50, 100, 1000 caplets.
Not all package sizes may be marketed.

Revised in August 2023 according to MOH guidelines.

**Drug registration number at the national drug registry of the Ministry of Health:**

**Adex 200:** 039-71-26007-00
**Adex Forte 400:** 110-28-29270-00

**Manufacturer and registration holder:**

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