

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

This medicine can be sold without a physician's prescription

Adex[®] Liquid Gel Capsules 200 - New

Each capsule contains ibuprofen 200 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.

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 of your illness get worse or if they do not improve or if use of the medicine continues for more than 10 days in adults and more than 3 days in adolescents (12-18 years).

1. What is the medicine intended for?

For the relief of mild to moderate pain, such as headache, toothache, menstrual pain, backache, muscular pain, and anti-inflammatory for rheumatic diseases. For the reduction of fever. For the treatment of migraine-related pain.

Therapeutic group: Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), that work by relieving pain and reducing inflammation, swelling, and fever.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (ibuprofen), or to any of the other ingredients this medicine contains (see section 6).
- You are hypersensitive (allergic) to aspirin, or if you suffer from airway constriction, asthma, rhinitis, angioedema or urticaria associated with the use of NSAID medicines.
- You suffer from an ulcer or bleeding in the stomach or have had two or more incidents of stomach ulcers or stomach bleeding in the past.
- You have suffered in the past from digestive system bleeding or perforation due to treatment with NSAID medicines.
- You suffer from cerebral haemorrhage, other active bleeding, or from a 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

Before treatment with Adex Liquid Gel Capsules, tell the doctor or pharmacist 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 that affects the connective tissue and causes joint pain, skin changes, and disorders in other organs.
- You suffer or have suffered in the past from digestive system disorders, such as Ulcerative Colitis or Crohn's Disease, because medicines such as ibuprofen can make these conditions worse.
- You are in the first 6 months of your pregnancy.
- You suffer from heart problems including heart failure, angina (chest pain), or if you have previously had a heart attack, bypass surgery, Peripheral Arterial Disease (a problem with the blood circulation in the legs or feet due to narrowing or blockage of arteries) or any type of stroke

- (including a "mini-stroke" or a Transient Ischemic Attack – "TIA").
- You suffer from high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
 - You suffer from an infection - please see subsection "Infections" in this section.

Immediately stop treatment with Adex Liquid Gel Capsules and immediately refer to the doctor or to a hospital if you notice symptoms of an allergic reaction, including difficulty breathing, swelling of the face and neck (angioedema), or chest pain (see section 4).

Medicines such as ibuprofen, may be associated with a slight increase in the risk of heart attack ("myocardial infarction") or stroke. The likelihood of any risk increases with higher dosage and prolonged treatment. Do not exceed the recommended dose or the recommended duration of treatment. See section 3.

Skin Reactions

Severe skin reactions including dermatitis involving extensive skin peeling, Erythema Multiforme, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Drug Rash with Eosinophilia and Systemic Symptoms Syndrome (DRESS syndrome), Acute Generalised Exanthematous Pustulosis (AGEP) have been reported as associated with the use of this medicine. Stop taking this medicine and seek immediate medical attention if you develop any kind of skin rash, sores in mucous membranes, blisters that may be associated with these conditions (see section 4).

Infections

Adex Liquid Gel Capsules may mask signs of infection such as fever and pain. Therefore, this medicine may delay appropriate treatment of infections, which may lead to a higher chance of complications. Such cases have been observed in cases of pneumonia caused by a bacterial infection and in cases of bacterial skin infections associated with chickenpox. If you are taking this medicine while having an infection and your infection symptoms persist or get worse, seek medical advice immediately.

Children and Adolescents

- Do not give the medicine to children under the age of 12, unless expressly instructed by the doctor.
- Between the ages of 12-18 there is a risk of kidney damage. Ask the doctor before use if a child or adolescent aged 12-18 is not drinking fluids or has lost fluids due to persistent vomiting or diarrhea.

Drug Interactions

Do not use this medicine if you are taking aspirin/acetylsalicylic acid at a daily dose higher than 75 mg or are taking other painkillers of the NSAIDs family.

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

Especially if you are taking:

- Anticoagulant medicines (blood thinners/medicines that prevent clotting, like aspirin/acetylsalicylic acid, warfarin, ticlopidine), diuretic medicines (increase the amount of urine your body produces).
- Medicines that lower high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-ii receptor antagonists such as losartan) or other medicines, as they may affect or be affected by treatment with ibuprofen.
- Other medicines such as corticosteroids (used for asthma management and to treat skin diseases and other conditions), antiplatelet medicines (usually used to help prevent stroke or heart problems), cardiac glycosides (used in patients with heart problems), Selective Serotonin Reuptake Inhibitors (SSRIs) (used to treat depression) or lithium (used to treat manic-depression), methotrexate (used to treat certain types of cancer 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 antibiotics (a type of antibiotic medicine 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 treatment with **Adex Liquid Gel Capsules**. Therefore, always consult a doctor or pharmacist before taking **Adex Liquid Gel Capsules** with other medicines.

Pregnancy, breastfeeding and fertility

Do not use **Adex Liquid Gel Capsules** if you are in the last 3 months of the pregnancy. Use of the medicine may cause fetal kidney and heart problems. This medicine may affect you and your baby's tendency to bleed and cause delayed or prolonged labor. **Adex Liquid Gel Capsules** should not be used **during the first 6 months of pregnancy, unless necessary and recommended by a doctor**. Starting from the 20th week of pregnancy onward, if taken for more than a few days, **Adex Liquid Gel Capsules** can cause fetal kidney problems, that may lead to low levels of amniotic fluid or to narrowing of the blood vessels in the fetus' heart. If you require treatment for longer than a few days, your doctor may recommend additional monitoring.

Ibuprofen appears in breast milk in very low concentrations, yet it is unlikely that the medicine will negatively impact the nursing infant.

Ibuprofen belongs to a group 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. Nevertheless, if you are having difficulty becoming pregnant or are trying to become pregnant, consult the doctor before using this medicine.

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

Driving and using machines

Effects on driving or using machines have not been tested.

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

Important information about some of the ingredients of the medicine

Adex Liquid Gel Capsules 200 contains about 56 mg of sorbitol in each capsule.

Sorbitol is a source of fructose. If the doctor has told you that you 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 the doctor before taking this medicine.

This medicine contains Ponceau 4R (E124), which may cause allergic reactions.

3. How to use the medicine?

This medicine is intended for short-term use only. You should always take the lowest dosage for the shortest time required to relieve your symptoms. If you have an infection and the symptoms (such as fever or pain) persist or become worse, refer to a doctor immediately.

If you are 12 to 18 years of age and the medicine is needed for more than 3 days or if the symptoms get worse, you should refer to the doctor.

If you are 18 years of age or older, do not take this medicine for more than 10 days unless explicitly instructed by the doctor. If the symptoms persist or get worse, consult a doctor.

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

The usual recommended 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 medication doses 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 ibuprofen) within a 24-hour period.

Method of administration

The capsules should be swallowed 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 accidentally taken a higher dosage

If you have accidentally taken an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room to get an opinion about the risk and advice on the required action. Bring the medicine package with you, including any remaining capsules, to show the doctor.

Symptoms may include nausea, stomach pain, vomiting (may include blood spots), headache, ringing in the ears, confusion, and shaky eye movement.

At high doses, there have been reports of drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in the urine, a feeling of being cold, and breathing problems.

If you have forgotten to take the medicine, do not take a double dose to make up for a forgotten 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 further questions on the use of this medicine, consult a doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Adex Liquid Gel Capsules** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

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

- Stomach ulcer or perforation: symptoms may include severe stomach pain, vomiting blood (or a liquid that looks like coffee grounds), bloody stool or black stool.
- Meningitis: symptoms may include stiff neck, headache, nausea, vomiting, or a sense of confusion.
- Severe allergic reactions (which can be life-threatening). Symptoms may include sudden symptoms of allergy, such as rash, itching or skin urticaria, fainting, low blood pressure, rapid pulse, swelling of the face, tongue and throat, shortness of breath, wheezing or difficulty breathing.
- Asthma/exacerbation of asthma and other breathing difficulties.
- Liver problems: symptoms may include yellowing of the skin or of the whites of the eyes. Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis Syndrome
- Skin symptoms such as skin redness without swelling, target-like or circular patches on the trunk, sometimes with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes. These severe skin rashes can be accompanied by fever and flu-like symptoms (Exfoliative Dermatitis, Erythema Multiforme, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- A red, scaly rash, with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the start of treatment (AGEP - Acute Generalized Exanthematous Pustulosis).

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

Additional side effects

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Allergic reactions such as urticaria, rash and itchiness of the skin (or Systemic Lupus

- Erythematosus - SLE).
- Stomach pain, indigestion, heartburn, and nausea.
- Headache or dizziness

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Diarrhea, flatulence, constipation, and vomiting.

Very rare side effects (effects that occur in less than 1 in 10,000 users):

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

Side effects of unknown frequency (effects for which a frequency has not yet been determined):

- Worsening of colitis and Crohn's Disease symptoms.
- Skin sensitivity to light.
- A severe skin reaction known as DRESS syndrome can occur. DRESS symptoms include: skin rash, fever, lymph node swelling and an increase in 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 start of treatment (Acute Generalised Exanthematous Pustulosis). If you develop these symptoms stop taking the medicine and seek immediate medical treatment (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 the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב" found on the home page 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 temperature below 25°C.
- Do not throw away any 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:

Macrogol 600, gelatin, sorbitol liquid, purified water, potassium hydroxide, ponceau 4R (E124), ink [opacode wb white ns-78-18011 (purified water, titanium dioxide (E171), propylene glycol, isopropyl alcohol, hypromellose 3cP)].

What the medicine looks like and what the package contains:

Transparent pink oval-shaped soft gelatin capsules with a white logo print.

Approved package sizes: 16, 20, 30, 40 capsules.

Not all package sizes may be marketed.

Revised in January 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health: 169-63-35888-00

Manufacturer and Registration Holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel.