



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

This medicine can be sold without a physician's prescription

### **ADEX<sup>®</sup> LIQUID GEL CAPSULES 400 – NEW**

Each capsule 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.

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 a doctor if the symptoms of your illness get worse or if they 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, unless advised by the doctor.**

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

#### **1. What is the medicine intended for?**

For the relief of mild to moderate pain, such as headache, toothache, menstrual pain, back pain and muscle pain. Anti-inflammatory in 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), to aspirin or to other NSAID pain relievers.
- You suffer from an ulcer or bleeding in the stomach or you had two or more separate incidents of stomach ulcers or bleeding in the past.
- You have suffered in the past from intestinal bleeding or perforation due to 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**

**Before treatment with Adex liquid gel capsules 400, tell the doctor or to 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 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 suffer from 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 suffer from high blood pressure, diabetes, high cholesterol, a family history of heart disease or stroke, or if you are a smoker.
- You suffer from an infection – please see sub-section "Infections" in this section.

**Medicines such as ibuprofen 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 immediate medical attention 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**

**Adex liquid gel capsules 400** may mask signs of infection, such as fever and pain. Therefore, **Adex liquid gel capsules 400** 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, seek medical advice immediately.

### **Smoking**

Talk to the doctor or the pharmacist before taking the medicine 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 doctor or the pharmacist 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**

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

**Do not use this medicine if you are taking aspirin/acetylsalicylic acid at a daily**

### **dosage higher than 75 mg or other NSAIDs.**

Especially, tell the doctor or the pharmacist if you are taking:

- Anticoagulant medicines (i.e. blood thinners/medicines that prevent clotting, such as aspirin/acetylsalicylic acid, warfarin, ticlopidine), diuretic medicines (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 antibiotics (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 **Adex liquid gel capsules 400**. Therefore, you should always consult a doctor or pharmacist before taking **Adex liquid gel capsules 400** along with other medicines.

### **Pregnancy, breastfeeding and fertility**

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 NSAID medicines 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 may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

### **Driving and using machines**

Effects on driving or using machines have not been examined.

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 400** contains about 96 mg sorbitol in each capsule. Sorbitol is a source of fructose. If the doctor has told you that you have an intolerance to some 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 a doctor before you take this medicine.

### **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 period necessary to relieve your symptoms. If you have an infection, consult a doctor without delay if the 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 the doctor.

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:**

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.

#### **Method of administration**

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 accidentally taken a higher dosage**

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room 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 high 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 forgot to take the medicine**, 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 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 liquid gel capsules 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 users), 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, itching or hives of the skin, 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**

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

- Allergic reactions, such as hives, rash and itchy skin (or systemic lupus erythematosus – SLE).
- Abdominal 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):

- 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.

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

- 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 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 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](http://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, potassium hydroxide, purified water, ink [opacode wb black ns-78-17821 (purified water, black iron oxide, propylene glycol, isopropyl alcohol, hypromellose 6cP)].

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

Transparent yellow oval soft gelatin capsules with black logo print

Approved package size: 20 capsules.

Revised in July 2023 according to MOH guidelines.

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

169 64 35847 00

**Manufacturer and registration holder:**

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