

Patient Package Insert according to Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed without a doctor's prescription

Exidol, caplets

Each caplet contains:
Acetylsalicylic acid 250 mg
Paracetamol 250 mg
Caffeine (anhydrous) 65 mg

Active ingredient and allergens in the medicine – see section 6 “Additional information”

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist. Take the medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require further information. Refer to the doctor if the symptoms of ailment worsen or do not improve after 5 days of treatment for pain or after 3 days of treatment for pain accompanied by fever (see section 3 “How to use the medicine”).

1. What is the medicine intended for?

Exidol is intended for temporary relief of headaches, mild to moderate headaches associated with migraines, menstrual pains and pain accompanied by fever.

Therapeutic group:

Acetylsalicylic acid - non-steroidal anti-inflammatory drug (NSAID). Paracetamol – analgesic and antipyretic. Caffeine - xanthine alkaloid, central nervous system stimulant.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredients or to any of the additional ingredients this medicine contains (see section 6 “Additional information”).
- **Symptoms of an allergic reaction** may include: asthma, wheezing or shortness of breath, a skin rash or hives, swelling of the face or tongue, runny nose. If you are not sure, ask your doctor or pharmacist.
- you are in the **last three months of pregnancy** (see below “Pregnancy, breastfeeding and fertility”).
- **you had an allergic reaction in the past to other medicines used to treat pain, inflammation or fever**, such as diclofenac or ibuprofen.
- **you suffer from a gastric or intestinal ulcer** or if you have a **history of digestive (peptic) ulcers**.
- you noticed **blood in your stools or black stools** (symptoms of bleeding or perforations in the digestive system).
- you suffer from **hemophilia or other blood disorders**.
- you suffer from **serious heart, liver or kidney problems**.
- You are taking **more than 15 mg of methotrexate per week** (see below “Drug interactions”).

Special warnings regarding the use of the medicine

Before treatment with Exidol tell the doctor if:

- you suffer from a **migraine so acute** that it **necessitates bedrest**, or if you have a headache that is different from your usual migraines, or if you suffer from **vomiting together with the migraine headaches**.
- you began to suffer from **headaches after or due to a head injury, exertion, cough or bending over**.
- you have chronic headaches (fifteen days or more in one month

for more than three months), or if you experienced your first headache after the age of 50.

- you have not been previously diagnosed as suffering from migraines, since potentially serious conditions that are related to the brain or nervous system should be ruled out prior to treatment.
- you suffer from a hereditary condition called **G6PD enzyme deficiency (glucose-6-phosphate dehydrogenase)** which affects the red blood cells and may cause anemia, jaundice or spleen enlargement upon exposure to certain foods and medicines such as certain anti-inflammatories (such as acetylsalicylic acid (aspirin)), or cause other illnesses.
- you have suffered in the past from **problems in the digestive system** such as a gastric ulcer, bleeding or black stools. If you have had abdominal discomfort or heartburn after taking analgesics or anti-inflammatories.
- you suffer from **bleeding disorders or abnormal vaginal bleeding** unlike menstruation (such as prolonged and heavy menstrual bleeding).
- you recently had **surgery** (including minor surgery such as dental surgery) or you are about to have surgery in the next seven days.
- you suffer from **adult asthma, hay fever (allergic rhinitis), nasal polyps, a chronic respiratory disease or you develop allergic symptoms** (such as skin reactions, itching, hives).
- you suffer from **gout, diabetes, hyperthyroidism, irregular heartbeat, uncontrolled hypertension, impaired kidneys or liver function**.
- you suffer from **alcohol addiction** (see below “Use of the medicine and alcohol consumption”).
- you are **taking other medicines that contain acetylsalicylic acid (aspirin) or paracetamol**, or other medicines, as certain medicines may interfere with Exidol and cause side effects (see below “Drug interactions”).
- you are in **danger of dehydration** (such as vomiting, diarrhea, or before or after major surgery).
- you are **less than 18 years old**. There is a possible association between acetylsalicylic acid (aspirin) and Reye's Syndrome when it is given to children and adolescents. Reye's syndrome is a rare syndrome that affects the brain and liver and can be fatal. For this reason, do not use Exidol in adolescents and children under 18 years old without an explicit instruction from the doctor.

Additional warnings:

As with taking any type of headache analgesics, taking Exidol too often (i.e., more than ten days per month for this medicine) when there are chronic headaches (fifteen days or more per month), for more than three months, may worsen your headache or migraine. If you think that this may be the case, refer to your doctor for advice. It may be necessary to stop taking Exidol in order to resolve the problem.

Exidol may reduce the symptoms of infection (such as headache, high fever) and therefore may make it harder to detect the infection. If you do not feel well and you need to refer to the doctor, remember to tell him that you are taking Exidol.

Children and adolescents

Exidol is not intended for children and adolescents under the age of 12.

Tests and follow-up

Exidol may affect the results of laboratory tests. If you have been asked to have blood, urine or other lab tests, remember to say that you are taking Exidol.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription drugs and nutrition

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

- **any other preparation that contains paracetamol, acetylsalicylic acid (aspirin), or any other analgesic/antipyretic.**
- **anticoagulants** such as oral anticoagulants (such as warfarin), heparin, thrombolytics (such as streptokinase), or other antiplatelets (ticlopidine, clopidogrel, clostazol).
- **sulfonylurea and insulin** (for the treatment of diabetes).
- **medicines for the treatment of gout.**
- **oral contraceptives.**
- **medicines for the treatment of epilepsy.**
- **barbiturates and benzodiazepines** (for the treatment of anxiety and insomnia).
- **metoclopramide** (for the treatment of nausea and vomiting).
- **certain medicines for the treatment of an infection** (such as rifampicin, isoniazid, chloramphenicol, ciprofloxacin, or piperimid acid).
- **levothyroxine** (for the treatment of hypothyroidism).
- **cholestyramine** (for the treatment of high cholesterol levels).
- **zidovudine** (for the treatment of human immunodeficiency virus (HIV)).
- **medicines for the treatment of hypertension and heart failure.**
- **lithium, selective serotonin reuptake inhibitors (SSRIs) or fluvoxamine** (for the treatment of depression).
- **theophylline** (for the treatment of asthma).
- **diuretics** (to increase urine production and reduce excessive fluids).
- **methotrexate** (for the treatment of certain types of cancer, arthritis or psoriasis).
- **corticosteroids** (used to relieve inflammation).
- **medicines for the treatment of slow gastric emptying** (such as propantheline).
- **clozapine** (for the treatment of schizophrenia)
- **sympathomimetic medicines** (to raise blood pressure or for the treatment of nasal congestion).
- **anti-allergy medicines** (for the treatment or relief of allergies).
- **terbinafine** (for the treatment of fungal infections).
- **cimetidine** (for the treatment of heartburn and peptic ulcer).
- **disulfiram** (for the treatment of alcohol dependency).
- **nicotine** (for cessation of smoking).

Use of the medicine and food

The recommended dose of this medicine contains a quantity of caffeine similar to that in a cup of coffee. While using the medicine, limit the intake of medicines, foods and drinks that contain caffeine as too much caffeine may cause irritability, restlessness, insomnia, and occasionally a rapid heartbeat. Take the medicine after a meal.

Use of the medicine and alcohol consumption

Avoid alcohol consumption while using the medicine. If you consume three or more alcoholic drinks every day, ask your doctor if you should take this medicine or other analgesics/antipyretics. Paracetamol and acetylsalicylic acid (aspirin) may cause damage to the liver and stomach bleeding.

Pregnancy, breastfeeding and fertility

If you are pregnant, think you may be pregnant or are planning to become pregnant, **tell your doctor and do not take Exidol**. It is especially important not to take Exidol during the last three months of pregnancy, as it may harm the fetus or cause problems during labor.

This medicine has a possible side effect of renal injury in the fetus and low levels of amniotic fluid as of the 20th week of pregnancy. It is recommended to avoid using medicines of the NSAIDs class as of the 20th week of pregnancy and consult a healthcare professional,

if necessary.

Exidol is not recommended during breastfeeding.

Consult the doctor or pharmacist before using any medicine.

Exidol belongs to a group of medicines (NSAIDs) that may impair fertility in women. This effect is reversible when stopping use of the medicine.

Driving and use of machinery

Taking Exidol has no known effect on your ability to drive and use machinery.

If you notice side effects such as dizziness or drowsiness, you should avoid driving and the use of machinery. Tell your doctor as soon as possible.

3. How should you use the medicine?

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

The usual recommended dosage is:

For treatment of migraine-related headache:

Adults: Two caplets. If the medicine was taken for migraine and there has been no improvement or it became worse after the first dose, consult the doctor.

Children under the age of 18: you should consult the doctor.

Do not take the medicine for more than 48 hours for treatment of a migraine.

For headaches, menstrual pain and pain accompanied by fever:

Adults and children over 12 years of age: 2 caplets every 6 hours. Pain relief may be felt within 15 minutes of taking the dose.

Do not take more than 8 caplets in 24 hours.

Do not exceed the recommended dose.

Do not use the preparation for more than 5 days for pain or 3 days for pain accompanied by fever without consulting the doctor. Elderly:

There is no special dosage recommendation. If you have low body weight you should consult the doctor or the pharmacist.

Swallow the caplet whole with a full glass of water.

Do not halve or crush the caplet. There is no information about halving/crushing/chewing.

Do not lie down for 15-30 minutes after taking the medicine.

Exidol caplets contain acetylsalicylic acid (aspirin), paracetamol and caffeine. Do not take more than the recommended dosage and do not take other medicines that may contain these ingredients or other ingredients that are used for the treatment of pain, inflammation or high fever (nonsteroidal anti-inflammatory drugs) while using Exidol.

If you have taken a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to the doctor or a hospital emergency room and bring the package of the medicine with you. Immediate medical treatment is critical, **in light of the possible risk of irreversible damage to the liver** caused by paracetamol. Do not wait for the appearance of symptoms because at the beginning the overdose may not cause noticeable symptoms.

- If symptoms of an overdose appear, they may be:
- for **acetylsalicylic acid (aspirin)**: dizziness, ringing in the ears, deafness, sweating, hyperventilation, high fever, nausea, vomiting, headache, confusion or unrest, circulatory collapse (of blood circulation) or respiratory failure.
 - for **paracetamol**: the first symptoms that may appear – nausea, vomiting, lack of appetite, paleness, drowsiness, sweating and afterwards stomachache.
 - for **caffeine**: anxiety, unrest, insomnia, excitement, muscle contraction, confusion, seizures, hyperglycemia, tachycardia (rapid heartbeat) or arrhythmia.

Even if these symptoms do not appear or if they disappear, it

is essential to seek medical assistance immediately.

If you forgot to take the medicine

Take the medicine as soon as you remember but do not take a double dose to compensate for a forgotten dose.

Do not take more than 8 caplets in 24 hours.

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

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

4. Side Effects

As with any medicine, the use of Exidol may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Discontinue the use of this medicine and refer to the doctor immediately if you experience one or more of the following serious side effects:

- an allergic reaction with swelling in the face, lips, mouth, tongue or throat. This may cause difficulty in swallowing, wheezing while breathing, breathing difficulties, and a feeling of pressure in the chest (signs of asthma). You may have a rash or itching, or experience fainting. A skin rash (including hives, itching), redness of the skin, blisters on the lips, eyes or mouth, peeling skin, sores, ulcers in the mouth.
- Bleeding in the stomach or intestines, gastric or intestinal ulcer, which may be accompanied by acute abdominal pain, bloody vomit, bloody or black stools. As with treatment with all analgesics and antipyretics, these effects may occur at any time during the treatment, without a previous history and may be fatal. This side effect is especially severe in the elderly.
- Yellowing of the skin or eyes (a sign of liver failure).
- Dizziness (signs of low blood pressure).
- Irregular heartbeat.

Additional Side Effects:

The following side effects were reported in 16 clinical trials that were carried out on more than 4,800 patients. Tell your doctor if you notice any of these side effects:

- Common side effects - appear in up to 1 out of 10 users:
- Nervousness, dizziness
 - Nausea, abdominal discomfort

Uncommon side effects - appear in up to 1 out of 100 users:

- Insomnia, tremor, numbness, headache
- Ringing in the ears
- Dry mouth, diarrhea, vomiting
- Tiredness, a feeling of nervousness
- Increase in the heart rate

Rare side effects - appear in up to 1 out of 1,000 users:

- Sore throat, difficulty swallowing, numbness or tingling around the mouth, excessive saliva
- Decreased appetite, altered sense of taste
- Anxiety, euphoria, stress
- Attention disorders, memory loss, changes in coordination (coordination of movements)
- Feeling pain in the cheeks and forehead
- Eye pain, visual disturbances
- Hot flashes, problems in peripheral blood vessels (such as in the arms or legs)
- Nose bleeds, slow and shallow breathing, rhinitis
- Burning, flatulence (gas)
- Excessive sweating, itching, itchy rash, increased skin sensitivity
- Muscle, bone, or joint rigidity; neck pain, backache, muscle cramps

- Weakness, chest discomfort

Side effects with unknown frequency (effects whose frequency has not yet been determined)

The following side effects have also been reported since the beginning of marketing the medicine. In general, the frequency during post-marketing surveillance cannot be determined precisely, therefore the frequency is indicated as "unknown":

- Restlessness, general bad or abnormal feeling
- Somnolence, migraine
- Skin redness, rash. Very rare cases of serious skin reactions have been reported.
- Palpitations, shortness of breath, sudden breathing difficulties and a feeling of tightness in the chest with wheezing or coughing (asthma)
- Abdominal pain, abdominal discomfort after meals
- Elevated liver enzymes

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

Reporting of side effects:

Side effects can be reported to the Ministry of Health via the link “Reporting Side Effects of Drug Treatment” that can be found on the home page of the Ministry of Health website (www.health.gov.il), directing to the online form of adverse events reporting, or via the following link: <https://sideeffects.health.gov.il>. In addition, side effects can be reported to Padagis via following address: Padagis.co.il.

5. How to Store the medicine

- Avoid poisoning! This medicine, and all other medicines, 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 (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at a temperature of up to 25°C.
- Can be used for 9 months after first opening, but not later than the expiry date.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional Information

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

Microcrystalline cellulose, hypromellose, stearic acid, crospovidone, titanium dioxide, pregelatinized starch, propylene glycol, povidone, carnauba wax, saccharin sodium, blue No. 1 FD&C lake.

What the medicine looks like and contents of the package:

The medicine is packed in vials containing 24, 50 or 100 white caplets with “L374” embossed on one side. Not all package sizes may be marketed. The package contains a desiccant. Do not swallow the desiccant or remove it from the bottle.

- **Registration Holder and address:** Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- **Manufacturer and address:** Perrigo Company, Allegan, Michigan, USA.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 13677.31055
- Revised in March 2022 according to MOH guidelines.

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