

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

**Excedrin caplets, 250 mg/250 mg/65 mg**



**Active ingredients and their amounts:**

Each caplet contains:

Acetylsalicylic acid     250 mg

Paracetamol                250 mg

Caffeine                     65 mg

For a list of inactive ingredients and allergens - see section 6.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Take the preparation according to the instructions in section 3 - How should you use the medicine. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 5 days of pain treatment or after 3 days of treatment of pain accompanied by fever (see section 3 - How should you use the medicine).

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

The medicine is intended for temporary relief of headaches, mild to moderate pain related to migraines, pain of menstrual discomfort and pain accompanied by fever.

**Therapeutic class:**

**Acetylsalicylic acid** - non-steroidal anti-inflammatory drug (NSAIDs)

**Paracetamol** - analgesic and antipyretic

**Caffeine** - xanthine alkaloid, central nervous system stimulant

**2. Before using the medicine**

**Do not use this medicine if:**

- **You are sensitive (allergic) to the active ingredients or to any of the additional components the medicine contains** (see section 6).  
**Symptoms of an allergic reaction** may include: Asthma, wheezing or shortness of breath, skin rash or hives, swelling of the face or tongue, runny nose. If you are unsure, ask your doctor or pharmacist.
- **You had an allergic reaction in the past to other medicines used to treat pain, inflammation or fever**, such as diclofenac or ibuprofen.
- You have **a stomach or intestinal ulcer**, or if you have a **history of peptic ulceration**.
- You have **observed blood in the stool or black stool** (symptoms of bleeding or perforations in the digestive tract).
- You are a **hemophiliac or suffering from other blood disorders**.
- You have **severe problems in the heart, liver and kidneys**.
- You are taking **more than 15 mg of methotrexate per week** (see the **Drug-drug interactions section**).
- You are **in the last three months of pregnancy** (see the "Pregnancy, breastfeeding and fertility" section).

## Special warnings regarding the use of the medicine

### ■ Before taking Excedrin, inform the doctor if:

- You have not been diagnosed with migraines in the past, since potentially severe conditions that are related to the brain or the nervous system should be ruled out before treatment.
- You have a **migraine so acute** that it **necessitates bedrest**, or if you have a headache that is different from your usual migraines, or if **the migraine headaches are accompanied by vomiting**.
- You started to have **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 have experienced your first headache after the age of 50.
- You are suffering from a hereditary condition called **G6PD (Glucose-6-Phosphate Dehydrogenase) deficiency**, which affects the red blood cells and may cause anemia, jaundice or spleen enlargement upon exposure to certain types of food and to medicines such as certain anti-inflammatory medicines (e.g. acetylsalicylic acid (aspirin)), or cause other illnesses.
- You had problems **in the digestive system** such as gastric ulcer, bleeding or black stool in the past. You had abdominal discomfort or heartburn after taking analgesics or anti-inflammatory medicines.
- You are suffering from **bleeding disorders or abnormal vaginal bleeding** that differs from your menstrual period (e.g., an unusually heavy and prolonged menstrual period).
- You have recently undergone a **surgical operation** (including minor ones such as dental surgery), or will undergo one within the next seven days.
- You have **adult asthma, hay fever (allergic rhinitis), nasal polyps, chronic respiratory disease or you are developing allergic symptoms** (such as skin reactions, itching, urticaria)
- You have **gout, diabetes, hyperthyroidism (overactive thyroid), arrhythmias, uncontrolled hypertension, impaired kidney or liver function**.
- You are **addicted to alcohol** (see the “Use of the medicine and food” section).
- You are **taking other medicines that contain acetylsalicylic acid (aspirin) or paracetamol**, or other medicines, since certain medicines may interfere with Excedrin and cause side effects (see the “Drug-drug interactions” section)
- You are at **risk of being dehydrated** (e.g. due to vomiting, diarrhea, or before or after a major surgery).
- **You are less than 18 years old**. There is a possible association between acetylsalicylic acid (aspirin) and Reye’s Syndrome when the medicine is given to children and adolescents. Reye’s Syndrome is a rare syndrome which affects the brain and the liver and can be fatal. For that reason, Excedrin should not be used in adolescents and children under 18 years old without an explicit instruction from the doctor.

### ■ Additional warnings:

As with any type of headache analgesics, taking Excedrin too often (i.e. more than ten days per month for this medicine) with concurrent chronic headaches (fifteen

days or more per month), for more than three months, could worsen your headache or migraine.

If you think this might be the case, consult with your doctor. You may have to stop taking Excedrin to resolve this problem.

Excedrin may reduce the symptoms of infection (e.g. headache, high temperature) and may therefore make it more difficult to detect. If you are feeling unwell and need to see a doctor, remember to inform him or her that you are taking Excedrin.

#### **❗ Children and adolescents**

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

#### **❗ Tests and follow-up**

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

#### **❗ Drug-drug interactions:**

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

- **Any other preparation that contains paracetamol, acetylsalicylic acid (aspirin) or any other analgesic/antipyretic.**
- **Medicines used to prevent blood clotting** such as oral anticoagulants (e.g. warfarin), heparin, thrombolytics (e.g. streptokinase) or other anti-platelets (ticlopidine, clopidogrel, cilostazol).
- **Corticosteroids** (used for relieving inflammation).
- **Barbiturates and benzodiazepines** (for treatment of anxiety and insomnia).
- **Lithium, SSRIs (Selective Serotonin Reuptake Inhibitors) or fluvoxamine** (for treatment of depression).
- **Sulfonylurea and insulin** (for treatment of diabetes).
- **Methotrexate** (for treatment of certain types of cancer, arthritis or psoriasis).
- **Certain medicines for treating infections** (e.g. rifampicin, isoniazid, chloramphenicol, ciprofloxacin or pipemidic acid).
- **Levothyroxine** (for treatment of hypothyroidism (underactive thyroid)).
- **Metoclopramide** (for treatment of nausea and vomiting).
- **Medicines for treatment of epilepsy.**
- **Medicines for treatment of hypertension and heart failure.**
- **Diuretics** (for increasing urine production and reducing excessive fluids).
- **Medicines for treatment of gout.**
- **Oral contraceptives.**
- **Zidovudine** (for treatment of human immunodeficiency virus (HIV)).
- **Medicines for treatment of slow gastric emptying**, such as propantheline.
- **Clozapine** (for treatment of schizophrenia).
- **Sympathomimetic agents** (for raising blood pressure or treating nasal congestion).
- **Anti-allergy medicines** (for treatment or relief of allergies).
- **Theophylline** (for treatment of asthma).
- **Terbinafine** (for treatment of fungal infections).
- **Cimetidine** (for treatment of heartburn and peptic ulcers).
- **Disulfiram** (for treatment of alcohol dependence).
- **Nicotine** (for smoking cessation).
- **Cholestyramine** (for treatment of high cholesterol levels).

**■ Use of the medicine and food:**

The recommended dose of this medicine contains an amount of caffeine similar to that in a cup of coffee. While using this medicine, limit your intake of caffeine-containing medicines, foods and beverages, because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat.

**■ Use of the medicine and alcohol consumption:**

You should refrain from alcohol consumption during treatment with this medicine. If you are consuming three or more alcoholic beverages a day, ask your doctor whether you should take this medicine or other medicines for relieving pain/lowering fever. Paracetamol and acetylsalicylic acid (aspirin) may damage the liver and cause stomach bleeding.

**■ Pregnancy, breastfeeding and fertility:**

If you are pregnant, think you might be pregnant or are planning to become pregnant, **inform your doctor and do not take Excedrin.**

It is especially important not to take Excedrin during the last three months of the pregnancy, since it may harm the fetus or cause problems during labor.

Excedrin is not recommended for breastfeeding mothers.

Consult with your doctor or pharmacist before taking any medicine.

Excedrin belongs to a group of medicines (NSAIDs) which may impair women's fertility. This effect is reversible when the medicine is stopped.

**■ Driving and operating machinery:**

Taking Excedrin has no known effect on your ability to drive and operate machinery. If you notice side effects such as dizziness or drowsiness, you should avoid driving and operating machinery. Tell your doctor as soon as possible.

**3. How should you use the medicine?**

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The generally accepted dosage is:

**For treatment of migraine-related headaches:**

Adults: Two caplets. If the medicine was taken for a migraine with no improvement, or if it became worse after one dose, consult a doctor.

Children under 18: Consult a doctor.

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

**For headaches, pain of menstrual discomfort and pain accompanied by fever:**

Adults and children over the age of 12 years: 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 this medicine for more than 5 days for pain or 3 days for pain with fever without consulting the doctor.

Elderly:

There are no special dosage recommendations. If you have low body weight, you should seek the advice of a doctor or a pharmacist.

The medicine should be swallowed whole with a full glass of water.

Halving/crushing/chewing:

The caplet should not be halved or crushed.

No information regarding halving/crushing/chewing is available.

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

Excedrin 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 for treatment of pain, inflammation or high fever (non-steroidal anti-inflammatory drugs) while using Excedrin.

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or the emergency room of a hospital immediately and take the package of the medicine with you.

Immediate medical treatment is critical, due to the possible risk of irreversible damage to the liver on account of the paracetamol. Do not wait for the appearance of symptoms, since in the beginning the overdose may not cause noticeable symptoms. If symptoms of overdose do appear, they may be:

- For **acetylsalicylic acid (aspirin)**: Dizziness, ringing in the ears, deafness, sweating, hyperventilation, high fever, nausea, vomiting, headache, confusion or restlessness, circulatory collapse or respiratory failure.
- For **paracetamol**: Initial symptoms that may appear are nausea, vomiting, loss of appetite, pallor, drowsiness, sweating and later abdominal pain.
- For **caffeine**: Anxiety, nervousness, restlessness, insomnia, excitement, muscle cramps, confusion, convulsions, hyperglycemia (high blood sugar), tachycardia (rapid heartbeat) or cardiac arrhythmia.

**Even if these symptoms do not appear or if they resolve, it is vital to seek medical help 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 every time you take a medicine. Wear glasses if you need them.**

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

#### **4. Side effects**

As with any medicine, using Excedrin 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.

**Discontinue treatment and contact a doctor immediately if you experience one or more of the following severe side effects:**

- An allergic reaction with swelling of the face, lips, mouth, tongue or throat. This may cause difficulty in swallowing, wheezing, breathing difficulties, and feeling of tightness in the chest (signs of asthma). You may also have a rash or itching, or you may faint.
- A skin rash (including hives, itching), skin redness, blisters in the lips, eyes or mouth, skin peeling, sores, mouth ulcers.
- Stomach or intestinal bleeding, stomach or intestinal ulcer, which may be accompanied by acute abdominal pain, bloody or black stool or bloody vomit. As with all analgesics and antipyretics, this can happen at any time during the treatment, without prior history, and may be fatal. This side effect is especially severe in the elderly.
- Yellowing of the skin or eyes (signs of liver failure).
- Dizziness (signs of low blood pressure).
- Irregular heartbeat.

### **Additional side effects**

The following side effects have been reported in 16 clinical trials done with Excedrin on more than 4800 patients.

Tell your doctor if you notice any of the following side effects:

Common side effects - side effects that occur in up to 1 out of 10 users:

- Nervousness, dizziness
- Nausea, abdominal discomfort

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

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

Rare side effects – side effects that occur in up to 1 out of 1,000 users:

- Sore throat, difficulty swallowing, numbness or tingling around the mouth, excessive saliva
- Decreased appetite, altered taste
- Anxiety, euphoric mood, stress
- Attention disorders, memory loss, changes in coordination
- Pain sensation in the cheeks and forehead
- Eye pain, vision disturbances
- Hot flashes, problems in peripheral blood vessels (such as in the arms or legs)
- Nose bleeds, slow and shallow breathing, runny nose
- Burping, flatulence
- Excessive sweating, itching, itchy rash, increased skin sensitivity
- Muscle, bone or joint rigidity, neck pain, back pain, 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 of Excedrin. In general, the frequency during post-marketing surveillance cannot be determined precisely, thus it is indicated as “unknown”:

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

**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 your doctor.**

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<https://sideeffects.health.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 without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C.

## **6. Additional information**

- In addition to the active ingredients, the medicine also contains:  
Cellulose microcrystalline, Hydroxypropyl cellulose low substitution, Hypromellose, Stearic acid, Titanium dioxide, propylene glycol, Carnauba wax, Benzoic acid
- What does the medicine look like and what are the contents of the package  
A white, oblong caplet, with the letter E embossed on one side, without a score line.  
Caplets are packed in blisters, in packs of 8, 10, 16, 20, 30, 32 or 50 caplets.

Not all package sizes may be marketed.

- License holder and the address: GSK Consumer Healthcare Israel Ltd., 25 Basel st., Petah Tikva.
- Name and address of the manufacturer: GSK Consumer Health SA, Nyon, Switzerland.
- This leaflet was reviewed and approved by the Ministry of Health in February 2014 and has been updated in accordance with the Ministry of Health instructions in March 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 114-82-31782