

## **Excedrin, Acetylsalicylic Acid 250mg, Paracetamol 250mg , Caffeine 65mg film-coated tablets**

**Acetylsalicylic Acid 250mg / Paracetamol 250mg / Caffeine 65mg**

**when should you not take this medicine or be extra careful with it?**

**When should you not use this medication?**

If you:

- are allergic (hypersensitive) to any of the ingredients in this medicine.
- have ever shown an allergic reaction to other medicines used to treat pain, inflammation or fever, such as acetylsalicylic acid and salicylates, or any other medicine that reduces fever and pain (NSAIDs such as diclofenac and ibuprofen). The reactions can be: asthma, wheezing or shortness of breath, skin rash or hives (rash on the skin with pink bumps and severe itching), swelling of the face or tongue, runny nose. If you are not sure, ask your doctor or pharmacist.
- have a stomach or intestinal ulcer or a history of peptic ulcer.
- have noticed blood in your stool or black stool (symptoms of gastrointestinal bleeding or perforation).
- have hemophilia or other blood disorders.
- have severe heart, liver, or kidney problems.
- take more than 15 mg methotrexate per week (see also Taking other medicines?).
- are in the last 3 months of pregnancy (see Pregnancy, breastfeeding and fertility).

**When should you be extra careful with this medicine?**

This medicine contains paracetamol. Do not take more than the recommended dose, as this can cause severe damage to your liver. Acetylsalicylic acid can cause bleeding. You should contact a doctor if you have unusual bleeding.

The following points are reasons why this medicine may not be suitable for you. Contact your doctor before taking this medicine if you:

- have not previously been diagnosed with migraines, as serious brain or nerve conditions need to be excluded before treatment.
- have a migraine so severe that you have to stay in bed, or a headache that is different from your usual migraine, or if you have to vomit during your migraine headache.
- start to get a headache after or caused by a head injury, exertion, coughing, or bending over.
- have chronic headaches (15 days or more per month for more than 3 months) or if you get your first headache after the age of 50.
- have liver or kidney problems, are underweight, or have been eating (nutrients) insufficiently for a long time, or if you regularly drink alcohol. You may not be able to use the medicine or may have to take less paracetamol.
- have a severe infection, have been eating (nutrients) insufficiently for a long time, are severely underweight, or have been drinking (too much) alcohol for a long time. This can cause a greater chance of your blood becoming acidic (metabolic acidosis). The symptoms of metabolic acidosis include: difficult, fast, and deep breathing, nausea, vomiting, less appetite. Contact a doctor immediately if you have multiple of these symptoms at the same time.
- suffer from an inherited disorder called glucose-6-phosphate dehydrogenase deficiency, a disorder that affects red blood cells and causes anemia, jaundice or enlargement of the spleen when exposed to certain foods, medicines such as anti-inflammatory drugs (such as acetylsalicylic acid), or other diseases.
- have ever had stomach or intestinal problems such as a stomach ulcer, bleeding or black stool. If you have ever had heartburn or acid reflux after taking painkillers or anti-inflammatory drugs.
- suffer from bleeding disorders or abnormal vaginal bleeding outside your menstrual periods.

### **Other precautions**

Like with any other type of pain reliever for headaches, taking this medication too often (meaning more than 10 days per month for this medication) can be associated with chronic headaches (15 days or more per month) that worsen your headaches or migraines for more than 3 months. If you think this may be the case, you should contact your doctor for advice. It may be necessary to stop taking this medication to resolve the problem.

This medication can reduce the symptoms of an infection (such as headache, high temperature), making it difficult to detect the infection. If you feel unwell and need to see a doctor, you should tell them that you are taking this medication.

This medication can affect the results of laboratory tests. If you need to undergo blood, urine, or other laboratory tests, you should tell them that you are taking this medication.

EXCEDRIN contains 0.03 mg benzoic acid (E210) in each tablet. Benzoic acid can worsen jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks old).

**Are you taking any other medicines?:** Are you taking any other medicines besides EXCEDRIN, have you recently taken them, or is there a possibility that you will be taking other medicines in the near future? Tell your doctor or pharmacist about it.

Especially tell your doctor if you are using any of the following medicines: another product that contains paracetamol, acetylsalicylic acid, another pain reliever, or another fever reducer. medicines used to prevent blood clotting ("blood thinners"), such as oral anticoagulants (such as warfarin), heparin, thrombolytics (such as streptokinase), or other platelet aggregation inhibitors (ticlopidine, clopidogrel, cilostazol). corticosteroids (used to reduce inflammation). barbiturates and benzodiazepines (used to treat anxiety and insomnia). lithium, selective serotonin reuptake inhibitors or fluvoxamine (used to treat depression). sulfonylurea derivatives and insulin (used to treat diabetes). methotrexate (used to treat certain forms of cancer, arthritis, or psoriasis). some medicines used to treat an infection (such as rifampicin,

isoniazid, chloramphenicol, ciprofloxacin, or piperimidic acid). levothyroxine (used to treat hypothyroidism). metoclopramide (used to treat nausea and vomiting). medicines for epilepsy. medicines for high blood pressure and heart failure. diuretics (used to increase urine production and reduce excess fluid). medicines to treat gout. oral contraceptives. zidovudine (used to treat HIV). medicines to treat slow stomach emptying, such as propantheline. clozapine (used to treat schizophrenia). sympathomimetics (used to raise low blood pressure or treat nasal congestion). medicines for allergy (used to prevent or relieve allergy symptoms). theophylline (used to treat asthma). terbinafine (used to treat fungal infections). cimetidine (used to treat heartburn and peptic ulcers). disulfiram (used to treat alcohol dependence). nicotine (used to quit smoking). cholestyramine (used to treat high cholesterol levels). flucloxacillin (antibiotics), as this can lead to a serious risk of blood and fluid abnormalities (metabolic acidosis with increased anion gap) that require urgent treatment. They can occur (sepsis can lead to organ damage), malnutrition, prolonged alcoholism, and with the use of maximum daily doses of paracetamol.

#### **What to watch out for with food, drink, and alcohol?**

- **Alcohol:** If you drink 3 or more glasses of alcohol per day, ask your doctor if you can take this medicine or other pain relievers/fever reducers. Paracetamol and acetylsalicylic acid can cause liver damage and stomach bleeding.
- **Caffeine:** The recommended dose of this medicine contains as much caffeine as a cup of coffee. Limit your intake of caffeine-containing medicines, foods, or beverages while taking this medicine because too much caffeine can cause nervousness, irritability, insomnia, and occasional rapid heartbeat.

**Pregnancy, breastfeeding, and fertility:** This medicine is not recommended for use during pregnancy. If you are pregnant, think you may be pregnant, want to become pregnant, or are breastfeeding, contact your doctor or pharmacist. Do not take this medicine. It is especially important not to take this medicine during the last 3 months of pregnancy, as it can harm your unborn child or cause problems during delivery.

Do not take this medicine if you are breastfeeding, as it could be harmful to your baby. Ask your doctor or pharmacist for advice before taking any medicine.

This medicine belongs to a group of medicines (NSAIDs) that can disrupt women's fertility. This effect is reversible upon discontinuation of the medicine.

**Driving and using machines:** As far as is known, taking this medicine does not affect your ability to drive or operate machinery. If you notice side effects such as dizziness or drowsiness, do not drive vehicles or operate machinery. Inform your doctor as soon as possible.

#### **How to take this medicine?**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Adults (18 years or older):

- **For the treatment of headaches:** Take 1 tablet with a full glass of water when the headache comes on. If necessary, you can take 1 more tablet 4 to 6 hours later. For more severe pain, take 2 tablets with a full glass of water when the headache comes on. If necessary, you can take 1-2 more tablets 4 to 6 hours later.

Do not use this medicine for headaches for more than 4 days without consulting your doctor.

- **For the treatment of migraines:** Take 2 tablets with a full glass of water when the migraine symptoms or migraine aura come on. If necessary, you can take 2 more tablets with 4 to 6 hours between doses. If your migraine does not improve within 2 hours after the first dose of 2 tablets of EXCEDRIN, you should consult a doctor.

Do not use this medicine for migraines for more than 3 days without consulting your doctor.

Do not take more than 6 tablets in 24 hours for the treatment of headache or migraine. This corresponds to 1500 mg of acetylsalicylic acid, 1500 mg of paracetamol, and 390 mg of caffeine. Long-term use, unless under medical supervision, can be harmful. Do not exceed the recommended dose. Use the lowest effective dose and do not use this medication longer than necessary to relieve your symptoms.

**Children and adolescents under 18 years of age:** EXCEDRIN should not be given to children and adolescents under 18 years of age (see When should you be extra careful with this medicine?).

**Elderly:** There are no special dosage recommendations. If you have a low body weight, ask your doctor or pharmacist for advice.

**Patients with kidney or liver problems:** You should inform your doctor if you have kidney or liver problems. Your doctor may need to adjust the time between doses or the duration of treatment. Do not take this medicine if you have severe liver or kidney problems.

**Have you taken too much of this medicine?:** These tablets contain acetylsalicylic acid, paracetamol, and caffeine. Do not take more than the recommended dosage and do not take other medicines that may contain these ingredients or other medicines to treat pain, inflammation, or fever (non-steroidal anti-inflammatory drugs) while using this medicine.

Contact your doctor or pharmacist or go to the nearest hospital if you think you have taken an overdose. Immediate medical attention is essential, given the possible risk of irreversible liver damage from paracetamol. Do not wait for symptoms to appear, as overdose may not cause clear symptoms at first.

**Did you forget to take this medicine?:** Take the dose as soon as you remember, but do not take a double dose to make up for a forgotten dose. Do not take more than 6 tablets over a period of 24 hours.

**Possible side effects.**

Like all medicines, this medicine can also have side effects, although not everyone experiences them. Stop taking this medicine and immediately tell your doctor if you experience any of the following serious side effects:

- allergic reaction with swelling of the face, lips, mouth, tongue, or throat. This can cause difficulty swallowing, wheezing, breathing difficulties, and a tight feeling in the chest (signs of asthma). You may also develop a rash or itching or faint.
- redness of the skin, blistering on the lips, eyes, or mouth, peeling of the skin or mouth ulcers.
- bleeding in the stomach or intestines, stomach or intestinal ulcers, which may be accompanied by severe stomach pain, bloody or black stools or vomiting blood. Like all painkillers and fever-reducing drugs, this can occur at any time during treatment, without a history, and can be fatal. This side effect is particularly serious in older people.
- yellowing of the skin or eyes (signs of liver failure).
- light-headedness or dizziness (signs of low blood pressure).
- irregular heartbeat.
- if you have had breathing problems before after taking acetylsalicylic acid or NSAIDs (non-steroidal anti-inflammatory drugs) and you get a similar reaction with this medicine.
- bleeding or bruising for an unknown reason.
- more frequent nosebleeds or bruising.
- your body is retaining water (your body is swelling).
- ringing in the ears or temporary hearing loss.
- changes in your behavior, feeling nauseous and vomiting (this may mean you have Reye's syndrome.
- This is a very dangerous disease).

The following side effects were reported in the 16 clinical studies conducted with this medicine in 4800 treated patients. Tell your doctor if you notice any of these other side effects:

**Common (occur in less than 1 in 10 users):** • nervousness, dizziness, • nausea, discomfort in the stomach

Uncommon (occur in less than 1 in 100 users): • insomnia, tremors, numbness, headache, • dry mouth, diarrhea, vomiting, • fatigue, feeling nervous, • faster heartbeat

**How to store this medicine?**

- Keep out of sight and reach of children.
- Do not use this medicine after the expiry date stated on the blister pack and the box after "EXP." The month and year are indicated. The last day of that month is the expiry date.
- Store below 25 °C.
- Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be disposed of in a responsible manner and will not harm the environment.