

PACKAGE LEAFLET: INFORMATION FOR THE USER

EXCEDRIN film coated tablets

Aspirin 250 mg, Paracetamol 250 mg and Caffeine 65 mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or your symptoms worsen or do not improve after 3 days for migraine and 4 days for headache.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What EXCEDRIN is and what it is used for
2. What you need to know before you take EXCEDRIN
3. How to take EXCEDRIN
4. Possible side effects
5. How to store EXCEDRIN
6. Contents of the pack and other information

1. What EXCEDRIN is and what it is used for

Each tablet of EXCEDRIN contains three active substances: acetylsalicylic acid (aspirin), paracetamol and caffeine.

- Acetylsalicylic acid (aspirin) and paracetamol reduce pain and fever, and acetylsalicylic acid (aspirin) also reduces inflammation.
- Caffeine is a mild stimulant and increases the effect of acetylsalicylic acid (aspirin) and paracetamol. EXCEDRIN is used for the acute treatment of headache and migraine attacks (symptoms such as headache, nausea, sensitivity to light and sound and functional disability) with or without aura.

2. What you need to know before you take EXCEDRIN

Do not take EXCEDRIN if you:

- are allergic (hypersensitive) to acetylsalicylic acid (aspirin), paracetamol, caffeine or any of the other ingredients of EXCEDRIN listed in section 6.

- have ever had an allergic reaction to other medicines used to treat pain, inflammation or fever, such as acetylsalicylic acid and salicylates, or any other anti-inflammatory medicines known as NSAIDs such as diclofenac or ibuprofen. Reactions may include asthma, wheezing or shortness of breath; skin rash or hives; 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 if you have a history of peptic ulceration.
- have noticed blood in your stools or black stools (symptoms of gastrointestinal bleeding or perforation).
- are a haemophiliac or suffering from other blood disorders.
- have severe heart, liver and kidney problems
- take more than 15 mg methotrexate per week (see Other medicines and EXCEDRIN)
- are in the last 3 months of pregnancy (see Pregnancy, breast-feeding and fertility)

Warnings and precautions:

EXCEDRIN contains paracetamol. Do not take more than the recommended dose as it may cause serious harm to your liver. Acetylsalicylic acid may cause bleeding. You must tell a doctor if you experience any unusual bleeding. The following are reasons why EXCEDRIN may not be suitable for you. Talk to your doctor before you take this medicine if you:

- have not been diagnosed with migraine before, as potentially serious conditions relating to the brain or nerves need to be excluded before treatment.
- have a migraine that is so severe as to require bed rest, or a headache different from your usual migraines, or if you have vomiting with your migraine headache.
- start having headaches after or caused by head injury, exertion, coughing or bending.
- have chronic headaches (15 days or more per month for more than 3 months), or if you experience your first headache after the age of 50.
- have liver or kidney problems are underweight or malnourished or regularly drink alcohol. You may need to avoid using the product altogether or limit the amount of paracetamol that you take.
- have a severe infection, are severely malnourished, are severely underweight, or are a chronic heavy alcohol user, as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include: deep, rapid, difficult breathing, feeling sick (nausea), being sick (vomiting), loss of appetite. Contact a doctor immediately if you get a combination of these symptoms.
- suffer from a hereditary condition called glucose 6-phosphate dehydrogenase deficiency that affects the red blood cells and could cause anaemia, jaundice or enlargement of the spleen when exposed to certain foods, medicinal products such as certain anti-inflammatory drugs (eg., acetylsalicylic acid (aspirin)), or to other diseases.
- have ever had gastrointestinal problems such as stomach ulcer, bleeding or black stools. If you have had stomach discomfort or heartburn after taking pain relievers or anti-inflammatory medicines in the past.

- suffer from bleeding disorders or abnormal vaginal bleeding other than your menstrual period (eg., unusually heavy and prolonged menstrual period).
- have recently undergone a surgical operation (including minor ones such dental surgery) or will undergo one within the next 7 days.
- have bronchial asthma, hay fever, nasal polyps, a chronic respiratory disease or develop allergic symptoms (eg., skin reaction, itching, urticaria).
- have gout, diabetes, hyperthyroidism, arrhythmia, uncontrolled hypertension, impaired kidney or liver function.
- have alcohol problems (see Taking EXCEDRIN with food and drinks).
- are already taking other medicinal products containing acetylsalicylic acid (aspirin) or paracetamol, or other medicines, since certain may interfere with EXCEDRIN and cause side effects (see Other medicines and EXCEDRIN).
- are at risk of being dehydrated (e.g. by vomiting, diarrhoea, or before or after major surgery).
- are less than 18 years of age. There is a possible association between acetylsalicylic acid (aspirin) and Reye's syndrome when given to children and adolescents. Reye's syndrome is a rare disease, which affects the brain and liver, and can be fatal. For this reason, EXCEDRIN should not be given to children or adolescents under 18 years unless specifically indicated by your doctor.

Other precautions

As with any type of painkiller for headaches, taking EXCEDRIN too often (meaning on more than 10 days per month for this product) with concurrent chronic headaches (15 days or more per month), for more than 3 months, could worsen your headache or migraine. If you think that this may be the case, please contact your doctor for advice. You may need to stop taking EXCEDRIN to resolve the problem. EXCEDRIN may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make it more difficult to detect. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking EXCEDRIN. EXCEDRIN may affect the results of laboratory tests. If you have been asked to have blood, urine or other laboratory testing, remember to tell that you are taking EXCEDRIN. EXCEDRIN contains 0.03 mg benzoic acid (E 210) per tablet. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Other medicines and EXCEDRIN

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following:

- any other medicinal product that contains paracetamol, acetylsalicylic acid (aspirin) or any other pain reliever/ fever reducer.
- medicines used to prevent blood-clotting ("blood thinners") such as oral anticoagulants (eg., warfarin), heparin, thrombolytics (eg., streptokinase), or other antiplatelets (ticlopidine, clopidogrel, cilostazol).
- corticosteroids (used to provide relief of inflammation).

- barbiturates and benzodiazepines (to treat anxiety and insomnia).
- lithium, selective serotonin reuptake inhibitors or fluvoxamine (to treat depression).
- sulphonylureas and insulin (to treat diabetes).
- methotrexate (to treat some kinds of cancer, arthritis or psoriasis).
- some medicines used to treat infection (eg., rifampicin, isoniazide, chloramphenicol, ciprofloxacin or pipemidic acid).
- levothyroxine (to treat hypothyroidism).
- metoclopramide (to treat nausea and vomiting).
- epilepsy medication. • high blood pressure and heart failure medication.
- diuretics (to increase urine production and reduce excess fluid).
- medicines to treat gout.
- oral contraceptives.
- zidovudine (to treat HIV).
- medicines to treat slow gastric emptying such as propantheline.
- clozapine (to treat schizophrenia).
- sympathomimetics (to raise low blood pressure or to treat nasal congestion).
- antiallergics (to prevent or relieve allergies).
- theophylline (to treat asthma).
- terbinafine (to treat fungal infections).
- cimetidine (to treat heartburn and peptic ulcers).
- disulfiram (to treat alcohol dependence).
- nicotine (used for smoking cessation)
- cholestyramin (to treat high cholesterol levels)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Taking EXCEDRIN with food and drinks

- Alcohol:

If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take this medicine or other pain relievers/fever reducers. Paracetamol and acetylsalicylic acid (aspirin) may cause liver damage and stomach bleeding.

- Caffeine:

The recommended dose of this medicine contains about as much caffeine as a cup of coffee. Limit your intake of caffeine-containing medications, foods, or beverages while taking this medicine because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat.

Pregnancy, breast-feeding and fertility

This medicine is not recommended during pregnancy. If you are pregnant or think you might be pregnant or are planning to have a baby, tell your doctor and do not take EXCEDRIN. It is especially important not to take EXCEDRIN during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Do not take EXCEDRIN if you are breast-feeding as it might be harmful for your infant.

Ask your doctor or pharmacist for advice before taking any medicine.

EXCEDRIN belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

Taking EXCEDRIN is not known to affect your ability to drive and use machines.

If you notice side effects such as dizziness or drowsiness, you should not drive or use machines. Tell your doctor as soon as possible.

3. How to take EXCEDRIN

Always take EXCEDRIN exactly as stated in this package leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults (18 years of age and older):

- For headache treatment:

Take 1 tablet with a full glass of water when headache pain appears. If needed, you can take another 1 tablet 4 to 6 hours later. In case of more intense pain, take 2 tablets with a full glass of water when headache pain appears. If needed, you can take another 2 tablets 4 to 6 hours later. Do not use EXCEDRIN for more than 4 days for headache without consulting your doctor.

- For migraine treatment:

Take 2 tablets with a full glass of water when migraine symptoms or migraine aura appear. If needed, you can take additional 2 tablets, with 4 to 6 hours between doses. If you get no migraine relief within 2 hours from the first 2-tablet dose of EXCEDRIN, you should seek the advice of a doctor. Do not use EXCEDRIN for more than 3 days for migraine without consulting your doctor.

For both headache and migraine treatment, do not exceed 6 tablets over a period of 24 hours. This corresponds to a dose of 1500 mg acetylsalicylic acid (aspirin), 1500 mg paracetamol and 390 mg caffeine.

Prolonged use except under medical supervision may be harmful.

Do not take more than the stated dose. Use the smallest dose that you need to treat your symptoms and use this medicine for the shortest period of time necessary.

Children and adolescents:

EXCEDRIN should not be given to children and adolescents under the age of 18 (see warnings and precautions).

Elderly:

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

Patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may need to adjust the dose interval or treatment duration. Do not take EXCEDRIN if you suffer from severe liver or kidney problems.

If you take more EXCEDRIN than you should

These tablets contain acetylsalicylic acid (aspirin), paracetamol and caffeine. Do not take more than the recommended dose and do not take any other medicines which may contain these ingredients or any other medicines used to treat pain, inflammation or fever (non-steroidal anti-inflammatory drugs) while using EXCEDRIN. Contact your doctor, pharmacist or go to the nearest hospital as soon as you think you might have taken an overdose. Immediate medical attention is critical, because of the potential risk of irreversible liver damage due to paracetamol. Do not wait for symptoms to appear as the overdose might not, at first, produce any noticeable symptoms.

Poison Information Centre: +353 (1) 809 2166.

If symptoms of overdose appear they could be:

- For acetylsalicylic acid (aspirin): dizziness, ringing in the ears, deafness, sweating, hyperventilation, fever, nausea, vomiting, headache, confusion or restlessness, circulatory collapse or respiratory failure.
- For paracetamol: the first symptoms that may appear are nausea, vomiting, lack of appetite, pallor, sleepiness, sweating, and later abdominal pain.
- For caffeine: anxiety, nervousness, restlessness, insomnia, excitement, muscle twitching, confusion, convulsions, hyperglycemia, tachycardia or cardiac arrhythmia. Even if these symptoms do not appear or if they vanish, it is essential to seek medical help immediately.

If you forget to take EXCEDRIN

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, EXCEDRIN can cause side effects, although not everybody gets them. Stop taking EXCEDRIN and tell your doctor immediately if you have any of these serious side effects:

- allergic reaction with swelling of the face, lips, mouth, tongue or throat. This may cause difficulty in swallowing, wheezing, difficulty in breathing and feelings of tightness in the chest (signs of asthma). You may also have a rash or itching and experience fainting.
- skin rash (including hives, itching), skin reddening, blistering of lips, eyes or mouth, skin peeling, sores, mouth ulcers.
- bleeding in the stomach or intestine, ulcer in stomach or intestine, which may be accompanied by severe stomach pain, bloody or black stools, or vomiting blood. As with all pain relievers and fever reducers, this can happen at any time during the treatment, without prior history, and may be fatal. This side effect is particularly serious in elderly people.
- yellowing of the skin or eyes (signs of liver failure).
- light-headedness or dizziness (signs of low blood pressure).
- irregular heart beat.
- have experienced breathing problems with acetylsalicylic acid or non-steroidal anti-inflammatories and experience a similar reaction with this product.
- unexplained bruising or bleeding.
- increase in the number of nosebleeds or bruising.
- swelling or water retention.
- ringing in your ears or temporary hearing loss.
- changes in behaviour, nausea and vomiting (it could be the sign of Reye's syndrome).

Below side effects were reported in the 16 clinical trials conducted with EXCEDRIN over 4800 treated subjects. Tell your doctor if you notice any of these other side effects:

Common (may affect up to 1 in 10 people):

- nervousness, dizziness
- nausea, abdominal discomfort

Uncommon (may affect up to 1 in 100 people):

- insomnia, trembling, numbness, headache
- dry mouth, diarrhoea, vomiting
- fatigue, feeling jittery
- heart rate increased

Rare (may affect up to 1 in 1,000 people):

- sore throat, difficulty in swallowing, numbness or tingling around the mouth, too much saliva
- decreased appetite, altered taste
- anxiety, euphoric mood, tension
- disturbance in attention, memory loss, altered coordination

- feeling of pain in the cheeks and forehead
- eye pain, vision disorder
- hot flushes, peripheral blood vessels problems (eg., in arms or legs)
- nose bleeds, slow and shallow breathing, runny nose
- eructation, flatulence
- excessive sweating, itching, itchy rash, increased skin sensitivity
- stiffness in muscles, bones or joints; neck pain, back pain, muscles spasms
- weakness, chest discomfort

Below side effects have also been reported since marketing EXCEDRIN. In general, frequency in post-marketing surveillance cannot be determined precisely, thus it is indicated as “not known”:

- restlessness, generally feeling unwell or not normal
- somnolence, migraine
- skin reddening, rash.

Very rare cases of severe skin reactions have been reported

- palpitations, breathlessness, sudden difficulty breathing and feeling of tightness in chest with wheezing or coughing (asthma)
- abdominal pain, stomach discomfort after meals
- increased liver enzyme
- swelling and irritation inside the nose
- renal problems

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store EXCEDRIN

- Keep this medicine out of the sight and reach of children.
 - Do not use EXCEDRIN after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
 - Do not store above 25°C.
 - Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
6. Further information What EXCEDRIN contains

- The active substances are: acetylsalicylic acid (aspirin), paracetamol, caffeine. Each film-coated tablet contains 250 mg acetylsalicylic acid (aspirin), 250 mg paracetamol and 65 mg caffeine.

- The other ingredients are: Tablet core: hydroxypropyl cellulose low substitution, cellulose microcrystalline (E460), stearic acid. Film-coating: hypromellose (E464), titanium dioxide (E171), propylene glycol, benzoic acid (E210), carnauba wax (E903).

What EXCEDRIN looks like and content of the pack

EXCEDRIN is a white, oblong-shaped, film-coated tablet with the letter “E” debossed on one side. The tablets are provided in blisters which are packed in boxes containing 10, 16, 20, 30 or 32 film-coated tablets. Not all pack sizes may be marketed.

Marketing authorisation holder:

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, City West Business Campus, Dublin 24, Ireland.

Manufacturer: Famar Italia S.P.A Via Zambelletti, 25 20021 Baranzate (MI), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Excedrinil 250 mg / 250 mg / 65 mg – Filmtabletten

Belgium: Excedryn, filmomhulde tabletten

Czech Republic: Excedrinil 250 mg/250 mg/65 mg potahované tablety

Germany: Paracetamol / ASS / Coffein Kopfschmerz & Migräne 250 mg / 250 mg / 65 mg Filmtabletten

Greece: Panmigran Ireland: Excedrin 250 mg / 250 mg / 65 mg film-coated tablets Luxemburg: Excedryn, comprimés pelliculés

The Netherlands: Excedrin, filmomhulde tabletten

Poland: Excedrin MigraStop Portugal: Excedrin Slovakia: Panadol Migréna

Spain: Excedite 250 mg / 250 mg / 65 mg comprimidos recubiertos con película

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