



Order – AWF	AWF 20529 – OTDC 343103
Reference	EXCEDRIN MIGRAINE 0010 TABS IE_310298_PIL
Format	163 x 420 mm – Recto/Verso
Pharma code	XXX
Colour	Pantone Reflex Blue U
Font	Helvetica World
Font min. size	8 pts
Reference MKT	XXXXXX
Production site	Gebze – TR
Reference SITE	XXXXXX
Pre-press	GSG408212 - JG - 25.09.2014
WARNING: Wrong display / print > switch overprint ON	



Verso

11 mm

11 mm

420 mm

163 mm

11 mm

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.

Children and adolescents:

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

Older people (over 65 years of age):

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 either of 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.

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 reddening, blistering of lips, eyes or mouth, skin peeling.
- 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.

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
- ringing in the ears
- 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
- palpitations, breathlessness, sudden difficulty breathing and feeling of tightness in chest with wheezing or coughing (asthma)
- abdominal pain, stomach discomfort after meals

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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, or 32 film-coated tablets. Not all pack sizes may be marketed.

Marketing authorisation holder:

Novartis Consumer Health Ltd, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey GU15 3YL, UK.

Manufacturer:

Novartis Consumer Health GmbH, Zielstattstraße 40, 81379 Munich (Germany).

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
Bulgaria: Excedrin 250mg / 250mg / 65mg
Филмирана таблетка
Czech Republic: Excedrinil
France: Excedrinil 250 mg/250 mg/65 mg comprimé pelliculé
Germany: Paracetamol/ASS/Coffein Kopfschmerz & Migräne 250 mg/250 mg/65 mg Filmtabletten
Greece: Excedrin
Ireland: Excedrin 250mg/250mg/65mg film-coated tablets
Italy: Cibalgina Emicrania Cefalea 250mg/250mg/65mg Compresa Rivestita Con Film
Luxemburg: Excedryn, comprimés pelliculés
The Netherlands: Excedrin, filmomhulde tabletten
Poland: Excedrin MigraStop
Portugal: Excedrin
Romania: Excedrinil 250 mg / 250 mg / 65 mg comprimate filmate
Slovakia: Excedrin
Spain: Excedite 250mg/250mg/65mg comprimidos recubiertos con película
United Kingdom: Excedrinil tablets

This leaflet was last approved on: September 2014

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