



Migraine and Headache Relief

250 mg / 250 mg / 65 mg film coated tablets

Aspirin, paracetamol and caffeine

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:

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2. Check before you take Panmigrol Migraine and Headache Relief film coated tablets
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1. What Panmigrol Migraine and Headache Relief film coated tablets do

Each tablet of Panmigrol Migraine and Headache Relief 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. Panmigrol Migraine and Headache Relief 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. Check before you take Panmigrol Migraine and Headache Relief film coated tablets



Do not take Panmigrol Migraine and Headache Relief film coated tablets if you:

- **are allergic (hypersensitive) to acetylsalicylic acid (aspirin), paracetamol, caffeine or any of the other ingredients** of Panmigrol Migraine and Headache Relief listed in section 6.
- **are taking any other prescription or non prescription medicines containing paracetamol** to treat pain, fever, symptoms of cold and flu, or to aid sleep.
- **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 haemophilic or suffering from other blood disorders**.
- **have severe heart, liver and kidney problems**
- **are in the last 3 months of pregnancy** (see *Pregnancy, breast-feeding and fertility*)



Ask 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.
- 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).

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- have **gout, diabetes, hyperthyroidism, arrhythmia, uncontrolled hypertension, impaired kidney or liver function**.
- have **alcohol problems** (see *Taking Panmigrol Migraine and Headache Relief with food and drinks*).
- **are already taking other medicinal products containing acetylsalicylic acid (aspirin) or paracetamol**, or other medicines, since certain may interfere with Panmigrol Migraine and Headache Relief and cause side effects (see *Other medicines and Panmigrol Migraine and Headache Relief*).
- 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, Panmigrol Migraine and Headache Relief should not be given to children or adolescents under 18 years unless specifically indicated by your doctor.

- have **severe infection or illnesses**, including **severe renal impairment or sepsis** (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from **malnutrition**, are **severely underweight**, suffer from **chronic alcoholism** or if you are also **taking flucloxacillin** (an antibiotic). A serious condition called **metabolic acidosis** (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. **Symptoms of metabolic acidosis may include:** serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea), being sick (vomiting) and loss of appetite.

Contact a doctor immediately if you get a combination of these symptoms.

Other precautions

Acetylsalicylic acid (aspirin) may cause bleeding. You must tell a doctor if you experience any unusual bleeding. When taking acetylsalicylic acid, serious allergic reactions which may include chest pain and even heart attack (Kounis syndrome) have been reported (see section 4). Seek medical care immediately when you notice chest pain with allergic reactions (such as skin rashes, shortness of breath).

As with any type of painkiller for headaches, taking Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief to resolve the problem.

Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief.

Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief.

Panmigrol Migraine and Headache Relief 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).



If you are taking other medicines

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 (called metabolic acidosis) that must have urgent treatment (see section 2).
- **carbonic anhydrase inhibitors**, such as acetazolamide (to treat glaucoma, seizure, or to increase urine production).

Taking Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief**. It is especially important not to take Panmigrol Migraine and Headache Relief during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Do not take Panmigrol Migraine and Headache Relief if you are breast-feeding as it might be harmful for your infant. Ask your doctor or pharmacist for advice before taking any medicine.

Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief film coated tablets

Always take Panmigrol Migraine and Headache Relief 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.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Adults (18 years of age and over):

• 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 Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief, you should seek the advice of a doctor.

Do not use Panmigrol Migraine and Headache Relief 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:

Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief if you suffer from severe liver or kidney problems.

If you take too many tablets

Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

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 Panmigrol Migraine and Headache Relief

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, Panmigrol Migraine and Headache Relief can cause side effects, although not everybody gets them.

Stop taking Panmigrol Migraine and Headache Relief 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.
- Chest pain with allergic reactions (such as skin rashes, shortness of breath); this can be a sign of a potentially serious allergic reaction (Kounis syndrome) (frequency not known).
- 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 Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief.

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
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Panmigrol Migraine and Headache Relief film coated tablets

- **Keep this medicine out of the sight and reach of children.**
- Do not use Panmigrol Migraine and Headache Relief 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 Panmigrol Migraine and Headache Relief contains

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.

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 Panmigrol Migraine and Headache Relief looks like and content of the pack

Panmigrol Migraine and Headache Relief 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 film coated tablets.

Marketing authorisation holder:

Haleon UK Trading Limited, The Heights, Weybridge, KT13 0NY, U.K. and all enquiries should be sent to this address.

Manufacturer:

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

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