

Panadol with Caffeine

Film coated tablets

Paracetamol 500mg

Caffeine 65mg

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Panadol with Caffeine tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT PANADOL WITH CAFFEINE IS AND WHAT IT IS USED FOR

Panadol with Caffeine tablets are used for the fast and effective relief of headache, migraine, backache, rheumatic pain, muscle pain, toothache and period pain. They also relieve discomfort in colds, flu, and sore throat and help reduce temperature.

Panadol with Caffeine tablets contain paracetamol which is an analgesic (a pain killer which reduces aches and shivers) and an antipyretic (it reduces body temperature when you have a fever); and caffeine which acts to further help the effectiveness of paracetamol.

2. BEFORE YOU TAKE PANADOL WITH CAFFEINE Do not take Panadol with Caffeine:

- If you are allergic to paracetamol, caffeine or any of the other ingredients (listed in Section 6).
- if you are taking any **other medicines containing paracetamol**
- If you are under 12 years of age.

Take special care and tell your doctor before taking this medicine if you:

- have liver or kidney problems including **alcoholic liver disease**, are **underweight (<50kg)** or **malnourished** or **regularly drink alcohol**. You may need to **avoid** using this product altogether or **limit the amount** of paracetamol that you take (see section 3).
- have severe dehydration
- are taking medicines that affect your liver
- have a **severe infection** 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.

Taking other medicines with Panadol with Caffeine

- Talk to your doctor or pharmacist before taking these tablets if you are taking any other medicines; particularly **metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick]) or **cholestyramine** (to lower **blood cholesterol**) or **flucloxacillin** (antibiotic). If you take **blood thinning drugs** (**anticoagulants** e.g. **warfarin**) and you need to take a pain reliever on a daily basis, talk **to your doctor** because of the risk of bleeding. But you can still take **occasional** doses of Panadol with Caffeine tablets at the same time as anticoagulants.

This product is not recommended if you are taking lithium.

Pregnancy and breastfeeding

Not recommended for use during pregnancy or breastfeeding.

3. HOW TO TAKE PANADOL WITH CAFFEINE

Adults, (including the elderly) and children aged 16 years and over:

Take 1-2 tablets every 4-6 hours as required. Do not take more than 8 tablets in 24 hours.

Do not take more than 4 tablets a day in the following situations, unless directed by your doctor:

- Weight less than 50kg
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

Children aged 12 -15 years:

Take 1 tablet every 4-6 hours as required. Do not take more than 4 tablets in 24 hours.

Do not exceed the stated dose and do not take more frequently than every 4 hours.

Do not give to children under 12 years.

Contains paracetamol.

Taking too much paracetamol can cause serious harm to your liver.

Always use the lowest effective dose to relieve your symptoms.

Avoid too much caffeine in drinks like tea and coffee. High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.

Prolonged use, except under medical supervision may be harmful. This medicine should only be taken when necessary.

If you have a high fever, or if symptoms get worse or persist for longer than 3 days, consult your doctor.

If you take more Panadol with Caffeine than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of irreversible liver damage.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Panadol with Caffeine can cause side effects, although not everybody gets them.

Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and tell your doctor immediately if:

- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- You experience a skin rash or peeling, or mouth ulcers.
- You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar experience with this product.
- You experience unexpected bruising or bleeding.

These reactions are very rare.

Other side effects include: insomnia, restlessness, anxiety, irritability, headaches, upset stomach, palpitations, nervousness and dizziness.

Excessive intake of coffee or tea with these tablets may make you tense and irritable.

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 PANADOL WITH CAFFEINE Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date (EXP) which is shown on the outer carton and blister. The expiry date refers to the last day of that month.

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 Panadol with Caffeine looks like and contains**

Panadol with Caffeine are white, capsule shaped, film-coated tablets.

Active ingredients: Each tablet contains Paracetamol 500mg and Caffeine 65mg.

Other ingredients: Pregelatinised and maize starch, povidone, potassium sorbate, talc, stearic acid and croscarmellose sodium. The film coat contains: hypromellose and triacetin.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Panadol with Caffeine contains 4, 6, 12, 16, 24, 30, 48, 60 or 96 tablets in blister strips. Not all pack sizes may be marketed.

The product authorisation holder is:

Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24 and all enquiries should be sent to this address.

The manufacturer is:

GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Ireland.

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