

Product information leaflet

Panadol ActiFast tablets 500mg paracetamol

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 ActiFast tablets carefully to get the best results from them.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your pharmacist.

In this leaflet:

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1. What Panadol ActiFast tablets are and what they are used for

Panadol ActiFast tablets are used for fast pain relief of headaches, toothache, backache, rheumatic and muscle pains and period pain.

It also relieves sore throat and the feverishness, aches and pains of colds and flu.

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

The tablets have been specially formulated so that the paracetamol is absorbed into the bloodstream twice as fast as standard paracetamol tablets and so gets to the source of pain fast.

2. Check before you take Panadol ActiFast tablets

Do not take Panadol ActiFast tablets:

- if you have ever had an allergic reaction to paracetamol or to any of the other ingredients (listed in Section 6).
- if you are taking any other medicines containing paracetamol.
- if you are under 12 years. Check with your doctor before use if you:
 - have liver or kidney problems, including alcoholic liver disease
 - are underweight or malnourished
 - regularly drink alcohol
- need 2 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet. Each tablet contains 176mg of sodium.
- 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. You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

If you are taking other medicines:

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]); colestyramine (to lower blood cholesterol).

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.

However you can still take occasional doses of Panadol ActiFast tablets at the same time as anticoagulants.

Please inform your doctor or pharmacist if you are taking 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.

Pregnancy and breastfeeding

If necessary, Panadol ActiFast can be used during pregnancy.

You should use the lowest possible dose for the shortest time possible.

Contact your doctor if the pain and/or fever are not reduced.

You can take this product whilst breastfeeding.

3. How to take Panadol ActiFast tablets

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

Take 1-2 tablets with half a glass of water (100ml), every 4-6 hours as required.

Children aged 12 - 15 years:

Give 1 tablet with half a glass of water (100 ml), every 4-6 hours as required.

Do not give to children for more than 3 days without consulting a doctor.

Children under 12 years:

Do not give to children under 12 years of age.

- **Contains paracetamol**
- Do not take more frequently than every 4 hours.

- **Do not take more than 4 doses in 24 hours.**
- **Do not take more than the recommended dose.**
- **If symptoms persist consult your doctor.**
- **Always use the lowest effective dose to relieve your symptoms.**

If you take too many tablets

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

4. Possible side effects

Like all medicines Panadol ActiFast tablets can have side effects, but 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 severe skin rash or peeling of the skin which may be accompanied by mouth ulcers.
- you may have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction to this product.
- you experience unexplained bruising or bleeding.

These reactions are very rare.

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 and dispose of Panadol ActiFast tablets

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 the blisters.

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

Active ingredient Each tablet contains Paracetamol 500mg.

Other ingredients Sodium hydrogen carbonate, starch pregelatinised, povidone, maize starch, microcrystalline cellulose, magnesium stearate, sodium starch glycolate, colloidal anhydrous silica, carnauba wax, titanium dioxide (E 171), polydextrose, hypromellose, triacetin and macrogol.

Panadol ActiFast tablets are white to off-white, capsule shaped, film-coated tablets and are marked with 'P' on one face and '--' on the other face.

Panadol ActiFast tablets are produced in packs of 4, 6, 8, 10, 12, 16, 20, 24 or 32 tablets.

Not all pack sizes may be marketed.

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

The manufacturer is Haleon Ireland Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, X35 RY76, Ireland.

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