

Panadol Sinus Relief

Film coated tablets

Paracetamol 500mg

Caffeine 25mg

Phenylephrine Hydrochloride 5mg

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 Sinus Relief tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- If you have any questions, or there is anything you do not understand, ask your pharmacist.

IN THIS LEAFLET:

1. What Panadol Sinus Relief is and what it is used for
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1. WHAT PANADOL SINUS RELIEF IS AND WHAT IT IS USED FOR

Panadol Sinus Relief provide effective relief from the major cold and flu symptoms. These symptoms include headache, shivers, aches and pains, blocked nose and painful sinuses, catarrh, sore throat, fatigue and tiredness.

Panadol Sinus Relief tablets contains three active ingredients. Paracetamol is a pain killer and reduces your temperature when you have a fever. Phenylephrine hydrochloride unblocks your nose and sinuses helping you breathe more easily. Caffeine is present as a mild stimulant which acts to further help the effectiveness of paracetamol.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PANADOL SINUSRELIEF

Do not take Panadol Sinus Relief:

- If you have ever had an allergic reaction to paracetamol, phenylephrine hydrochloride, caffeine or any of the other ingredients (listed in Section 6).
- if you have severe kidney or severe liver problems, overactive thyroid, diabetes, phaeochromocytoma, enlarged prostate, glaucoma or are under the care of your doctor for high blood pressure or heart disease
- if you are taking tricyclic antidepressants (e.g. imipramine or amitriptyline) or have taken monoamine oxidase inhibitors (MAOIs) prescribed for depressions in the last two weeks
- if you are taking beta blockers, digoxin or ergot alkaloids
- if you are taking lithium
- If you are under 12 years of age.

DO NOT TAKE WITH ANY OTHER PARACETAMOL-CONTAINING PRODUCTS

DO NOT TAKE WITH ANY OTHER FLU, COLD OR DECONGESTANT PRODUCTS

Talk to your doctor before taking this medicine

- if you have liver or kidney problems including alcoholic liver disease
- if you have a blood vessel disease such as Raynaud's phenomenon
- if you have a severe infection, are severely malnourished, 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.

Other medicines and Panadol Sinus Relief

- 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 appetite suppressants or stimulants or blood thinning drugs (anticoagulants e.g. warfarin) or flucloxacillin (an antibiotic).

Important information about some of the ingredients:

- contains colour sunset yellow (E110) which may cause allergic reactions
- contains caffeine. Avoid drinking too many caffeine containing drinks (e.g. tea, coffee and caffeine containing canned drinks) when taking this medicine.

Pregnancy and breastfeeding

Do not take Panadol Sinus Relief if you are pregnant. Talk to your doctor before taking this product if you are breastfeeding.

Driving and using machinery

This medicine may cause dizziness. If affected do not drive or operate machinery.

3. HOW TO TAKE PANADOL SINUS RELIEF

Adults, elderly and children aged 16 years and over:

Swallow 2 tablets with water every 4-6 hours as required..

Children aged 12 - to 15 years:

Swallow 1 tablet with water every 4-6 hours as required. Do not take more than 4 doses in 24 hours.

Do not give to children under 12 years

Do not take more frequently than every 4 hours

Do not exceed the stated dose

If your symptoms persist, see your doctor

The lowest dose necessary to achieve efficacy should be used for the duration of treatment.

Do not take for longer than 3 days without seeing a doctor

If you take more than you should IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF AN OVERDOSAGE, EVEN IF YOU FEEL WELL because of the risk of delayed, serious liver damage

4. POSSIBLE SIDE EFFECTS

Like all medicines, Panadol Sinus Relief can cause side effects, although not everybody gets them.

You may experience headache, dizziness, nervousness, difficulty sleeping, increased blood pressure, nausea and vomiting

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.

-you experience loss of vision, which may be due to abnormally high blood pressure in the eye. This is very rare but is more likely to occur in those with glaucoma.

-you experience an unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat.

-you experience difficulty in passing water. This is more likely to occur in men with an enlarged prostate gland

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

5. HOW TO STORE PANADOL SINUS RELIEF

Keep out of the sight and reach of children.

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.

Do not store above 25°C. Store in the original container in order to protect from moisture

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. CONTENTS OF THE PACK AND OTHER INFORMATION

Panadol Sinus Relief tablets are orange film-coated tablets embossed with “B” on one side.

Active ingredients: Each tablet contains Paracetamol 500mg, Caffeine 65mg and phenylephrine hydrochloride 5mg

Other ingredients: Pregelatinised starch, maize starch, povidone, sodium laurilsulfate, stearic acid, talc, microcrystalline cellulose, hypromellose, macrogol 400, potassium sorbate and colours: titanium dioxide (E171), sunset yellow (E110) and quinoline yellow (E104).

Panadol Sinus Relief contains 16 and 24 tablets.

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.

This leaflet was last revised in May 2023.

Panadol Sinus Relief is a registered trademark of the Haleon group of companies. PA 678/44/1

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