Panadol® Sinus Pain & Congestion Relief Day & Night Caplets

Day caplet: 500 mg Paracetamol / 5 mg Phenylephrine hydrochloride; Night caplet: 500 mg Paracetamol / 5 mg Phenylephrine hydrochloride / 2 mg Chlorpheniramine maleate

Consumer Medicine Information

Please read this information before you start using this medicine.

What is in this leaflet

This leaflet answers some common questions about PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLETS. It does not contain all the available information.

It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits.

If you have any concerns about using this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET is used for

PANADOL Sinus Pain & Congestion Relief Day & Night is used for the temporary relief of the following symptoms of sinusitis:

- Sinus headache
- Sinus pain
- Nasal congestion.

Paracetamol is used for the fast effective temporary relief of pain and discomfort associated with sinus pain or headache. Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Phenylephrine HCl works to reduce nasal stuffiness.

Chlorpheniramine maleate belongs to a group of medicines called 'antihistamines'. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason.

Before you take PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET

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

When you must not take it

Do not take PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET if you have an allergy to:

- Any medicine containing paracetamol, phenylephrine HCl or chlorpheniramine maleate
- Any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always read and follow the label.

Do not take PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET:

- If you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.
- If you have severe high blood pressure, heart problems or are taking antidepressant medicines.
- If you have stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction, pyloroduodenal obstruction.
- If you are taking or have taken within the last 14 days, medicines called monoamine oxidase inhibitors, medicines used to treat depression.
- if you are taking other medicines for the relief of colds and flu, congestion or blocked nose,

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appetite suppressants or stimulant drugs called amphetamines (sometimes used for attention deficit disorder), or other medicines containing paracetamol or antihistamines (sometimes used to treat allergy).

• In children under 12 years of age.

The DAY caplet may cause sleeplessness if taken within several hours of going to bed.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- liver or kidney disease
- high blood pressure
- heart problems
- diabetes
- an overactive thyroid
- high pressure in the eye (angle closure glaucoma)
- tumour of the adrenal gland (phaeochromocytoma)
- enlarged prostate gland
- occlusive vascular disease (poor blood flow or narrowing of the blood vessels e.g. Raynaud's Phenomenon)
- epilepsy
- asthma, bronchitis or a chronic lung disorder
- are underweight or malnourished
- regularly drink alcohol You may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- a severe infection as this may increase the risk of metabolic acidosis.
 Sign 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.

Ask your pharmacist or doctor about using this medicine if you are pregnant or plan to become pregnant, or breastfeeding.

This medicine should not be taken if you are pregnant or breastfeeding unless your doctor has told you to.

If you have not told your pharmacist or doctor about any of the above, tell them before you take PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET.

Using other medicines

Tell your pharmacist or doctor if you are using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PANADOL SINUS PAIN & CONGESTION RELIEF Day & Night CAPLETS may interfere with each other. These include:

- Warfarin, a medicine used to prevent blood clots or similar medicines used to thin the blood
- Pain relievers or medicines to treat anxiety, or help you sleep or relax (sedatives and hypnotics)
- Metoclopramide, a medicine used to control nausea and vomiting
- Anti-convulsants
- Phenytoin, a medicine used to treat epilepsy (fits)
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Probenecid, medicine used to treat gout
- Cholestyramine, medicine used to lower cholesterol levels in the blood

- Sympathomimetic amines, appetite suppressants or stimulants
- Medicines used to treat:
 high blood pressure such as beta-blockers
 - depression such as Monoamine oxidase inhibitors (MAOIs)
 heart conditions such as digoxin or similar medicines
 congestion.
- Alcohol
- Medicines containing antihistamines.

Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while using this medicine.

How to take PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your pharmacist or doctor for help.

Do not exceed the stated dose or frequency of dosing.

Always use the lowest effective dose to relieve your symptoms.

When to take it

Adults and children aged 12 years and over:

Take 2 DAY caplets every 4 - 6 hours with water as necessary. Do not take more than 4 DAY caplets in 24 hours.

Take 2 NIGHT caplets with water as necessary, at bedtime. Do not take more than 2 NIGHT caplets in 24 hours.

Do not take the NIGHT caplets within 6 hours of the DAY caplets.

How long to take it

Adults and children 12 years and over:

Only take PANADOL SINUS PAIN & CONGESTION RELIEF Day & Night CAPLETS for a few days at a time unless your doctor tells you to take it for longer.

Children 12 to 17 years: **Do not take for more than 48 hours except on medical advice.**

Do not use in children below 12 years old.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone: 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much **PANADOL SINUS PAIN & CONGESTION RELIEF DAY &** NIGHT. Seek medical advice immediately even if there are no signs of discomfort or poisoning because of the risk of liver failure. You may need urgent medical attention.

Taking too much paracetamol can lead to delayed, serious liver damage.

While you are using PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Things you must not do

Children: Do not give PANADOL SINUS PAIN & CONGESTION RELIEF

DAY & NIGHT CAPLETS to children under the age of 12 years.

Children 12 to 17 years: Do not give PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET for more than 48 hours unless a doctor has told you to.

Adults:

Do not take for more than a few days at a time unless your doctor tells you to.

Do not take more than the recommended dose unless your doctor tells you to.

Do not take PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET to treat any other complaints unless your pharmacist or doctor tells you to.

Things to be careful of

Only drink small quantities of alcohol (beer, wine or spirits) while using PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET.

Drinking large quantities of alcohol while taking PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET may increase the risk of liver side effects.

Be careful driving or operating machinery until you know how this medication affects you. Chlorpheniramine maleate, which is in the NIGHT caplet, may cause drowsiness, dizziness or blurred vision in some people. If this happens, do not drive or use machinery.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET.

This medicine helps most people with temporary relief of the following symptoms of sinusitis: sinus headache, sinus pain and nasal congestion. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

These side effects are rare and you may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

If any of the following happen, stop using the product, tell your pharmacist or doctor immediately or go to Accident and Emergency at your nearest hospital:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue, throat or other parts of the body
- Rash, peeling, itching or hives on the skin or mouth ulcers
- Unexplained bruising or bleeding
- Rapid or irregular heartbeat
- Difficulty in passing urine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when taken for a short period of time.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET

Storage

Keep your medicine in the original pack until it is time to take it.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET or any other medicine in the bathroom or

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near a sink. Do not leave it on a window sill or in a car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product Description

What it looks like

PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET (DAY) Caplets are a white, capsule-shaped tablet with flat edges. They are marked with a sun inside an oval on one side.

PANADOL PAIN & CONGESTION RELIEF DAY & NIGHT (NIGHT) Caplets are a green capsule-shaped tablet with flat edges.

This medicine comes in blister packs of 24 caplets consisting of 16 DAY caplets and 8 NIGHT caplets.

Ingredients

PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET (DAY) Caplets contain 500 mg of paracetamol and 5 mg phenylephrine hydrochloride as the active ingredients.

They also contain:

- Cellulose-microcrystalline
- Starch-pregelatinised maize
- Starch-maize
- Talc-purified
- Stearic acid
- Sodium lauryl sulfate
- Potassium sorbate
- Povidone.

PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLET (NIGHT) Caplets contain 500 mg of paracetamol, 5 mg phenylephrine hydrochloride and 2 mg chlorpheniramine maleate as the active ingredients.

They also contain:

- Starch-pregelatinised maize
- Cellulose-microcrystalline
- Starch-maize
- Talc-purified
- Stearic acid
- Povidone
- Sodium lauryl sulfate
- Potassium sorbate
- Sunset yellow FCF
- Brilliant blue FCF.

Manufacturer/Distributor

PANADOL SINUS PAIN & CONGESTION RELIEF DAY & NIGHT CAPLETS are supplied in Australia and New Zealand by:

GlaxoSmithKline Consumer Healthcare 82 Hughes Avenue, Ermington NSW and Auckland, New Zealand This leaflet was prepared in September 2015.

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