

PANADOL Night Caplets

500mg Paracetamol & 25 mg Diphenhydramine Hydrochloride

Consumer Medicine Information

Please read this information before you start taking this medicine.

What is in this leaflet?

This leaflet answers some common questions about PANADOL Night. 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. Your pharmacist or doctor has weighed the risks of you taking PANADOL Night against the benefits they expect it will have for you.

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

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

What PANADOL Night is used for

PANADOL Night is used to give temporary relief of pain when associated with sleeping difficulty.

It is useful for headache, migraine, backache, arthritis, rheumatic and muscle pain, neuralgia, toothache or period pain.

Paracetamol is an analgesic. It works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Diphenhydramine hydrochloride is an antihistamine that helps you sleep.

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

Your pharmacist or doctor may have given you this for another reason.

This medicine is only available from your pharmacist.

Before you take PANADOL Night

Do not take more than the recommended dose as it may cause serious harm to your liver.

When you must not take it

Do not take PANADOL Night if you have an allergy to:

- any medicine containing paracetamol or diphenhydramine hydrochloride
- 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

Do not use this medicine 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.

Always read and follow the label.

Do not take PANADOL Night if you have or have had any of the following medical conditions:

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer or other stomach problems
- prostate problems
- bladder problems

Do not take PANADOL Night if you are taking monoamine oxidase inhibitors (MAOIs), a type of medicine used to treat depression.

Do not take PANADOL Night if you have taken other medicine containing paracetamol in the last 4 hours.

Do not take PANADOL Night if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

Do not give PANADOL Night to newborn or premature babies.

Do not give PANADOL Night to children under 12 years of age.

Do not take this medicine after the expiry date (EXP) printed on the pack. If you take it after the expiry has passed, it may not work as well.

Do not take PANADOL Night 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 taking 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
 - Underweight or malnourished
 - Regularly drink alcohol
- You may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- You have a severe infection, are severely malnourished 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

- Epilepsy
- Myasthenia gravis (a muscle dysfunction)
- Prostate gland enlargement or difficulty urinating
- Glaucoma
- Asthma
- Bronchitis or chronic lung disease

Tell your pharmacist or doctor if you take sedatives.

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant.

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Consider taking the lowest effective dose for the shortest period of time.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking PANADOL Night.

Please see your doctor if your symptoms do not improve.

Keep out of sight and reach of children.

Taking other medicines

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

Some medicines and PANADOL Night may interfere with each other. These include:

- Warfarin, a medicine used to prevent blood clots
- Metoclopramide, a medicine used to control nausea and vomiting
- Medicines used to treat epilepsy or fits
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Alcohol
- Medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- Medicines used to help you sleep or relax (sedatives and hypnotics)
- Opioid analgesics, medicines used to treat pain
- Other antihistamine medicines including cough and cold medicines and those you use on your skin
- Medicines which make you drowsy or give you a dry mouth (sometimes called anticholinergics). Taking such medicines while you are taking this medicine may increase the chances of side effects
- Probenecid, a medicine used to treat gout or sometimes given with an antibiotic
- Cholestyramine, a medicine used to treat high cholesterol levels in the blood

These medicines may be affected by PANADOL Night or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

This product contains paracetamol. If you are taking any other medicine containing paracetamol, you must make sure you do not take more than 4000mg paracetamol (including this product) in any 24 hour period. If in doubt, consult your doctor or pharmacist.

How to take PANADOL Night

Do not exceed the stated dose.

Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

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.

How much to take

Take two caplets.

Do not take more than the stated dose.

If you are over 65 years of age, talk to your pharmacist or doctor about how much to use. Elderly patients are more likely to have side effects from taking this medicine. Carers should be aware that this medicine should not be given to elderly patients with confusion.

How to take it

Take with water or other fluid.

When to take it

Take the caplets at bedtime.

How long to take it

Adults should not take this medicine for more than a few days

at a time unless your doctor tells you to take it for longer.

Children aged 12 to 17 years should not take this medicine for more than 48 hours unless on the advice of a doctor.

Children under 12 years of age should not be given PANADOL Night unless a doctor has told you to.

If you forget to take it at bedtime

If you forget to take PANADOL Night at bedtime, you may take it through the night. Do not take a second dose.

If you are not sure what to do, ask your pharmacist or doctor.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much PANADOL Night. Do this even if there are no signs of discomfort or poisoning because of the risk of liver failure.

You may need urgent medical attention. Keep telephone numbers of these places handy.

While you are using PANADOL Night

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.

Use PANADOL Night exactly as your pharmacist or doctor has told you to.

Tell all your doctors, dentists and pharmacists that you are using PANADOL Night.

Things you must not do

Children 12 to 17 years:

Do not give paracetamol 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 use this medicine to treat any other complaint unless your pharmacist or doctor tells you to.

Do not give this medicine to anyone else even if they have the same condition as you.

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

Do not drink alcohol while taking PANADOL Night.

The sedation effects of alcohol may be increased.

Things to be careful of

This product may cause dizziness, drowsiness, difficulty concentrating or blurred vision. Be careful driving or operating machinery until you know how the medicine affects you.

Please see your doctor if your symptoms do not improve.

Keep out of sight and reach of children.

This medicine may cause sleepiness in some people. If this happens, do not drive or operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking PANADOL Night.

This medicine helps most people with pain when associated with sleeping difficulty, but it may have unwanted side effects in a few people. 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. You may not experience any of them.

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

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- nausea or dyspepsia
- drowsiness or sleepiness
- dry mouth, nose and throat
- constipation
- nervousness and irritability
- anxiety
- hallucinations
- twitching or jerking muscles
- fast heart beat
- tiredness
- dizziness
- difficulty concentrating
- unsteadiness

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- difficult or painful urination
- seizures (fits)

The above list includes serious side effects that may require medical attention. These side effects are rare.

If any of the following happen, tell your 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
- previous breathing problems with aspirin or non-steroidal anti-inflammatories, and you experience a similar reaction with this product.
- unexplained bruising or bleeding

The above list includes very serious side effects. You may need urgent

medical attention or hospitalisation. These side effects are very rare.

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 taking PANADOL Night

Storage

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

If you keep the caplets out of their packaging, they will not keep well.

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

Do not store PANADOL Night or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children and pets cannot reach it.

A locked cupboard at least one and a 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 Night is a blue, film coated caplet.

It is marked "Panadol" on the front face and "Night" on the back.

PANADOL Night is supplied in packs of 20 caplets.

Ingredients

Each PANADOL Night caplet contains 500 mg paracetamol and 25 mg diphenhydramine hydrochloride as active ingredients.

It also contains:

- Starch-maize
- Starch-pregelatinized maize
- Povidone
- Potassium sorbate
- Magnesium stearate
- Talc-purified
- Cellulose-microcrystalline
- Water-purified
- Carnauba wax
- Opadry II complete film coating system 85G60844 Blue
- PANADOL Night contains no sugar, lactose, alcohol or wheat starch.

Marketed by:

GlaxoSmithKline Consumer Healthcare
82 Hughes Avenue,
Ermington NSW 2115, Australia
AUST R 167596 (PANADOL NIGHT)

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Helpful advice on managing night pain

Managing pain at night can often be complicated by affecting your ability to get to sleep. When your sleep pattern is affected, pain at night can seem stronger than normal. For this reason we have included some helpful advice on managing pain and getting to sleep.

Pain Management

1. Application of gentle heat to the painful area. This increases the

blood flow to the affected area which works to relieve the sensation of pain and aids the healing process. Hot water bottles, hot showers and heat bags can be useful.

2. Pain as a result of inflammation can also be treated by the application of cold to the affected area. Cold packs can often be more effective in the early stages of an injury than heat. See your doctor or pharmacist for advice on the best way to treat your pain.
3. For some people, massage can also help to increase blood flow to an area and contribute to increasing flexibility of joints and muscles. Massage oils may help.

Sleep Routines

1. Avoid alcohol, caffeine products and nicotine before bedtime.
2. Avoid large meals before bedtime.
3. Develop a regular bed time routine. This helps signal to your mind that it is time to go to sleep.
4. Practice relaxation techniques. There are many useful books and courses available to instruct you on simple, effective techniques.
5. Ensure your bed is comfortable. Sometimes changing a mattress or pillows can increase your comfort and ability to get to sleep, particularly if you suffer from muscle or joint pain.

NOTE

Suffering from night time pain can be a lonely experience if it also stops you sleeping. Just remember, many people suffer from night time pain, you are not alone. Try some of the above techniques which could help you manage your night time pain.