

MERSYNONIGHT™ Night Time Pain Relief

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MersynoNight Night Time Pain Relief?

MersynoNight Night Time Pain Relief contains the active ingredients paracetamol and diphenhydramine hydrochloride. MersynoNight Night Time Pain Relief is used to give temporary relief of pain when associated with sleeping difficulty.

For more information, see Section 1. Why am I using MersynoNight Night Time Pain Relief? in the full CMI.

2. What should I know before I use MersynoNight Night Time Pain Relief?

Do not use if you have ever had an allergic reaction to paracetamol, diphenhydramine hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MersynoNight Night Time Pain Relief?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MersynoNight Night Time Pain Relief and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MersynoNight Night Time Pain Relief?

- Take 1- 2 tablets with water or other fluid only at bedtime. Maximum of two tablets in 24 hours. Do not exceed the stated dose.
- Allow at least four hours between taking any paracetamol containing product and MersynoNight Night Time Pain Relief tablets.

More instructions can be found in Section [4. How do I use MersynoNight Night Time Pain Relief?](#) in the full CMI.

5. What should I know while using MersynoNight Night Time Pain Relief?

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| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MersynoNight Night Time Pain Relief. Use only as recommended.• Talk to your pharmacist or doctor if your symptoms do not improve. |
| Things you should not do | <ul style="list-style-type: none">• Do not give to children under 12 years of age. Do not take for more than a few days at a time unless your doctor tells you to.• Do not exceed the recommended dose. There have been case reports of abuse with diphenhydramine. |
| Driving or using machines | <ul style="list-style-type: none">• This medicine may cause sleepiness in some people. If this happens, do not drive or operate machinery. |

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|---|---|
| <p>Things you should do</p> | <ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are using MersynoNight Night Time Pain Relief. Use only as recommended. ● Talk to your pharmacist or doctor if your symptoms do not improve. |
| <p>Drinking alcohol</p> | <ul style="list-style-type: none"> ● Do not drink alcohol while taking MersynoNight Night Time Pain Relief. The sedation effects of alcohol may be increased. |
| <p>Looking after your medicine</p> | <ul style="list-style-type: none"> ● Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from moisture. ● Keep it where children cannot reach it. |

For more information, see Section [5. What should I know while using MersynoNight Night Time Pain Relief?](#) in the full CMI.

6. Are there any side effects?

- Tell your doctor or pharmacist 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.

MersynoNight Night Time Pain Relief™

Active ingredients: *paracetamol and diphenhydramine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MersynoNight Night Time Pain Relief. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MersynoNight Night Time Pain Relief.**

Where to find information in this leaflet:

- [1. Why am I using MersynoNight Night Time Pain Relief?](#)
- [2. What should I know before I use MersynoNight Night Time Pain Relief?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MersynoNight Night Time Pain Relief?](#)
- [5. What should I know while using MersynoNight Night Time Pain Relief?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MersynoNight Night Time Pain Relief?

MersynoNight Night Time Pain Relief contains the active ingredient paracetamol and diphenhydramine hydrochloride.

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.

MersynoNight Night Time Pain Relief 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.

2. What should I know before I use MersynoNight Night Time Pain Relief?

Warnings

Do not use MersynoNight Night Time Pain Relief if:

- you are allergic to paracetamol, diphenhydramine hydrochloride, or any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can use this medicine

- you have liver failure
- you have glaucoma (high pressure in the eyes)
- you have stomach or duodenal ulcer or other stomach problems
- you have bladder problems
- you are breastfeeding or plan to breastfeed. It passes into the breast milk and there is a possibility that the baby may be affected.
- you are taking monoamine oxidase inhibitors (MAOIs), a type of medicine used to treat depression
- you have taken other medicine containing paracetamol in the last 4 hours

Use this medicine only as recommended. Do not exceed the recommended dose. There have been reports of abuse with diphenhydramine.

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 this medicine 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 doctor.

Check with your doctor or pharmacist if you:

- have kidney or liver disease (such as Gilbert Syndrome)
- have epilepsy
- glaucoma
- have myasthenia gravis (a muscle dysfunction)
- have prostate gland enlargement or difficulty urinating
- have asthma
- have bronchitis or chronic lung disease
- are underweight or malnourished
- regularly drink alcohol; you may need to avoid using this product altogether or limit the amount of paracetamol you take
- have a severe infection as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include deep rapid difficult breathing, nausea or vomiting, and loss of appetite. Contact a doctor immediately if you get a combination of these symptoms.
- have an enzyme deficiency, glucose-6-phosphate dehydrogenase
- have had previous breathing problems with aspirin or non-steroidal anti-inflammatories
- are taking sedatives
- are taking a type of medicine used to treat depression like monoamine oxidase inhibitors (MAOIs), or within two weeks of stopping an MAOI.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Do not take 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. Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Infants and children

Do not give MersynoNight Night Time Pain Relief to:

- newborn or premature babies
- children under 12 years of age.

Elderly

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 and agitation (shaking movements of the body).

3. What if I am taking other medicines?

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

This medicine contains paracetamol. If you are taking any other medicine containing paracetamol, do not take more than 4000 mg paracetamol (including this medicine) in any 24 hour period.

This medicine contains diphenhydramine an antihistamine. Do not take this medicine if you are taking other medicines containing diphenhydramine or antihistamines such as those to treat cough and colds, allergies and skin rashes (including those you use on your skin).

Talk to your doctor or pharmacist if you are unsure.

Some medicines and MersynoNight Night Time Pain Relief may interfere with each other.

These include:

- warfarin, a medicine used to prevent blood clots
- metoclopramide and domperidone, medicines used to treat nausea and vomiting
- propantheline, a medicine used to reduce stomach acid and treat stomach cramps
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections

- flucloxacillin and rifampicin, medicines used to treat infections
- alcohol
- probenecid, a medicine used to treat gout or sometimes given with an antibiotic
- cholestyramine, a medicine used to treat bile problems or high cholesterol levels in the blood
- metoprolol, a medicine used to treat high blood pressure
- medicines used to control electrolytes levels in kidney disease
- medicines used to treat depression, especially monoamine oxidase inhibitors, tricyclic antidepressants and venlafaxine
- medicines used to help you sleep or relax such as sedatives and hypnotics
- opioid analgesics, medicines used to treat pain
- other medicines containing antihistamines such as those to treat cough and colds, allergies and skin rashes
- 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.

Taking such medicines while you are taking this medicine may increase the chances of side effects.

These medicines may be affected by MersynoNight Night Time Pain Relief or may affect how well it works. You may need different amounts of your medicines, or

you may need to take different medicines, or separate the doses.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MersynoNight Night Time Pain Relief.

4. How do I use MersynoNight Night Time Pain Relief?

How much to take

- Take one or two tablets with water or other fluid
- Follow the instructions provided with the medicine
- Use this medicine only as recommended. Do not exceed the recommended dosage.
- If you are over 65 years of age, talk to your pharmacist or doctor about how much to use

When to take MersynoNight Night Time Pain Relief

- MersynoNight Night Time Pain Relief should be taken at bedtime

How long to use it for

- 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

If you forget to use MersynoNight Night Time Pain Relief

- If you forget to take MersynoNight Night Time Pain Relief at bedtime, you may take it through the night.
- Do not take a second dose

If you use too much MersynoNight Night Time Pain Relief

If you think that you have used too much MersynoNight Night Time Pain Relief, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MersynoNight Night Time Pain Relief?

Things you should do

Call your doctor immediately or go to Accident and Emergency at your nearest hospital if you have any of the following symptoms which may be due to an allergic reaction:

- 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.

If you develop a skin rash while taking this medicine you must stop taking it immediately and seek medical advice.

Remind any doctor, dentist or pharmacist you visit that you are using MersynoNight Night Time Pain Relief.

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 should not do

Do not use this medicine to treat any other complaints unless your pharmacist or doctor tells you to

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

Things to be careful of

Use this medicine only as recommended. Do not exceed the recommended dose.

There have been case reports of abuse with diphenhydramine. This medicine may be habit forming, especially if you have had addiction problems in the past or if you have severe mental health problems.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MersynoNight Night Time Pain Relief affects you.

This medicine may cause sleepiness, dizziness, drowsiness, difficulty concentrating or blurred vision in some people.

If this happens, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Do not drink alcohol while taking MersynoNight Night Time Pain Relief. Alcohol may increase the sedative effects of alcohol.

Looking after your medicine

- Store below 25°C. Protect from moisture.
- Keep your medicine in the original pack until it is time to take it. If you keep the tablets out of their packaging, they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

Keep it where children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>Gastrointestinal related:</p> <ul style="list-style-type: none">• nausea or indigestion• constipation <p>Head and neurology related:</p> <ul style="list-style-type: none">• dry mouth, nose and throat• drowsiness, sleepiness, tiredness• nervousness, irritability or agitation• anxiety• hallucinations• dizziness• difficulty concentrating• headache• confusion <p>Heart related:</p> <ul style="list-style-type: none">• fast or irregular heart beat | <p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|--|------------|
| <p>Muscle and movement related:</p> <ul style="list-style-type: none"> ● twitching or jerking muscles ● unsteadiness ● tingling or numbness of the hands or feet <p>Eyes related:</p> <ul style="list-style-type: none"> ● blurred vision. | |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Allergy related:</p> <ul style="list-style-type: none"> ● shortness of breath ● wheezing or difficulty breathing ● swelling of the face, lips, tongue or other parts of the body ● previous breathing problems with aspirin or non-steroidal anti-inflammatories, and you experience a | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|--|-------------------|
| <p>similar reaction with this product</p> <ul style="list-style-type: none"> ● rash, itching or hives on the skin <p>Skin related:</p> <ul style="list-style-type: none"> ● severe blisters and bleeding in the lips, eyes, mouth, nose and genitals ● painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills ● yellowing of the skin and eyes <p>Infection related:</p> <ul style="list-style-type: none"> ● frequent infections such as fever, severe chills, sore throat or mouth ulcers <p>Bleeding related:</p> <ul style="list-style-type: none"> ● unexplained bruising or bleeding <p>Neurological system related:</p> <ul style="list-style-type: none"> ● seizures (fits) | |

| Serious side effects | What to do |
|---|------------|
| <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • nausea, vomiting <p>Urinary related:</p> <ul style="list-style-type: none"> • difficult or painful urination • dark coloured urine | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription although is only available from your pharmacist.

What MersynoNight Night Time Pain Relief contains

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| Active ingredient (main ingredient) | Each tablet contains 500 mg paracetamol and 25 mg diphenhydramine hydrochloride |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• Maize starch• Potassium sorbate• Povidone• Croscarmellose sodium• Purified talc• Stearic acid• Opadry complete film coating system 03F505035 Blue |

Do not take this medicine if you are allergic to any of these ingredients.

What MersynoNight Night Time Pain Relief looks like

MersynoNight Night Time Pain Relief is a blue, capsule shaped, film coated tablet debossed with “PD5” on one side and plain on the other side.

(AUST R 301428).

Who distributes MersynoNight Night Time Pain Relief

Sanofi Consumer Healthcare

87 Yarraman Place Virginia QLD 4014

Australia

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