

NEW ZEALAND CONSUMER MEDICINE INFORMATION

MERSYNONIGHT™ NIGHT TIME PAIN RELIEF

Paracetamol 500 mg and diphenhydramine hydrochloride 25 mg

CONSUMER MEDICINE INFORMATION

Please read this leaflet carefully before you start using MERSYNONIGHT™ NIGHT TIME PAIN RELIEF

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about MERSYNONIGHT NIGHT TIME PAIN RELIEF. It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using MERSYNONIGHT NIGHT TIME PAIN RELIEF against the benefits it is expected to have for you.

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

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

WHAT MERSYNONIGHT NIGHT TIME PAIN RELIEF IS USED FOR

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.

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 doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

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

This medicine is only available from your pharmacist.

BEFORE YOU USE MERSYNONIGHT NIGHT TIME PAIN RELIEF

When you must not use it

Do not take MERSYNONIGHT NIGHT TIME PAIN RELIEF 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 take MERSYNONIGHT NIGHT TIME PAIN RELIEF if you have or had any of the following medical conditions:

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer or other stomach problems
- prostate gland enlargement
- bladder problems (including difficulty urinating)
- liver problems

Do not take MERSYNONIGHT NIGHT TIME PAIN RELIEF:

- if you are taking monoamine oxidase inhibitors (MAOIs), a type of medicine used to treat depression.
- if you have taken other medicine containing paracetamol in the last 4 hours.
- 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.

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

Do not give MERSYNONIGHT NIGHT TIME PAIN RELIEF:

- to newborn or premature babies.
- 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 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 pharmacist or doctor.

Before you start to use it

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

- Liver or kidney disease (such as Gilbert's Syndrome)
- Epilepsy
- Myasthenia gravis (a muscle dysfunction)
- Prostate gland enlargement or difficulty urinating
- Glaucoma
- Asthma
- Bronchitis or chronic lung disease
- You are underweight or malnourished
- You regularly drink alcohol; you may need to avoid using this product altogether or limit the amount of paracetamol you take
- You have a severe infection such as sepsis as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include deep rapid difficult breathing, nausea or vomiting. Loss of appetite. Contact a doctor immediately if you get a combination of these symptoms
- You have an enzyme deficiency, glucose-6-phosphate dehydrogenase
- You have low glutathione reserves
- You have had previous or underlying sensitivity to aspirin or non-steroidal anti-inflammatories (NSAIDs), including breathing problems.
- are taking a type of medicine used to treat depression like monoamine oxidase inhibitors (MAOIs), or within two weeks of stopping an MAOI.

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.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking MERSYNONIGHT NIGHT TIME PAIN RELIEF.

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

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 MERSYNONIGHT NIGHT TIME PAIN RELIEF may interfere with each other. These include:

- Warfarin or other antivitamin K, medicines used to prevent blood clots

- Metoclopramide and domperidone, medicines used to control 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
- 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.
- Chelating resin

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.

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.

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).

HOW TO USE MERSYNONIGHT NIGHT TIME PAIN RELIEF

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. Use this medicine only as recommended. Do not exceed the recommended dosage.

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

How much to use

Take one or two tablets.

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 and agitation (shaking movements of the body).

When to use it

Take with water or other fluid. Take the tablets at bedtime.

Maximum of 2 tablets per day.

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.

Children under 12 years of age should not be given MERSYNONIGHT NIGHT TIME PAIN RELIEF.

If you forget to use it

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 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 use too much (overdose)

If you have taken too much MERSYNONIGHT NIGHT TIME PAIN RELIEF, you may experience nausea, vomiting, anorexia, unhealthy pale appearance, stomach pain, dilated pupils, fever, flushing, agitation, tremor, muscle contraction reactions, hallucinations and heart monitoring (electrocardiogram) changes. Large overdoses may cause the breakdown of muscle, convulsions, delirium, toxic psychosis, irregular heartbeat, coma and heart collapse. Overdosage may cause liver cell disruption (hepatic cytolysis) which can lead to liver insufficiency, failure or damage, gastrointestinal bleeding, accumulation of acid in the body (metabolic acidosis), disorder/disease of the brain (encephalopathy), abnormal blood clotting, coma and death, inflammation of the pancreas, acute kidney failure and reduction in red/white blood cells and platelets.

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 MERSYNONIGHT NIGHT TIME PAIN RELIEF. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places handy.

WHILE YOU ARE USING MERSYNONIGHT NIGHT TIME PAIN RELIEF

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 MERSYNONIGHT NIGHT TIME PAIN RELIEF exactly as your pharmacist or doctor has told you to. Tell all your doctors, dentists and pharmacists that you are using MERSYNONIGHT NIGHT TIME PAIN RELIEF.

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 MERSYNONIGHT NIGHT TIME PAIN RELIEF.

The sedation effects of alcohol may be increased.

Use MERSYNONIGHT NIGHT TIME PAIN RELIEF only as recommended. Do not exceed the recommended dose. There have been case reports of abuse with diphenhydramine.

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 MERSYNONIGHT NIGHT TIME PAIN RELIEF.

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 list 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
- tingling or numbness of the hands or feet
- fast or irregular heart beat
- tiredness
- dizziness
- difficulty concentrating
- unsteadiness
- blurred vision
- headache
- confusion

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 or other parts of the body
- rash, itching or hives on the skin
- previous breathing problems with aspirin or non-steroidal anti-inflammatories, and you experience a similar reaction with this product.
- unexplained bruising or bleeding
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- painful red areas with blisters and peeling layers of skin which be accompanied by fever and/or chills
- frequent infection such as fever, severe chills, sore throat or mouth ulcers
- vomiting
- serious breathing difficulties with deep rapid breathing, drowsiness, nausea and vomiting may be a sign of metabolic acidosis.

The above list includes very serious side effects. You may need urgent medical attention or hospitalization. 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 USING MERSYNONIGHT NIGHT TIME PAIN RELIEF

Storage

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.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light. Protect from moisture.

Do not store MERSYNONIGHT NIGHT TIME PAIN RELIEF 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 cannot reach it. A locked cupboard at least one-and-a-half meters 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

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, supplied in blister packs of 20 tablets.

Ingredients

Each MERSYNONIGHT NIGHT TIME PAIN RELIEF tablet contains 500 mg paracetamol and 25 mg diphenhydramine hydrochloride as active ingredients.

It also contains:

- Maize starch
- Potassium sorbate
- Povidone
- Croscarmellose sodium
- Purified talc
- Stearic acid
- Opadry complete film coating system 03F505035 Blue

SUPPLIER

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand
Phone: (09) 918 5100