

Mersyndol®

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 Mersyndol?

Mersyndol contains the active ingredients paracetamol, codeine phosphate hemihydrate and doxylamine succinate. Mersyndol is used to relieve pain and tension. For more information, see Section [1. Why am I using Mersyndol?](#) in the full CMI.

2. What should I know before I use Mersyndol?

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

Talk to your doctor 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 Mersyndol?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mersyndol 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 Mersyndol?

- The standard dose of this medicine for adults and children 12 years or over is one or two tablets every 4 to 6 hours, as needed for pain relief.

More instructions can be found in Section [4. How do I use Mersyndol?](#) in the full CMI.

5. What should I know while using Mersyndol?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Mersyndol.• If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Mersyndol.• If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine
Things you should not do	<ul style="list-style-type: none">• Do not take more than 8 tablets in a 24-hour period.• Do not give Mersyndol to anyone else, even if they have the same condition as you.• Do not take high doses of Mersyndol for long periods of time unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Do not drive a car, operate machinery, or do anything else that could be dangerous while taking Mersyndol.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while taking Mersyndol
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C. Store in a cool, dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

Common side effects include skin rash, constipation, nausea, vomiting, dizziness, drowsiness, sweating, blurred vision. Serious side effects include difficulty breathing or swelling of the face, lips, mouth or other parts of the body, hives. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Mersyndol

Active ingredients: *paracetamol, codeine phosphate hemihydrate and doxylamine succinate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mersyndol. **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 Mersyndol.**

Where to find information in this leaflet:

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

1. Why am I using Mersyndol?

Mersyndol contains the active ingredients paracetamol, codeine phosphate hemihydrate and doxylamine succinate. Mersyndol is a type of analgesic used to relieve pain and tension.

Mersyndol is used for the relief of moderate to severe pain including toothache or pain from injury or surgery, and for the temporary relief of headache. In addition, the calmative properties of Mersyndol may be especially useful in the treatment of tension headache, migraine and period pain.

Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Doxylamine succinate is an antihistamine with calmative effects.

Your doctor, however, may prescribe Mersyndol for another purpose.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

This medicine may be habit-forming if taken frequently or over long periods.

2. What should I know before I use Mersyndol?

Warnings

Do not use Mersyndol if:

- you are allergic to paracetamol, codeine phosphate hemihydrate or doxylamine succinate or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- A cough and cold and if you are under 18 years of age.
- Respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing)
- Compromised respiratory function (respiratory illness)
- Severe liver failure or impaired liver function

- G6PD deficiency, a human enzyme deficiency
- Ultra-rapid metaboliser of CYP 2D6
- Had your tonsils or adenoids removed and are under 18 years of age
- Using antidepressant medication (Monoamine inhibitors (MAOIs)), or have stopped taking antidepressant medication within the past 14 days
- Do not give to children under 12 years of age
- Do not give to children 12 to 18 years of age who have breathing problems. This includes breathing problems while sleeping, breathing problems related to obesity, or other lung problems
- Do not take Mersyndol during the third trimester of pregnancy
- Do not take Mersyndol during labour, especially if the baby is premature
- Do not take it if you are breastfeeding or planning to breastfeed

Check with your doctor if you:

- have allergies to
 - any other medicines
 - aspirin or any other non-steroidal anti-inflammatory drug (NSAID)
 - any other substances, such as foods, preservatives or dyes take any medicines for any other condition
- have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - problems with your pancreas
 - history of heart problems including changes in your heart's ECG (QT interval prolongation)
 - low blood pressure
 - blood abnormalities such as low levels of potassium or magnesium
 - difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
 - sleep problems such as sleep apnoeaMersyndol can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.
- known analgesic intolerance
- if you know you are a CYP 2D6 ultra-rapid metaboliser
- chronic alcohol use including recent cessation of alcohol intake
- suffered from alcoholism, drug abuse or dependence.
- malnutrition and other sources of low glutathione reserves

- mild-to-moderate hepatocellular insufficiency
- severe renal insufficiency and sepsis
- Gilbert's syndrome
- prostate problems
- thyroid problems
- Multiple sclerosis
- urinary, bowel or gallbladder conditions
- Addison's disease
- convulsions, fits or seizures
- pre-existing opioid dependence
- chronic constipation
- head injury or trauma
- prone to angle closure glaucoma (high pressure in the eye)
- pain due to nerve problems
- a history of sudden death in the family
- plan to have surgery.

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 if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Mersyndol is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

Do not take Mersyndol during the third trimester of pregnancy.

Do not take Mersyndol during labour, especially if the baby is premature. This medicine may produce withdrawal effects in the newborn baby. Withdrawal symptoms in the newborn can also occur with long-term use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take it if you are breastfeeding or planning to breastfeed.

Mersyndol passes into breast milk and there is a possibility your baby may be affected.

Use in Children

- Do not give Mersyndol to children under 12 years.

Addiction

You can become addicted to Mersyndol even if you take it exactly as prescribed. Mersyndol may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking Mersyndol. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop

taking Mersyndol suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Mersyndol may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning increased sweating.

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.

Some medicines may interfere with Mersyndol and affect how it works.

These include:

- Antihistamines
- Sleeping tablets
- Tranquillisers (medicines used for anxiety or nerves)
- Benzodiazepines (medicines used as sedatives or to treat anxiety)
- Medicines containing alcohol (ethanol), e.g. some cough syrups
- Any medicine which thins the blood
- Antihypertensives (medicines used to help lower blood pressure)
- Medicines to treat epilepsy
- Metoclopramide or domperidone, medicines used to control nausea and vomiting
- Propantheline, a medicine used to treat stomach ulcers
- Chloramphenicol (antibiotic used to treat ear and eye infections)
- Flucloxacillin, zidovudine or rifampicin, medicines used to treat infections
- Antidepressants
- Antipsychotics (medicines used to treat mental illnesses)
- Chelating resin
- Buprenorphine
- Naltrexone
- Fluoxetine, paroxetine, bupropion, cinacalcet
- methadone
- Rifampicin

- Gabapentinoids, gabapentin and pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- Medicines known to alter your heart beats, namely change your heart's ECG.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mersyndol.

4. How do I use Mersyndol?

How much to take

- The standard dose of this medicine for adults and children 12 years or over is one or two tablets every 4 to 6 hours, as needed for pain relief.
- Do not take more than 8 tablets in a 24 hour period.
- Mersyndol is not recommended for use in children under 12 years of age.
- Follow the instructions provided and use Mersyndol until your doctor tells you to stop. Your doctor may have prescribed a different dose.
- If you take the wrong dose, Mersyndol may not work as well and your problem may not improve.
- **This medicine may be habit-forming if taken frequently or over long periods.**
- Ask your doctor or pharmacist if you are unsure of the correct dose for you.

When to take Mersyndol

- Swallow the prescribed dose of Mersyndol whole with a glass of water or other liquid. It can be taken with or without food.
- **If you are not sure when to take it, ask your doctor or pharmacist.**

If you forget to use Mersyndol

If you miss your dose at the usual time, do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Remember to wait 4 to 6 hours between doses.

Do not take a double dose to make up for the dose you missed.

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

If you use too much Mersyndol

If you think that you have used too much Mersyndol, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 764 766 in New Zealand**), 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.

Large amounts of paracetamol can cause liver damage.

Other signs of overdose can include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If children take too many Mersyndol they can suffer from nightmares, hallucinations, fitting or have difficulty sleeping.

5. What should I know while using Mersyndol?

Things you should do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Mersyndol.

If your pain gets worse after you take this medicine do not take more without first talking to your doctor.

Talk to your doctor, if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking this medicine.

Be careful if you are over 65 and unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Call your doctor straight away if you:

- **are about to be started on any new medicine**
- **plan to have surgery that needs a general anaesthetic**
- **become pregnant while you are taking this medicine**
- **experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.**

Remind any doctor, dentist or pharmacist you visit that you are using Mersyndol.

Things you should not do

- Do not take more than the recommended dose unless your doctor or pharmacist tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mersyndol affects you.

Mersyndol may cause dizziness, drowsiness or light-headedness in some people, especially after the first dose.

Do not drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Children should not ride bicycles if affected and should be supervised to avoid potential harm.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol increases the likelihood of becoming drowsy while taking Mersyndol. Drinking alcohol and taking paracetamol at the same time can cause liver damage. It is not recommended that you drink alcohol while taking Mersyndol.

Mersyndol may be habit forming if taken at high doses for extended periods of time.

Ask your doctor or pharmacist if you are concerned about this.

Looking after your medicine

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

Keep your tablets in the pack until it is time to take them.

Store below 30° C.

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 young 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 about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none">• Nausea• Vomiting• Constipation• Diarrhoea• Dry mouth• Severe abdominal pain• Have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time <p>Head and neurology related:</p> <ul style="list-style-type: none">• Depression• Increased sensitivity to pain or increased levels of pain• Headache <p>Skin related:</p> <ul style="list-style-type: none">• Skin rashes• Sweating <p>Reproductive related:</p> <ul style="list-style-type: none">• Low libido• Impotence or Erectile dysfunction• Loss of menstrual cycle• Infertility <p>Sleep related:</p> <ul style="list-style-type: none">• Sleep apnoea <p>General:</p> <ul style="list-style-type: none">• Drowsiness/tiredness• Ringing in the ear• Blurred vision• Visible slowing of physical and emotional reactions• Thickened phlegm• Weakness• Anorexia• Fatigue• Low blood pressure <p>Urinary related:</p> <ul style="list-style-type: none">• Difficulty or inability to pass urine	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none">Irregular heartbeat <p>Head and neurology related:</p> <ul style="list-style-type: none">Feeling confusedUnusual or extreme mood swingsHeadacheDizziness, light-headednessFaintingSeizure <p>Bleeding related:</p> <ul style="list-style-type: none">Bleeding, bruising more easilySevere blisters and bleeding in the lips, eyes, mouth, nose and genitals <p>Liver related:</p> <ul style="list-style-type: none">Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes (jaundice), light coloured bowel motions, dark coloured urine) <p>General:</p> <ul style="list-style-type: none">Flushing of the faceShortness of breathMouth ulcers, fever and sore throatStomach painSlow or shallow breathingPainful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills <p>Metabolism related:</p> <ul style="list-style-type: none">Symptoms of rapid breathing, rapid heart rate, changes in consciousness, drowsiness, nausea or vomiting caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due to low levels of a protein called glutathione). <p>Allergy related:</p> <ul style="list-style-type: none">Swelling of the face, lips, mouth, or throat or other parts of the bodyRash, itching or hives on the skinDifficulty breathing, or shallow breathing	<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>

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 in New Zealand online at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Mersyndol contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">Paracetamol - 450 mg (as COMPAP-L)Codeine phosphate hemihydrate - 9.75 mgDoxylamine succinate - 5 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">Microcrystalline cellulosePurified talcMagnesium stearateSodium starch glycollateColouring agents – quinoline yellow and sunset yellow FCFMaize starch

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

Mersyndol does not contain aspirin, gluten, sucrose, lactose, tartrazine or any other azo dyes.

What Mersyndol looks like

Mersyndol is available in tablets:

Tablet – yellow, flat, round, scored tablet marked "MERSYNDOL 008" and a break line on one side and "M" inside two concentric circles on the non-scored side.

Mersyndol tablets are available in a blister pack of 20.

Who distributes Mersyndol

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
Freecall: 0800 283 684
Email: medinfo.australia@sanofi.com

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