

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Mersyndol?

Mersyndol contains the active ingredients paracetamol, codeine phosphate hemihydrate and doxylamine succinate. Mersyndol is used for short term use to relieve moderate pain and fever. 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/caplets every 4-6 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.

WARNING:**Limitations of use**

Mersyndol should only be used when doctor decides other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Mersyndol contains codeine which may be habit forming. Mersyndol poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will assess your risks and monitor you regularly during treatment.

Life threatening respiratory depression

Mersyndol can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when recommended. These problems can occur at any time during use, but the risk is higher when first starting Mersyndol and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using Mersyndol

Using Mersyndol with other medicines can make you feel drowsy such as sleeping tablets (benzodiazepines (medicines used as sedatives or to treat anxiety), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (medicines used for epilepsy or neuropathic pain), antihistamines, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in severe drowsiness decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Mersyndol.

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 is a type of analgesic used for the short-term use to relieve moderate pain and fever.

Mersyndol contains three active ingredients,

- **Paracetamol.**
- **Codeine phosphate hemihydrate, and**
- **doxylamine succinate**

Paracetamol is an analgesic (pain-relieving medicine) and antipyretic (lowers body temperature). Codeine phosphate hemihydrate is a potent analgesic that helps to relieve pain. The body must convert codeine into morphine before it can provide pain relief. Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Doxylamine succinate is an antihistamine with calmative effects

2. What should I know before I use Mersyndol?

Warnings**Do not use Mersyndol if:**

- you are allergic to paracetamol, codeine phosphate hemihydrate, 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.**
- you have or have had any of the following medical conditions:
 - o severe and/or acute respiratory disease
 - o respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing)
 - o severe liver failure or impaired liver function
 - o other problems with breathing such as, shallow breathing, difficulty breathing, or slow breathing.
 - o G6PD deficiency, a human enzyme deficiency
- you are a CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme)
- you have an allergic reaction to paracetamol, codeine or doxylamine
- you are aged between 12-18 years of age and may have lowered respiratory function including having had your tonsils or adenoids removed
- you are pregnant or in labour, especially if the baby is premature.
- you are breastfeeding or planning to breastfeed.
- you have a history of drug dependence, including alcohol dependence.

- If you are using antidepressant medication (Monoamine Inhibitors (MAOIs), or have stopped taking antidepressant medication within the past 14 days
- the person going to take the tablets is under 12 years.
- The expiry date has passed.
- The packaging is torn/damaged or shows signs of tampering.

Check with your doctor if you:

- have allergies to:
 - o any other medicines
 - o aspirin or any other non-steroidal anti-inflammatory drugs (NSAID)
 - o any other substances, such as foods, preservatives or dyes
- have or have had any medical conditions, especially the following:
 - o Liver problems
 - o Gilbert's syndrome
 - o Kidney problems
 - o Heart problems
 - o Low blood pressure
 - o Difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
 - o Intolerance to pain relieving medicine
 - o You are a CYP 2D6 ultra-rapid metabolizer
 - o Chronic alcohol use including recent cessation of alcohol intake
 - o Low glutathione reserves
 - o Gilbert's syndrome
 - o Prostate problems
 - o Thyroid problems
 - o Multiple sclerosis
 - o Urinary, bowel or gallbladder conditions
 - o Have problems with the adrenal glands
 - o Convulsions, fits or seizures
 - o Pre-existing opioid dependence
 - o Chronic constipation
 - o Head injury or trauma
 - o A history of drug dependence, including alcohol dependence. Caution is particularly for use in adolescents and young adults with a history of drug and/or alcohol abuse.
 - o Prone to angle closure glaucoma (high pressure in the eye)
 - o Difficulty or inability to pass urine
 - o Pain due to nerve problems

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.

Do not take Mersyndol during the third trimester of pregnancy.

Do not take Mersyndol during labour, especially if the baby is premature.

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

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

Use in children

Do not give Mersyndol to children under 12 years. If you are over 65 years of age

Talk to your doctor or pharmacist about how much to take.

Elderly patients are more likely to have less effective kidney function due to age. This may increase the risk of side effects.

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.

Mersyndol given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

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.

Tell your doctor or pharmacist if you are taking any other medicines, which contain paracetamol, codeine or doxylamine.

Do not take Mersyndol with Monoamine Oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs. Tell your doctor or pharmacist if you are taking any other medicines, which contain paracetamol, codeine or doxylamine.

- Antihistamines
- Gabapentinoids, gabapentin and pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- Medicines used to help relax, sleep or relieve anxiety, such as sedatives, hypnotics, gabapentinoids, cannabis and centrally active anti-emetics
- 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
- Other opioid analgesics used to treat pain
- Monoamine oxidase inhibitors, medicine used to treat depression, taken within the last 14 days
- 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
- Medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone).

Medicines that may decrease the effect of Mersyndol include:

- Medicines that inhibit the liver enzyme, CYP 2D6 inhibitors such as fluoxetine, paroxetine, bupropion, cinacalcet, and methadone.
- Medicines that increase the activity of the liver enzyme, CYP 3A4 inducers such as rifampicin.

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

Adults and children 12 years or over

- The usual dose 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 to be used in children under 12 years.
- Follow the instructions provided and use Mersyndol until your doctor tells you to stop. Their directions may differ from the information contained in this leaflet.

When to take Mersyndol

- Swallow the prescribed dose of Mersyndol whole with a glass of water. It can be taken with or without food.

How to take Mersyndol

- Swallow the prescribed dose of Mersyndol whole with a glass of water. It can be taken with or without food.

If you forget to use Mersyndol

If you miss your dose at the usual time, do not try to make up for missed doses. If it is almost time for your next dose, skip the dose you missed and take your 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.

- [include explanation of what “almost time for your next dose” refers to for the specific medicine where possible e.g. oral contraceptives]
- [include any other medicine-specific action and advice about missed dose, as appropriate]

If you take too much Mersyndol

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Mersyndol that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

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

You should immediately:

- phone the Australian 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.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

Large amount of paracetamol can cause liver damage. If children take too many Mersyndol they can suffer from nightmares, hallucinations, fitting or have difficulty sleeping.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take Mersyndol as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

5. What should I know while using Mersyndol?

Things you should do

Remind any doctor including surgeons, dentist or pharmacist you visit that you are taking Mersyndol.

Keep all your appointments, including those for blood tests.

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.

Call your doctor straight away if you:

- Feel you need to take the medicine for longer periods of time.
- Feel you need to take more than the prescribed dose
- Feel very unwell when you stop taking the medicine but feel better when you start taking the medicine again.
- Plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.
- Become pregnant while you are taking this medicine.
- Are about to be started on any new medicine.

Things you should not do

- **Do not give Mersyndol to anyone else, even if they have the same condition as you.**
- **Do not take Mersyndol to treat any other complaints unless your doctor tells you to.**
- **Do not take high doses of the medicine for long periods of time unless your doctor tells you to.**
- **Do not stop taking Mersyndol or change the dose without checking with your doctor.**

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 drowsiness, dizziness 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 while taking Mersyndol.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while you are taking Mersyndol.

Drinking alcohol increases the likelihood of becoming drowsy while taking Mersyndol. Drinking alcohol and taking paracetamol at the same time can cause liver damage.

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

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.

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

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
Gastrointestinal related: <ul style="list-style-type: none">• Nausea• Vomiting• Constipation• Diarrhoea• Dry mouth• Indigestion Head and neurology related: <ul style="list-style-type: none">• Depression• Increased sensitivity to pain or increased levels of pain	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> Headache <p>Skin related:</p> <ul style="list-style-type: none"> Skin rashes Sweating <p>General:</p> <ul style="list-style-type: none"> Drowsiness Ringing in the ear Blurred vision Visible slowing of physical and emotional reactions Thickened phlegm <p>Urinary related:</p> <ul style="list-style-type: none"> Difficulty or inability to pass urine 	

Serious side effects	What to do
<ul style="list-style-type: none"> Painful 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 and changes in consciousness 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 body Rash, itching or hives on the skin Difficulty breathing, or shallow breathing 	

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 confused Unusual or extreme mood swings Headache Dizziness, light-headedness Fainting <p>Bleeding related:</p> <ul style="list-style-type: none"> Bleeding, bruising more easily Severe 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, light coloured bowel motions, dark coloured urine) <p>General:</p> <ul style="list-style-type: none"> Flushing of the face Shortness of breath Mouth ulcers, fever and sore throat Stomach pain Slow 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 as follows:

For Australia: 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.

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 Codeine phosphate hemihydrate - 9.75 mg Doxylamine succinate - 5 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Microcrystalline cellulose Purified talc Magnesium stearate Sodium starch glycollate Colouring agents - quinoline yellow and sunset yellow FCF

- | | |
|--|---|
| | <ul style="list-style-type: none">• COMPAP L (PI 910) |
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Do not take this medicine if you are allergic to any of these ingredients.

What Mersyndol looks like

Mersyndol is available in tablets and caplets:

Tablet – yellow, round, scored tablet marked "MERSYNDOL" "008" with "M" inside two concentric circles on the non-scored side.

Caplet – yellow, capsule-shaped tablets with 'Mersyndol' on one side and a breakline on the other side.

Mersyndol tablets and caplets are available in a blister pack of 20.

Australian Registration Number: AUST R 10110 (Tablets)

Australian Registration Number: AUST R 56535 (Caplets).

Who distributes Mersyndol

Distributed by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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