

Mersyndol[®]

Paracetamol, codeine phosphate, doxylamine succinate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mersyndol.

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 taking this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Mersyndol is used for

Mersyndol is a type of analgesic used to relieve pain and tension.

It 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 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.

Before you take it

When you must not take it

Do not take Mersyndol if you have:

- * **an allergic reaction to paracetamol, codeine or doxylamine**
- * **respiratory depression**
- * **lung disease (with symptoms such as wheezing, difficulty breathing, chronic cough)**
- * **asthma**
- * **G6PD deficiency, a human enzyme deficiency**
- * **known intolerance to medicines used to treat or prevent pain**
- * **liver problems**
- * **acute alcoholism**
- * **head injuries or conditions in which pressure within the head is raised**
- * **risk of developing paralytic ileus, a condition where the small bowel does not work properly.**

Do not take Mersyndol if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the

face, lips or tongue, which may cause difficulty in swallowing or breathing.

Mersyndol is not recommended for use in children under 12 years of age.

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.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn/damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- * **any of the ingredients listed at the end of this leaflet**
- * **any other substances, such as foods, preservatives or dyes.**

Tell your doctor or pharmacist 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.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- * **hypothyroidism**

- * adrenocortical insufficiency
- * prostate problems
- * low blood pressure
- * myasthenia gravis, a condition where the muscles become weak and tire easily. The eyes, face, throat and limb muscles are most commonly affected.
- * convulsions, fits or seizures
- * gall bladder disease or gall stones
- * recent gastrointestinal surgery
- * urinary tract surgery
- * lung problems
- * obstructive and inflammatory bowel disease
- * liver problems
- * kidney problems
- * asthma.

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Mersyndol.

Taking other medicines

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

These include:

- * antihistamines
- * anticholinergics, medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- * sleeping tablets
- * antidiarrhoeal medicines
- * medicines used to help lower high blood pressure
- * opioid antagonists
- * tranquillisers or anxiolytics (medicines used for anxiety or nerves)
- * medicines used to treat certain mental and emotion conditions

- * any medicine which thins the blood
- * medicines to treat epilepsy
- * metoclopramide or domperidone, medicines used to control nausea and vomiting
- * propantheline, a medicine used to treat stomach ulcers
- * chloramphenicol
- * alcohol
- * ciprofloxacin
- * quinidine
- * ritonavir
- * mexiletine
- * cimetidine
- * zidovudine and rifampicin, medicines used to treat infections
- * monoamine oxidase inhibitors (such as phenelzine and tranylcypromine), even if you have stopped taking them now, but have taken them within the last 14 days
- * antidepressants.

These medicines may be affected by Mersyndol, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Mersyndol.

How to take it

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.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how many to take.

Follow the instructions they give you.

If you take the wrong dose, Mersyndol may not work as well and your problem may not improve.

Mersyndol is not recommended for use in children under 12 years of age.

How to take it

Swallow the tablets whole with a full glass of water or other liquid.

When to take it

Mersyndol 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 take it

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.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or

anyone else may have taken too much Mersyndol.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Large amounts of paracetamol can cause liver damage.

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

While you are taking it

Things you must do

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

If you are about to be started on any new medicine, tell your doctor and 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.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist that you are taking Mersyndol.

Things you must 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.

Things to be careful of

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

Make sure you know how you react to it before you 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.

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.

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.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- * drowsiness
- * dizziness
- * blurred vision
- * nausea
- * diarrhoea

- * vomiting
- * stomach pain
- * constipation
- * irregular heart beats
- * skin rashes
- * sweating
- * difficulty breathing
- * dry mouth
- * muscle stiffness

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- * swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- * hives
- * fainting
- * yellowing of the skin and eyes (jaundice).

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Mersyndol. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 30 degrees C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor or pharmacist tells you to stop taking Mersyndol, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Mersyndol is available as a tablet.

Yellow, flat and round with 'M' inside two circles on one side and 'Mersyndol 008' and a breakline on the other side

Tablets are available in a box containing 20 tablets.

Ingredients

Active Ingredient:

Each Mersyndol tablet contains:

- * Paracetamol 450 mg
- * Codeine phosphate 9.75 mg
- * Doxylamine succinate 5 mg

Inactive Ingredients:

Each Mersyndol tablet contains:

- * cellulose
- * purified talc
- * magnesium stearate
- * sodium starch glycollate
- * colouring agents - quinoline yellow and sunset yellow

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

Manufacturer/Sponsor

Mersyndol is made in India.

Mersyndol is supplied in New Zealand by:
sanofi -aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie
Auckland

This leaflet was prepared in October 2011.

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