

MERSYNDOL® DAYSTRENGTH

paracetamol and codeine phosphate hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mersyndol DayStrength.

It does not, however, contain all the available information. It does not take the place of talking to your pharmacist or doctor.

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 pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What Mersyndol DayStrength is used for

Mersyndol DayStrength contains paracetamol and codeine.

Codeine phosphate hemihydrate belongs to a group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Paracetamol and codeine work together to stop the pain messages from getting through to the brain.

Mersyndol DayStrength is a type of analgesic intended for short term

use to relieve moderate pain and fever.

Your pharmacist or doctor, however, may prescribe Mersyndol DayStrength for another purpose.

Ask your pharmacist or doctor if you have any questions about this medicine.

Mersyndol DayStrength 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 DayStrength if you have:

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema (a serious lung disease)
- glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
- ultra-rapid metaboliser of CYP 2D6 (a fast metaboliser of codeine by the CYP 2D6 enzyme)
- had your tonsils or adenoids removed and are aged between 12 - 18 years
- severe liver or kidney disease
- diarrhoea caused by antibiotics or poisoning
- chronic constipation

Do not take Mersyndol DayStrength if you are allergic to 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.

Do not take codeine if you have alcohol dependence.

Do not give Mersyndol DayStrength to children under 12 years of age.

Do not take Mersyndol DayStrength during the third trimester of pregnancy.

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

This may produce withdrawal effects in the newborn baby.

Tell your pharmacist or doctor if you are pregnant or intend to become pregnant.

Your pharmacist or doctor will discuss the benefits and risks of taking the medicine during pregnancy.

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

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

Do not take Mersyndol DayStrength 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 Mersyndol DayStrength if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet

- any other substances, such as foods, preservative or dyes
- aspirin, anti inflammatory medication or any other medicines

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

Tell your pharmacist if you take sedatives (medicines used to help you relax or sleep).

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

- difficulty in breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)
- known analgesic intolerance
- heart, liver or kidney problems
- underactive thyroid
- a history of drug dependence, including alcohol dependence
- pre-existing opioid dependence
- chronic alcohol use including recent cessation of alcohol intake
- low glutathione reserves
- Gilbert's syndrome
- recent surgery of the stomach or intestine
- prostate problems
- Multiple sclerosis
- low blood pressure
- head injury or trauma
- urinary, bowel or gallbladder conditions
- chronic constipation
- problems with the adrenal glands
- myasthenia gravis, a muscle disorder
- convulsions, fits or seizures
- if you know you are a CYP 2D6 ultra-rapid metaboliser

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

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 store.

Some medicines may interfere with the absorption of Mersyndol DayStrength. These include:

- medicines used to help relax, sleep or relieve anxiety, such as barbiturates and sedatives
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- medicines used to treat epilepsy or fits
- medicines which thin the blood such as warfarin
- other opioid analgesics used to treat pain
- monoamine oxidase inhibitors, medicine used to treat depression, taken within the last 14 days
- flucloxacillin, zidovudine or rifampicin, medicines used to treat infections
- metoclopramide or domperidone, medicines used to control nausea and vomiting
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- chloramphenicol, an antibiotic used to treat ear and eye infection
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- medicines used to treat high blood pressure
- cholestyramine, a medicine used to lower high cholesterol levels

- chelating resin
- buprenorphine
- naltrexone

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

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

How to take it

How much to take

The standard dose for this medicine is:

Adults and children 12 years or over:

One or two tablets every 3 to 4 hours as needed for relief. Do not take more than 8 caplets in 24 hour period.

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

Mersyndol Daystrength is not recommended for use over an extended period of time.

Do not take more than the recommended dose.

Talk to your pharmacist or doctor about pain control if Mersyndol DayStrength is not helping.

If your body cannot metabolise codeine properly, you may be getting reduced benefit from this medicine.

If you are over 65 years of age, talk to your pharmacist or doctor 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.

How to take it

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

Mersyndol DayStrength can be taken with or without food.

If you forget to take it

You may take Mersyndol DayStrength as soon as you remember or if you think you need it.

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

This may increase the chance of getting unwanted side effect.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Mersyndol DayStrength.

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

You may need medical attention.

Large amounts of paracetamol, one of the active ingredients, can cause liver damage. Children who take too much Mersyndol DayStrength can also suffer extreme drowsiness, rash or have trouble seeing.

While you are taking it

Things you must do

Tell your doctors, dentists and pharmacists who are treating you that you are taking Mersyndol DayStrength.

If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking Mersyndol DayStrength.

If you plan to have surgery that needs a general anaesthetic, tell

your doctor or dentist that you are taking this medicine.

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 Mersyndol DayStrength.

Things you must not do

Children:

Do not give this medicine for more than 48 hours unless a doctor tells you.

Adults:

Do not take more than a few days at a time unless your doctor tells you to.

Do not take more than the recommended dose 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 use this medicine to treat any other complaints unless your pharmacist or doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Mersyndol DayStrength affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or operate machinery.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Codeine may be habit forming.

Avoid alcohol while taking Mersyndol DayStrength as it may interfere with the effects of the medicine and may increase the risk of liver side effects.

Drinking large quantities of alcohol while taking Mersyndol DayStrength may increase the risk of liver side effects due to paracetamol.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your pharmacist or doctor has weighed the risk 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 pharmacist or doctor as soon as possible if you do not feel well while you are taking Mersyndol DayStrength.

It helps most people with their condition but it may have some unwanted side effects in some people.

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

- constipation
- vomiting
- nausea
- dizziness
- drowsiness
- indigestion
- sweating
- difficulty in passing urine

These are mild side effects of this medicine and usually short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat
- severe stomach pain, nausea and vomiting
- wheezing or difficulty breathing, shallow breathing or shortness of breath, swelling of the face, lips, tongue or other parts of the body
- skin rashes

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

These side effects are very rare.

Tell your pharmacist or doctor 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 pharmacist or doctor 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 pharmacist or doctor.

Storage

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

Keep the medicine in a cool place where the temperature stays below 30°C.

Do not store it or any other medicines in the bathroom, near a sink, or on a window sill.

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

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Mersyndol DayStrength is available as capsule-shaped tablets or 'caplets', which are yellow and are embossed with 'MERSYNDOL' on one side and 'DS' and a breakline on the other.

Mersyndol DayStrength is available in boxes of 24 & 36 tablets.

Ingredients

Active Ingredients:

- 500mg paracetamol per tablet
- 9.6 mg codeine phosphate hemihydrate per tablet

Inactive Ingredients:

- purified talc
- magnesium stearate
- sodium starch glycollate
- quinoline yellow CI 47005
- compap L

Mersyndol DayStrength does not contain aspirin, sucrose, lactose, gluten or tartrazine.

Manufacturer

Mersyndol DayStrength is supplied in Australia by:

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

This leaflet was prepared in
September 2017

Australian Registration Number
AUST R 59985

® Registered Trademark

mersyndol-daystrength-ccsiv1-
cmiv10-26sept17