

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

MERSYNDOL® with codeine

Acetaminophen, codeine phosphate, doxylamine succinate

This patient medication information is written for the person who will be taking **MERSYNDOL® with codeine**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **MERSYNDOL® with codeine**, talk to a healthcare professional.

What MERSYNDOL® with codeine is used for:

For temporary relief of: headaches, muscular aches and pains, cold symptoms: sneezing, runny nose, itchy, watery eyes, itchy nose and throat.

This preparation contains codeine and should not be administered to children except on the advice of a physician, dentist, or nurse practitioner.

How MERSYNDOL® with codeine works:

MERSYNDOL® with codeine contains 3 medicinal ingredients. The analgesic effects of acetaminophen are combined with codeine phosphate, which relieves mild to moderate pain by acting on your brain and spinal cord. Doxylamine succinate relieves symptoms of allergy and the common cold by blocking natural substances (i.e. histamines) your body makes.

The ingredients in MERSYNDOL® with codeine are:

Medicinal ingredients: acetaminophen 325 mg (analgesic); codeine phosphate 8 mg (analgesic), doxylamine succinate 5 mg (antihistamine).

Non-medicinal ingredients: croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pregelatinized starch, povidone and silicon dioxide.

MERSYNDOL® with codeine comes in the following dosage forms:

Tablet of acetaminophen 325 mg, codeine phosphate 8 mg and doxylamine succinate 5 mg

Do not use MERSYNDOL® with codeine if you:

- are allergic to acetaminophen, doxylamine, codeine, or other opioids, or to any of the non-medicinal ingredients (see Inactive Ingredients section)
- have difficulty breathing, acute asthma attacks or other chronic lung disease
- have suffered head injury
- are at risk of blocked intestines or constipation
- suffer from seizures

- are in your last trimester of pregnancy, in case of risk of premature birth, or are breastfeeding. Codeine may cause serious harm to a breastfed baby.
- have severe liver dysfunction
- are taking other drugs containing **acetaminophen, codeine and doxylamine succinate**. If you are not sure whether a drug contains these ingredients, ask a doctor or pharmacist.
- **do not use** in children under 18 years old.
- are taking monoamine inhibitors (MAOIs) or within 14 days of stopping MAOIs
- have conditions with elevated intracranial pressure and head trauma
- have compromised respiratory function and chronic obstructive airway disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MERSYNDOL® with codeine. Talk about any health conditions or problems you may have, including if you:

- have chronic alcoholism, or you are taking 3 or more alcoholic beverages per day
- suffered from alcoholism, drug abuse or dependence
- have a liver disease or serious kidney disease
- have a liver disease called Gilbert's syndrome
- have a heart disease, hypertension, a thyroid disease or a disease called Addison's disease
- have chronic constipation
- are or have been dependent to other medications called opioids
- have had a surgery to remove the gallbladder
- have recently had surgery under general anaesthesia
- are taking Warfarin-containing blood thinning drugs
- are taking other medications that can make you sleepy or less alert, for example: narcotic analgesics, benzodiazepines or sedating antihistamines, or you are currently taking anti-depressants, other prescription drugs or natural health products
- are taking gabapentin or pregabalin which are medications to treat epilepsy or pain due to nerve problems (neuropathic pain)
- have glaucoma
- have difficulty in urination due to enlargement of the prostate gland
- have glucose-6-phosphate-dehydrogenase deficiency
- are pregnant
- are planning to breastfeed
- have low levels of glutathione as this may result in the build up of acid in your body
- have sepsis (when bacteria and their toxins circulate in the blood leading to organ damage)
- suffer from malnutrition
- are also taking flucloxacillin (an antibiotic)

Other warnings you should know about:

Liver warning: severe or possibly fatal liver damage may occur if you take:

- more than the recommended dose in 24 hours
- with other drugs containing acetaminophen
- while drinking three (3) or more alcoholic drinks every day

Symptoms of liver damage may include:

- yellow skin or eyes
- dark urine
- sweating
- nausea
- vomiting
- stomach pain
- unusual tiredness
- loss of appetite

Allergy alert: Acetaminophen may cause serious skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

Pain:

- if you have pain that gets worse after you take this medicine, do not take more without first talking to your doctor.
- if you feel more sensitive to pain, or if you have new pain after taking this medicine

If any of the above noted symptoms occur, stop use and seek medical help right away.

Elderly persons, small children, patients with liver disorders, chronic alcohol consumption, as well as patients concomitantly treated with other medicines are at an increased risk of intoxication, including fatal outcome.

Blood and fluid abnormality: A serious condition that can make blood more acidic (called metabolic acidosis which is a blood and fluid abnormality) can happen in patients:

- with liver disease
- with severe illnesses, such as severe kidney disease or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage)
- suffering for malnutrition or chronic alcoholism
- with glucose-6-phosphate-dehydrogenase deficiency
- with a liver disease called Gilbert's syndrome

Metabolic acidosis has been reported in patients in these situations when acetaminophen is used at regular doses for a prolonged period or when acetaminophen is taken together with flucloxacillin (an antibiotic).

Symptoms of metabolic acidosis may include:

- serious breathing difficulties with deep rapid breathing
- drowsiness
- feeling sick (nausea)
- being sick (vomiting)

Contact your doctor immediately if you develop any of these symptoms during treatment with MERSYNDOL® with codeine.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may also interact with MERSYNDOL® with codeine:

- Drugs affecting the nervous system such as tranquilizers, hypnotics, psychotherapeutic agents, narcotic analgesics, antitussives, antihypertensives, antihistamines or any other drug which affects the nervous system
- Imipramine
- Amitriptyline
- Mono Amine Oxidase Inhibitors (e.g. tranylcypromine)
- Drugs used to treat diarrhea
- Morphinic agonists-antagonists (e.g. buprenorphine, naltrexone)
- Benzodiazepines
- Opioids
- Phenobarbital
- Phenytoin
- Carbamazepine
- Topiramate
- Rifampicin
- Flucloxacillin
- Warfarin
- Antivitamin K
- Chloramphenicol
- Zidovudine
- Metoclopramide
- Domperidone
- Chelating Resins
- Drugs which inhibit the metabolism of Codeine, which include Quinidine, Fluoxetine, Paroxetine, Bupropion, Cinacalcet and Methadone
- Rifampin
- Gabapentinoids (gabapentin and pregabalin)

How to take MERSYNDOL® with codeine:

Usual dose:

Do not take more than directed (see liver warnings).

Adults (18years and older): 1 or 2 tablets every 4-6 hours as required. To be used only on the advice of a physician. Do not exceed 12 tablets in 24 hours unless advised by a doctor.

Overdose:

If you think you, or a person you are caring for, have taken too much MERSYNDOL® with codeine, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are

no signs or symptoms.

Possible side effects from using MERSYNDOL® with codeine:

These are not all the possible side effects you may have when taking MERSYNDOL® with codeine. If you experience any side effects not listed here, tell your healthcare professional.

When using this product:

- drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- do not drive or engage in activities requiring alertness
- avoid alcoholic drinks
- excitability may occur, especially in children
- addiction may occur following prolonged use and at high doses

Stop use and ask a doctor if:

- your symptoms worsen or last for more than five days
- you feel sedated or drowsy, confused, have shallow breathing or severe constipation

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C.

Keep out of reach and sight of children.

If you want more information about MERSYNDOL® with codeine:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.sanofi.com/en/canada, or by calling 1-800-265-7927.

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