

PART III: CONSUMER INFORMATION

^NMARINOL[®]
dronabinol;
delta-9-tetrahydrocannabinol

This leaflet is part III of a three-part "Product Monograph" published when MARINOL was approved for sale in Canada and is designed specifically for Consumers. Please read it and keep it with your medicines in case you need to look at it again. This leaflet is a summary and will not tell you everything about MARINOL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

MARINOL is intended to:

- help regain the loss of appetite associated with weight loss in patients with AIDS
- prevent nausea (feeling of sickness) and vomiting, which can occur while undergoing cancer chemotherapy treatment.

What it does:

MARINOL increases appetite and decreases nausea (feeling of sickness) and vomiting.

When it should not be used:

If you have any of the following conditions, you should **not** use this product:

- known or suspected allergy to marijuana, other cannabinoids, or sesame oil
- significant liver or kidney problems
- serious heart disease
- history of schizophrenia or any other psychotic disorder
- in children or adolescents under 18 years of age.
- are pregnant or nursing
- are female at risk of pregnancy and not using a reliable contraceptive
- are male and intending to father a child while on treatment with MARINOL

What the medicinal ingredient is:

MARINOL contains delta-9-tetrahydrocannabinol (THC), which is a synthetic form of the naturally occurring THC in *Cannabis sativa L.* (marijuana).

What the important nonmedicinal ingredients are:

sesame seed oil

Other non-medicinal ingredients include: gelatin, glycerin, iron oxide black (5 mg capsules), iron oxide red (5 mg capsules), and titanium dioxide.

What dosage forms it comes in:

2.5 mg and 5 mg capsules

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

THC, the active component of MARINOL, has numerous effects on the central nervous system such as changes in mood, decreased mental performance and memory and altered perceptions of reality. Symptoms such as fainting and interference in the physical ability to carry out complicated tasks have been seen in patients taking MARINOL. Therefore you should not drive, operate machinery or engage in activities that require unimpaired judgement and coordination.

While taking MARINOL you should not drink alcohol or take other drugs which may have an effect on the central nervous system such as sedatives or hypnotics, without consulting your doctor, as these products have a further additive effect on some of the effects listed above.

Do not smoke marijuana while using MARINOL. This can cause an overdose.

BEFORE you use MARINOL talk to your doctor or pharmacist if you:

- suffer from any allergic reactions
- suffer from epilepsy
- suffer from any liver, kidney or heart disease
- suffer from schizophrenia or depression
- have an irregular heart beat/rhythm, including a fast or slow pulse
- have high blood pressure
- have abused or are abusing drugs or alcohol
- are taking other prescription medicines, over-the-counter medicines or natural health products.

You and your partner must ensure reliable contraceptive precautions are taken during your treatment and for at least three months after you stop taking MARINOL.

There may be a potential for abuse or development of dependence in some individuals with long-term use. Discuss with your doctor.

If you see another doctor or go into hospital, let them know what medicines you are taking.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with MARINOL include: alcohol, amitriptyline, amoxapine, amphetamines, antihistamines, antipyrene, atropine, barbiturates, benzodiazepines, buspirone, CNS depressants, disulfiram, cocaine, desipramine, fluoxetine, lithium, muscle relaxants, opioids, scopolamine, sleeping pills, theophylline, tricyclic antidepressants.

Care should be taken with sedatives and hypnotics as co-administration with MARINOL may possibly enhance the effect.

Do not smoke or use other forms of cannabis while using MARINOL since it can cause an overdose.

Alcohol may interact with MARINOL, particularly in affecting coordination, concentration and the ability to respond quickly.

PROPER USE OF THIS MEDICATION

MARINOL must be swallowed whole to work effectively. Do not crush or chew the capsules.

MARINOL should be taken exactly as directed by your doctor.

Your doctor must write a new prescription each time you need more MARINOL. It is important to call your doctor before you take your last capsule. You should also give your pharmacist a few days notice of your need for more MARINOL.

Your doctor has prescribed this drug for your use only. Do not let anyone else use it.

Usual starting dose:

One white capsule (2.5 mg) of MARINOL twice daily, before lunch and supper.

Dose adjustments:

Your doctor may adjust your MARINOL dosage if needed to maximize its effect or to decrease any side effects.

Overdose:

- Signs of a **mild** overdose would include drowsiness, euphoria, heightened sensory awareness, altered time perception, red eyes, dry mouth and rapid heart rate (tachycardia).
- **Moderate** overdosage would produce memory problems, depersonalization, mood alteration, urinary retention, and constipation.
- **Severe** overdosage would lead to decreased motor coordination, lethargy, slurred speech, and dizziness when standing up too fast (postural hypotension).
- An overdose might cause you to faint.

If you accidentally take more than you normally do and you experience severe intoxication reactions, contact your nearest hospital emergency department, or tell your doctor immediately. Bring any remaining medicine with you.

Missed Dose:

If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double your dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you notice any symptoms that bother you, stop the MARINOL and call your doctor at once.

If You Have Problems in the First Few Days

When you first use MARINOL your body is more sensitive and you may experience dizziness, confusion, sleepiness, or a high feeling. These symptoms usually go away in 1 to 3 days with continued dosage. If these symptoms are troublesome or persist, notify your doctor at once. Your doctor may then reduce the dose to one capsule before supper, or later in the evening, or even at bedtime.

What to Do When Problems Occur

IF YOU NOTICE ANY WORRISOME SYMPTOMS OR PROBLEMS, STOP THE MARINOL AND CALL YOUR DOCTOR AT ONCE.

You may experience changes in mood or have other effects such as euphoria, dizziness, somnolence and thinking abnormalities, when taking MARINOL. Be sure that there is a responsible person nearby when you first take MARINOL or when there is an adjustment in your dose. MARINOL may produce physical and psychological dependence.

You may also experience uncommon side effects such as feeling tired, dry mouth or allergic reactions (e.g. rash, itchiness).

You should not smoke marijuana while using MARINOL. It is possible to get too much delta-9-tetrahydrocannabinol (an overdose), especially if you use MARINOL and smoke marijuana at the same time.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	anxiety	√		
	confusion	√		
	dizziness	√		
	drowsiness	√		
	feeling abnormal		√	
	hallucination			√
	palpitations			√
paranoia			√	
Un-common	depression		√	
	hypotension			√
	seizure			√
	fall		√	

This is not a complete list of side effects. For any unexpected effects while taking MARINOL, contact your doctor or pharmacist.

HOW TO STORE IT

Store in a cool place (between 2° and 8°C), in the original container.

Be careful that the capsules don't freeze. Heat or moisture may cause your MARINOL to break down or stick together. Keep your medicine away from heat, direct light and damp places like the bathroom or near the kitchen sink or stove.

Keep MARINOL out of the reach of children. If a child puts a capsule in their mouth or swallows MARINOL, take the medicine away from the child and contact a poison control centre immediately, or contact a doctor immediately.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
 By toll-free fax: 866-678-6789
 Online:
www.healthcanada.gc.ca/medeffect
 By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
 Canada Vigilance National Office
 Marketed Health Products Safety and Effectiveness
 Information Bureau
 Marketed Health Products Directorate
 Health Products and Food Branch
 Health Canada
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Should you require information related to the

management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
[http:// www.hc-sc.gc.ca](http://www.hc-sc.gc.ca) (Drug Product Database) or by contacting the sponsor, Abbott Laboratories, Limited, at: 1-800-268-4276.

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