

PATIENT INFORMATION

MARINOL[®] (dronabinol capsules, USP)

2.5 mg, 5 mg, 10 mg

**for use in the loss of appetite
associated with weight loss
in patients with AIDS.**

IMPORTANT

YOUR DOCTOR HAS PRESCRIBED THIS DRUG FOR YOUR USE ONLY. DO NOT LET ANYONE ELSE USE IT.

KEEP THIS MEDICINE OUT OF THE REACH OF CHILDREN AND PETS. If a child puts a capsule in his or her mouth or swallows MARINOL[®] capsules, take the medicine away from the child and contact a poison control center immediately, or contact a doctor immediately.

Do not drive a car or operate machinery until you know how MARINOL capsules affects you. While taking MARINOL capsules, do not drink alcohol, smoke marijuana, or take other drugs that have an effect on the central nervous system (such as sedatives or hypnotics). Unless advised by your doctor, do not use MARINOL capsules if you are pregnant or nursing.

INTRODUCTION

This leaflet provides a summary of information about MARINOL capsules. Please read it and keep it with your medicines in case you need to look at it again. Ask your doctor, nurse, or pharmacist if you have any questions.

MARINOL capsules contains man-made dronabinol (THC). Dronabinol also occurs naturally, and has been extracted from *Cannabis sativa L.* (marijuana).

PRECAUTIONS

Be sure to tell your doctor if you:

- have or had heart disease
- have or had cardiac disorders because of occasional hypotension, possible hypertension, syncope, or tachycardia
- have current or a history of drug abuse
- have current or a history of alcohol abuse
- have or had mental health problems (mania, depression, schizophrenia)
- have a history of seizure disorder and/or seizure-like activity
- have allergies to drugs
- are pregnant or nursing, or become pregnant

If you become pregnant while taking MARINOL capsules, stop using it until you have talked to your doctor.

MARINOL capsules should be used with caution in children because it has not been studied in children.

MARINOL capsules should be used with caution in elderly patients because they may be more sensitive to the neurological, psychoactive, and postural hypotensive effects of the drug.

MARINOL capsules can dangerously interact with alcohol and with other drugs that have an effect on the central nervous system (such as Valium, Librium, Xanax, Seconal, Nembutal, or Phenobarbital).

Do not drive or operate machinery until you are sure how MARINOL capsules affects you and you are able to perform safely.

You may experience changes in mood or have other effects when first taking MARINOL capsules. Be sure that there is a responsible person nearby when you first take MARINOL capsules or when there is an adjustment in your dose.

Tell your doctor if you are taking any other prescription or nonprescription medicines.

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

INFORMATION ABOUT USING MARINOL CAPSULES

Introduction

Eating a nutritionally balanced diet is fundamental for all stages of life. For persons living with Human Immunodeficiency Virus (HIV); it's especially important to ensure an adequate diet to maintain an ideal weight and good nutritional status. There is some indication that optimal nutrition can help maintain the integrity of the immune system, and an adequate diet will allow you to better withstand the diseases associated with an AIDS diagnosis.

Many conditions, frequently interrelated, may cause a loss of appetite. Chewing and swallowing may become difficult or painful, due to inflammation or sores in your mouth and throat.

You may experience intermittent diarrhea or overall physical discomfort associated with AIDS. Sometimes, shopping for food and preparing adequate meals may drain your energy and desire to eat. Mental depression also may result in a loss of your appetite, or you simply may grow increasingly frustrated with repeated eating problems.

A loss of appetite may occur at various times during illness associated with HIV infection. It often leads to the selection of an inadequate diet. Because a poor nutrient intake can result in weight loss and malnutrition, it's important to learn to recognize and handle a temporary loss of your appetite.

Your doctor may prescribe an appetite stimulant such as MARINOL capsules. MARINOL capsules should be taken exactly as directed by your doctor, and indicated on the prescription label. You will most likely start therapy by taking one white capsule (2.5 mg) of MARINOL capsules twice daily, before lunch and supper. Your doctor may adjust your MARINOL capsules dosage if needed to maximize its effect or to decrease any side effects.

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

It is important not to take sedatives, hypnotics, other mind altering substances, or alcohol, while taking MARINOL capsules without notifying your health care givers (physician, pharmacists

and nurses). Do not drive or attempt other activities requiring full alertness while taking MARINOL capsules. Your doctor will advise when you may resume these activities.

Your doctor and pharmacist should be made aware of any other prescription medications or over-the-counter products you may be taking, as they could affect the way you respond to MARINOL capsules.

Remember to keep this and all other medication out of the reach of children.

Increasing your appetite is only the first step in improving your nutritional status. How, what, and when you eat are also very important.

How to Eat

The purpose of consuming an adequate diet, even at times when you don't feel like eating, is to maintain an ideal weight and good nutritional status. Key to an adequate diet for HIV-infected individuals are foods dense in calories and nutrients. In other words, when you find it difficult to eat, make the most of what you do consume by selecting foods that provide many calories or nutrients in each mouthful.

Try some of the following ideas to boost your food intake. Keep in mind the foods you previously may have limited in your diet, especially those higher in fat, now can provide a significant source of calories. Enjoy an ice cream sundae frequently.

Cool or cold foods can dull pain from mouth and throat sores; popsicles may even numb your mouth prior to eating a larger meal. The cooler temperatures also diminish the aroma of unappetizing food.

Blend one cup of nonfat dry milk powder with one quart of whole milk. Refrigerate and use "double strength" milk for all traditional uses (puddings, cereal, shakes, soups).

Foods with a softer consistency, such as applesauce, may aid swallowing. Creamed sauces or gravies also moisten food to encourage swallowing.

Creating an appetizing meal involves more than just food. Try to eat in a pleasant atmosphere – sit in a comfortable chair, use a tablecloth and china, invite a friend to share your meal.

What to Eat

Planning ahead is one of the most effective ways to deal with a loss of appetite. Stock up on staple foods, particularly those high in calories and protein, so they're available when you need them. Include favorite foods on your shopping list. Also consider these protein and nutrient dense foods:

- Nonfat dry milk powder
- Powdered breakfast drinks
- Peanut butter and jelly
- Pudding cups
- "Trail mix" (dried fruit, nuts, cereals)
- Creamed soups
- Canned (or frozen) fruit in heavy syrup
- Canned tuna, chicken or other sandwich spreads
- Boxed macaroni and cheese

In addition to staples, refrigerated and frozen foods contribute important nutrients to an adequate diet. Several key choices, high in protein and calories, are listed below:

- Yogurt
- Cheeses
- Cold cuts, beef and poultry
- Cottage cheese
- Ice cream and sherbet
- Popsicles or pudding pops
- Hard cooked eggs or pasteurized eggs*

*Raw or undercooked cracked eggs pose danger of *Salmonella*. The compromised immune function of persons with AIDS places them at greater than average risk from *Salmonella* infection.

Commercial food supplements are also available to boost your caloric and nutrient intake. Offered in a variety of flavors and textures, these products supply a concentrated source of calories and protein. You may want to ask your treatment provider for more information about supplements. You may also request a referral to a registered dietitian who can provide individualized dietary recommendations to you.

When to Eat

“Nutritious” meals can be eaten three times a day, but frequent, small snacks or meals can help you consume the calories and protein you need without feeling full from a large meal. Eat when you feel hungry, using modern technology, including your microwave, to quickly prepare a nutritious snack or meal.

Storage Instructions

The best place to store MARINOL capsules is in a cool place (46-59°F; 8-15°C) or in the refrigerator. Be careful that the capsules don’t freeze. Heat or moisture may cause your MARINOL capsules to break down or stick together, so keep your medicine away from heat and direct light, and potentially damp places like in the bathroom or near the kitchen sink.

If You Are Taking Medicines

MARINOL capsules use may change the effect of other medicines. It is important to tell your doctor about all the medicines you are taking including all non-prescription medication.

What to Watch For (Adverse Effects)

You should not smoke marijuana while using MARINOL capsules. It is possible to get too much dronabinol (an overdose), especially if you use MARINOL capsules and smoke marijuana at the same time. 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 Have Problems in the First Few Days

When you first use MARINOL capsules 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 CAPSULES AND CALL YOUR DOCTOR AT ONCE.

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