

PATIENT INFORMATION
MARINOL[®] (mare in all)
(dronabinol)
capsules, for oral use, CIII

What is the most important information I should know about MARINOL?

MARINOL can cause serious side effects, including:

- **Worsening mental (psychiatric) symptoms.** Psychiatric symptoms can worsen in people who have mania, depression, or schizophrenia and who take MARINOL. MARINOL taken with medicines that cause psychiatric symptoms can worsen psychiatric symptoms. Elderly people who take MARINOL may have a greater risk of having psychiatric symptoms. Tell your doctor if you have new or worsening mood symptoms, including symptoms of mania, depression, or schizophrenia.
- **Problems thinking clearly.** Tell your doctor if you have trouble remembering things, concentrating, have increased sleepiness, or confusion. Elderly people may have a greater risk of having problems thinking clearly.
- **Changes in your blood pressure.** MARINOL may increase or decrease your blood pressure, especially when you start taking MARINOL or when your dose is changed. Tell your doctor if you have signs or symptoms of changes in your blood pressure including: headaches, vision problems, dizziness, feeling lightheaded, fainting, or a fast heartbeat. Elderly people, especially those with dementia, and people with heart problems may have an increased risk of changes in blood pressure and an increased risk of falls.

What is MARINOL?

- **MARINOL is a prescription medicine used in adults to treat:**
 - loss of appetite (anorexia) in people with AIDS (Acquired Immune Deficiency Syndrome) who have lost weight.
 - nausea and vomiting caused by anti-cancer medicine (chemotherapy) in people whose nausea and vomiting have not improved with usual anti-nausea medicines.

MARINOL is a controlled substance (CIII) because it contains dronabinol, which can be a target for people who abuse prescription medicines or street drugs. Keep your MARINOL in a safe place to protect it from theft. Never give your MARINOL to anyone else because it may cause death or harm them. Selling or giving away this medicine is against the law.

It is not known if MARINOL is safe and effective in children.

Do not take MARINOL if you:

- had an allergic reaction to dronabinol. Signs and symptoms of an allergic reaction to dronabinol include: swelling of the lips, hives, a rash over your whole body, mouth sores, skin burning, flushing, and throat tightness.
- had an allergic reaction to sesame oil.

Before taking MARINOL, tell your doctor about all of your medical conditions, including if you:

- have or had heart problems.
- have or had problems with drug abuse or dependence.
- have or had problems with alcohol abuse or dependence.
- have or had mental health problems including mania, depression, or schizophrenia.
- have had a seizure or have a medical condition that may increase your risk of having a seizure.
- are pregnant or plan to become pregnant. MARINOL may harm your unborn baby. Avoid the use of MARINOL if you are pregnant.
- are breastfeeding or plan to breastfeed. The Centers for Disease Control and Prevention recommends that mothers with HIV not breastfeed because they can pass the HIV through their breast milk to the baby. It is not known if MARINOL passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take MARINOL. Do not breastfeed while taking MARINOL and for 9 days after your last dose of MARINOL if you are being treated for nausea and vomiting caused by anti-cancer medicine.

Tell your doctor about all the medicines you take or have taken in the last 14 days, including prescription and over-the-counter medicines, vitamins, and herbal supplements. MARINOL and certain other medicines can affect each other, causing serious side effects.

How should I take MARINOL?

- Take MARINOL exactly as your doctor tells you to. Your doctor may change your dose after seeing how it affects you. Do not change your dose unless your doctor tells you to change it.
- **If you are an adult with AIDS with loss of appetite and weight loss:**
 - MARINOL is usually taken 2 times each day, 1 hour before lunch and 1 hour before dinner. If you are elderly or unable to tolerate this dose of MARINOL, your doctor may prescribe MARINOL to be taken 1 time each day, 1

hour before dinner or bedtime to reduce your chance of having nervous system problems.

- **If you are an adult with nausea and vomiting caused by anti-cancer medicine:**
 - MARINOL is usually taken 1 to 3 hours before your chemotherapy treatment and then every 2 to 4 hours after chemotherapy for up to 4 to 6 doses each day. If you are elderly, your doctor may prescribe MARINOL to be taken 1 to 3 hours before your chemotherapy, 1 time each day to reduce your chance of having nervous system problems.
 - Take your first dose of MARINOL on an empty stomach at least 30 minutes before eating. After your first dose of MARINOL, you can take MARINOL with or without food. Always take your dose at the same time with regard to meals.
- **If you take too much MARINOL, call your Poison Control Center at 1-800-222-1222 right away.**

What should I avoid while taking MARINOL?

- Do not drive, operate machinery, or do other dangerous activities until you know how MARINOL affects you. MARINOL taken with other medicines that cause dizziness, confusion, and sleepiness may make these symptoms worse.

What are the possible side effects of MARINOL?

MARINOL may cause serious side effects, including:

- See “**What is the most important information I should know about MARINOL?**”
- **Seizures.** MARINOL may increase your risk of seizures. Stop taking MARINOL and call your doctor and get medical care right away if you have a seizure during treatment with MARINOL.
- **Drug and alcohol abuse.** You may have an increased risk of abusing MARINOL if you have a history of drug or alcohol abuse or dependence, including marijuana. Tell your doctor if you develop abuse behaviors such as increased irritability, nervousness, restlessness or want more or higher doses of MARINOL during your treatment.
- **Nausea, vomiting, or stomach-area (abdominal) pain.** Tell your doctor if you have nausea, vomiting, or abdominal pain or if your nausea, vomiting, or abdominal pain gets worse during treatment with MARINOL.

The most common side effects of MARINOL include:

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| • dizziness | • abnormal thoughts |
| • feeling extremely happy (euphoria) | • stomach-area (abdominal) pain |
| • overly suspicious or feeling people want to harm you (paranoid reaction) | • nausea |
| • sleepiness | • vomiting |

These are not all the possible side effects of MARINOL. Tell your doctor if you have any side effect that bothers you or does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store MARINOL?

- Store MARINOL in a cool place such as in a refrigerator, at a temperature between 46°F to 59°F (8°C to 15°C).
- **Do not** freeze MARINOL capsules.
- Keep the MARINOL container closed tightly.

Keep MARINOL and all medicines out of the reach of children.

General information about the safe and effective use of MARINOL

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use MARINOL for a condition for which it was not prescribed. Do not give MARINOL to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about MARINOL that is written for health professionals.

What are the ingredients in MARINOL?

Active ingredient: dronabinol

Inactive ingredients: 2.5 mg capsules contain gelatin, glycerin, sesame oil, and titanium dioxide; 5 mg capsules contain iron oxide red and iron oxide black, gelatin, glycerin, sesame oil, and titanium dioxide; 10 mg capsules contain iron oxide red and iron oxide yellow, gelatin, glycerin, sesame oil, and titanium dioxide.

Manufactured by: Patheon Softgels Inc., High Point, NC 27265

Manufactured for: AbbVie Inc., North Chicago, IL 60064, U.S.A.

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For more information, go to www.rxabbvie.com or call 1-800-633-9110.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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