

Medication Guide

MITIGARE™ (mīt-ah-gär-ay) Capsules

What is the most important information I should know about MITIGARE™?

MITIGARE™ can cause serious side effects or death if levels of MITIGARE™ are too high in your body.

- Taking certain medicines with MITIGARE™ can cause your level of MITIGARE™ to be too high, especially if you have kidney or liver problems.
- Tell your healthcare provider about all your medical conditions, including if you have kidney or liver problems. Your dose of MITIGARE™ may need to be changed.
- Even medicines that you take for a short period of time, such as antibiotics, can interact with MITIGARE™ and cause serious side effects or death.

What is MITIGARE™?

MITIGARE™ is a prescription medication used to prevent gout flares in adults.

It is not known if MITIGARE™ is safe and effective for the treatment of:

- acute gout flares

MITIGARE™ is not a pain medicine and it should not be taken to treat pain related to other conditions unless specifically for those conditions.

It is not known if MITIGARE™ is safe and effective in children.

Who should not take MITIGARE™?

Do not take MITIGARE™ if you have liver and kidney problems and you take certain other medicines. Serious side effects, including death, have been reported in these people even when taken as directed. See **“What is the most important information I should know about MITIGARE™?”**

What should I tell my healthcare provider before taking MITIGARE™?

Before you take MITIGARE™, tell your healthcare provider:

- about all of your medical conditions
- if you have kidney or liver problems
- if you are pregnant or plan to become pregnant. It is not known if MITIGARE™ can harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- if you are breastfeeding or plan to breastfeed. MITIGARE™ can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take MITIGARE™.

Tell your healthcare provider about all the medicines you take, including prescription, over-the-counter medicines, vitamins, or herbal supplements.

- Using MITIGARE™ with certain other medicines can affect each other causing serious side effects and/or death.
- Do not take MITIGARE™ with other medicines unless your healthcare provider tells you to.
- Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.
- Especially tell your healthcare provider if you take:
 - medicines that may affect how your liver works (CYP3A4 inhibitors)
 - cyclosporine (Neoral®, Gengraf®, Sandimmune®)
 - cholesterol lowering medicines
 - antibiotics

Ask your healthcare provider or pharmacist if you are not sure if you take any of the medicines listed above. This is not a complete list of all the medicines that can affect MITIGARE™.

How should I take MITIGARE™?

- Take MITIGARE™ exactly as your healthcare provider tells you to take it.
- MITIGARE™ can be taken with or without food.
- If you take too much MITIGARE™ call your healthcare provider or go to the nearest hospital emergency room right away.
- Do not stop taking MITIGARE unless your healthcare provider tells you to.
- If you miss a dose of MITIGARE™, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.
- If you have a gout flare while taking MITIGARE™, tell your healthcare provider.

What should I avoid while taking MITIGARE™?

- Avoid eating grapefruit or drinking grapefruit juice while taking MITIGARE™. It can increase your chances of getting serious side effects.

What are the possible side effects of MITIGARE™?

MITIGARE™ can cause serious side effects or death. See **“What is the most important information I should know about MITIGARE™?”**

Get medical help right away, if you have:

- unusual bleeding or bruising
- increased infections

- weakness or fatigue
- muscle weakness or pain
- numbness or tingling in your fingers or toes
- pale or gray color to your lips, tongue, or palms of your hands
- severe diarrhea or vomiting

The most common side effects of MITIGARE™ include abdominal pain, diarrhea, nausea, and vomiting.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of MITIGARE™. For more information ask your healthcare provider or pharmacist.

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 MITIGARE™?

- Store MITIGARE™ at room temperature between 68° to 77°F (20° to 25°C).
- Keep MITIGARE™ in a tightly closed container.
- Keep MITIGARE™ out of the light and away from moisture.

Keep MITIGARE™ and all medicines out of the reach of children.

General information about the safe and effective use of MITIGARE™.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take MITIGARE™ for a condition for which it was not prescribed. Do not give MITIGARE™ to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about MITIGARE™. If you would like more information, talk to your pharmacist or healthcare provider for information about MITIGARE™ that is written for health professionals.

For more information, go to www.hikma-americas.com or call 1-877-233-2001.

What are the ingredients in MITIGARE™ Capsules?

Active Ingredient: Colchicine

Inactive Ingredients: colloidal silicon dioxide, lactose anhydrous, magnesium stearate, microcrystalline cellulose and sodium starch glycolate. The capsule shell contains gelatin, purified water, titanium dioxide, erythrosine, Brilliant Blue FCF and Quinoline Yellow.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Rx Only