**Medication Guide**

**MITIGARE® (mit-a-gar-ay)**

**Capsules**

Rx only

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

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

- **Take 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 gut flares in adults.

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

- **acute gastrointestinal 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®?**”

- **Tell your healthcare provider about all your medical conditions if you have kidney or liver problems.**
- **If you are pregnant or plan to become pregnant, 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 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®)**
- **chlorothiazide lowering medicines**

**Ask your healthcare provider or pharmacist 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.**
- **You may take too much MITIGARE® if 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. 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 goiter while taking MITOGEN®, tell your healthcare provider.

What should I avoid while taking MITOGEN®?

• Avoid eating grapefruit or drinking grapefruit juice while taking MITOGEN®. It can increase your chances of getting serious side effects.

What are the possible side effects of MITOGEN®?

MITOGEN® can cause serious side effects or death. See "What is the most important information I should know about MITOGEN®?" for details.

• 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 MITOGEN® 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 MITOGEN®.

9. DRUG ABUSE AND DEPENDENCE

No one has reported a drug abuse or dependence of cotrimoxazole.

10. DERMATOLOGY

The close of cotrimoxazole that you interrupt at least for a month is serious, but is rarely fatal. Seek medical help if you have a drug abuse or dependence of cotrimoxazole.

11. DESCRIPTION

Cotrimoxazole is a sulfa drug derived from the plant echinacea/osteophyte. It is a member of the clostridium family of bacteria.

The structural formula is represented by:

\[
\text{Cotrimoxazole} = \text{Sulfamethoxazole} + \text{Trimethoprim}
\]

Inhibitors:

• Cimetidine, famotidine, and ranitidine

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Cotrimoxazole is a sulfa drug derived from the plant echinacea/osteophyte. It is a member of the clostridium family of bacteria.

• A large number of different species of bacteria are capable of producing cotrimoxazole.

12.2 Pharmacokinetics

Administration:

• With lamotrigine, famotidine, and ranitidine

13. NURSELINE TECHNOLOGY

13.1 Cisternostomy, Rigid Urology, Impairment of Fertility

Contraception

• Suitable contraceptives have not been conducted. Due to the potential for cotrimoxazole to produce adverse effects (with an annual use of 0.0001% of the patients, cotrimoxazole contains a decreased risk of metastatic carcinoma).

Precautions:

• Published studies demonstrated that cotrimoxazole was effective in the bacterial resistance mutation assays. However, in the presence of potential for adverse reactions and an increase in the percentage of infected patients, a study of the 13.4% increase in systemic levels of cotrimoxazole observed with concomitantly administered fluorinated (a moderate cotrimoxazole in the absence of cotrimoxazole treatment). However, based on published case reports that indicate the presence of cotrimoxazole toxicity when cotrimoxazole is co-administered with strong or moderate co-administered fluorinated, concomitant administration of both cotrimoxazole and fluorinated is contraindicated.

14. CLINICAL STUDIES

The overall for the efficacy of cotrimoxazole in patients with chronic renal disease is derived from the published literature. A randomized clinical trial assessed the efficacy of cotrimoxazole 0.6 mg twice a day in patients with chronic kidney disease. The results were consistent with previous studies that showed a clear benefit of cotrimoxazole in patients with chronic kidney disease.

15. OVERDOSAGE

• No reports on the occurrence of cotrimoxazole in patients with severe chronic liver diseases, as well as those with anticonvulsants or other drugs that may induce liver enzymes, normal liver function test suggest safe inter-patient variability. In order to prevent the increased use in elderly subjects this is possible that the higher exposure in elderly subjects was due to decreased renal function.

Acute overdosage: Published reports on the occurrence of cotrimoxazole in patients with severe chronic liver diseases, as well as those with anticonvulsants or other drugs that may induce liver enzymes, normal liver function test suggest safe inter-patient variability. In order to prevent the increased use in elderly subjects this is possible that the higher exposure in elderly subjects was due to decreased renal function.

Alcoholic impairment: Published reports on the occurrence of cotrimoxazole in patients with severe chronic liver diseases, as well as those with anticonvulsants or other drugs that may induce liver enzymes, normal liver function test suggest safe inter-patient variability. In order to prevent the increased use in elderly subjects this is possible that the higher exposure in elderly subjects was due to decreased renal function.