

 **Mitigare[®]**
(colchicine) 0.6mg capsules



Are you treating only half of the disease?

**Consider gout flare prophylaxis with
colchicine 0.6 mg for adults receiving
urate-lowering therapy (ULT).^{1,2}**

True. Blue. Mitigare.

Indication

Mitigare[®] is indicated for prophylaxis of gout flares in adults. The safety and effectiveness of Mitigare[®] for acute treatment of gout flares during prophylaxis have not been studied. Mitigare[®] is not an analgesic medication and should not be used to treat pain from other causes.

Please see Important Safety Information on pages 4-5 and enclosed Full Prescribing Information and Medication Guide.

ULT alone may increase the risk of gout flares, potentially impacting treatment adherence.³

Although ULT is a key component of gout management, its use is associated with an increase in the number of gout flares.²

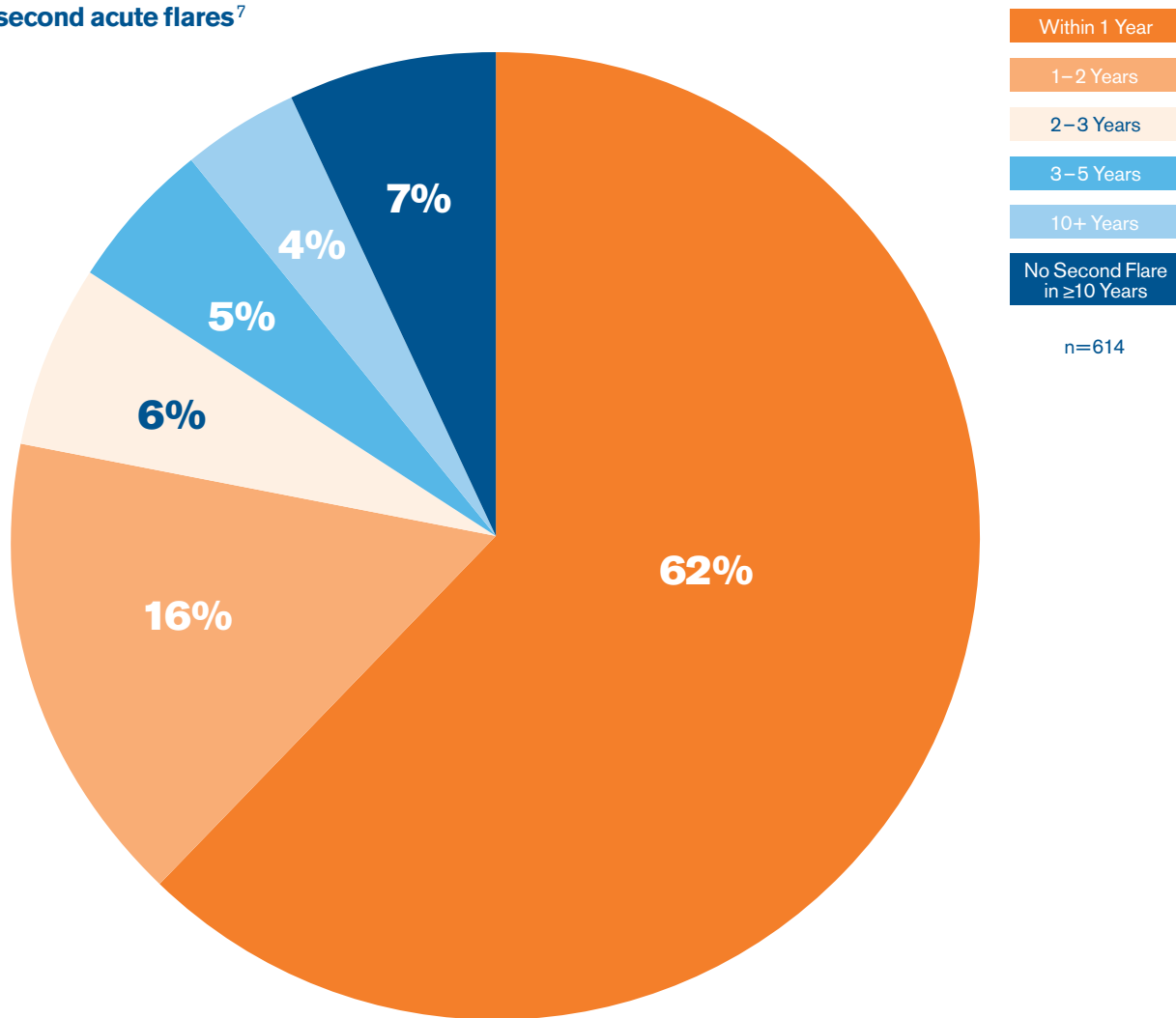
- In gout, monosodium urate (MSU) crystals form in joints as a consequence of chronic hyperuricemia.⁴
- The goal of ULT is to lower serum urate level of <6 mg/dl.³
- As urate levels are lowered below the limit of MSU solubility, crystals began to dissolve and disperse.⁵
- Dispersion of MSU crystals may expose patients to an increased risk of gout flares that could contribute to poor treatment adherence.^{3,5}

Poor adherence to ULT is prevalent and a significant contributor to poor patient outcomes.³

- Over time, untreated chronic hyperuricemia increases body urate stores, advancing the severity of the disease.⁴
- Chronic recurrent gout flares can lead to the development of tophi and ultimately joint destruction.⁶

Second acute gout flares may occur within 1 year for many patients not receiving colchicine prophylaxis⁷

Percentage of second acute flares⁷



In a longitudinal analysis of the frequency of acute gouty attacks before colchicine prophylaxis was begun, 62% of patients not on colchicine prophylaxis experienced a second acute flare within 1 year of the first flare⁷

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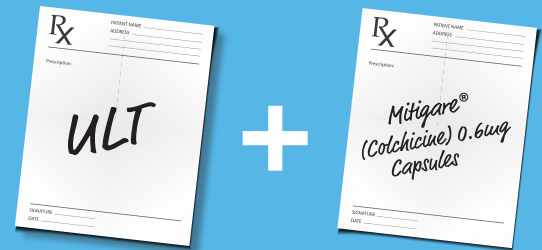
Consider colchicine prophylaxis for your adult patients receiving ULT.^{1,2}

Colchicine is one of the most frequently used drugs for preventing the inflammation associated with acute gout by^{1,5}:

- Modulating chemokine production.
- Inhibiting neutrophils and endothelial cell adhesion molecules.

American College of Rheumatology (ACR) Guidelines for Management of Gout support colchicine prophylaxis with ULTs²:

- Patients should begin anti-inflammatory prophylaxis prior to or concurrent with ULT.
- Low-dose colchicine (0.6 mg orally once or twice a day) is a first-line option.



According to the ACR Guidelines, anti-inflammatory prophylaxis should continue for the greater of²:

- At least 6 months *OR*
- 3 months after achieving target serum urate appropriate for the patient (no tophi detected on physical exam)
- 6 months after achieving target serum urate appropriate for the patient (one or more tophi detected on physical exam)

Important Safety Information

- Colchicine 0.6 mg capsules are contraindicated in patients with renal or hepatic impairment who are currently prescribed drugs that inhibit both P-gp and CYP3A4. Combining these dual inhibitors with colchicine in patients with renal or hepatic impairment has resulted in life-threatening or fatal colchicine toxicity. Patients with both renal and hepatic impairment should not be given Mitigare®.
- Fatal overdoses have been reported with colchicine in adults and children. Keep Mitigare® out of the reach of children.
- Blood dyscrasias such as myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, and aplastic anemia have been reported in patients taking colchicine at therapeutic doses.
- Monitor for toxicity and if present consider temporary interruption or discontinuation of colchicine.

ULT manufacturers also recommend gout flare prophylaxis prior to and during treatment with ULT.⁸⁻¹¹

	Prescribing Information Recommendation
allopurinol⁸	"...maintenance doses of colchicine generally should be given prophylactically when allopurinol is begun. The use of colchicine or other anti-inflammatory agents may be required to suppress gouty attacks on some cases."
DUZALLO[®] (lesinurad and allopurinol)^{9*}	"For patients not currently taking lesinurad, gout flare prophylaxis is recommended when starting DUZALLO [®] , according to practice guidelines."
Uloric[®] (febuxostat)^{10*}	"Flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended upon initiation of Uloric [®] . Prophylactic therapy may be beneficial for up to six months."
ZURAMPIC[®] (lesinurad)^{11*}	"Gout flare prophylaxis is recommended when starting Zurampic [®] , according to practice guidelines."

These therapies may not be appropriate for all adult patients; the full Prescribing Information, including contraindications, warnings, precautions, and other dosing considerations, should always be consulted.

**Contact the product manufacturer for information regarding co-administration with colchicine.*

- Drug interaction with dual P-gp and CYP3A4 inhibitors: Co-administration of colchicine with dual P-gp and CYP3A4 inhibitors has resulted in life-threatening interactions and death.
- Neuromuscular toxicity and rhabdomyolysis may occur with chronic treatment with colchicine in therapeutic doses, especially in combination with other drugs known to cause this effect. Patients with impaired renal function and elderly patients (including those with normal renal and hepatic function) are at increased risk. Consider temporary interruption or discontinuation of Mitigare[®].
- The most commonly reported adverse reactions with colchicine are gastrointestinal symptoms, including diarrhea, nausea, vomiting and abdominal pain.

Please see Important Safety Information on pages 4-5 and enclosed Full Prescribing Information and Medication Guide.

allopurinol + colchicine prophylaxis = reduced gout flares in adults.¹²

0 0.5 1.0 1.5 2.0 2.5 3.0



82%

reduction in gout flares with colchicine prophylaxis.¹²

n=43

Patients were randomized to receive colchicine 0.6 mg or placebo for up to 6 months in combination with allopurinol. Over the study period, the mean number of gout attacks in patients receiving colchicine plus ULT was 0.52, compared with 2.91 gout attacks among patients receiving placebo.¹²

Colchicine 0.6 mg has been shown to be well tolerated¹²

In a 6-month study of patients with recurrent gout, the prophylactic use of colchicine was well tolerated. The most common adverse reactions experienced by patients taking colchicine once or twice daily are gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain.¹

Request free samples today at
www.mitigare.com/free-mitigare-sample-kit/

Indication

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- Fatal overdoses have been reported with colchicine in adults and children. Keep Mitigare[®] out of the reach of children.
- Blood dyscrasias such as myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, and aplastic anemia have been reported with colchicine used in therapeutic doses.
- Monitor for toxicity and, if present, consider temporary interruption or discontinuation of colchicine.
- Drug interaction with dual P-gp and CYP3A4 inhibitors: Co-administration of colchicine with dual P-gp and CYP3A4 inhibitors has resulted in life-threatening interactions and death.
- Neuromuscular toxicity and rhabdomyolysis may occur with chronic treatment with colchicine in therapeutic doses, especially in combination with other drugs known to cause this effect. Patients with impaired renal function and elderly patients (including those with normal renal and hepatic function) are at increased risk. Consider temporary interruption or discontinuation of Mitigare[®].
- The most commonly reported adverse reactions with colchicine are gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain.

Prescribing Information and Medication Guide Enclosed.

References

1. Mitigare[®] (colchicine) capsules [prescribing information]. Eatontown, NJ: West-Ward Pharmaceutical Corp; 2018.
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3. Aung T, Myung G, FitzGerald JD. Treatment approaches and adherence to urate-lowering therapy for patients with gout. *Patient Prefer Adherence*. 2017;11:795–800.
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Consider gout flare prophylaxis with colchicine 0.6 mg for your adult patients receiving ULT.^{1,2}

- Mitigare[®] (Colchicine) 0.6 mg Capsules are specifically indicated for the prevention of flares in adults with gout.¹
- The ACR guidelines and ULT manufacturers recommend colchicine prophylaxis with ULT or adherence to practice guidelines.^{2,8-11}
- Gout flares were reduced by 82% with colchicine prophylaxis plus ULT.¹² In a 6-month study of patients with recurrent gout, the prophylactic use of colchicine was well tolerated. The most common adverse reactions experienced by patients taking colchicine once or twice daily are gastrointestinal symptoms, including diarrhea, nausea, vomiting and abdominal pain.¹
- Hikma Specialty USA Inc. offers the lowest-price colchicine products—Mitigare[®] (Colchicine) 0.6 mg Capsules and its Authorized Generic Colchicine 0.6 Capsules.¹³
- The Mitigare[®] True Blue Savings card offers the first 30 days \$0* and \$5* refills to eligible patients.

*For all eligible patients 18 years or older who are legal residents of the United States or Puerto Rico. Maximum savings of \$65 on the first fill and \$50 on refills. Visit www.mitigare.com for complete eligibility restrictions.

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Please see Important Safety Information on page 7 and enclosed Full Prescribing Information and Medication Guide

Visit www.mitigare.com for more information.

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