



Understanding Gout and Preventing Flares in Adults With Mitigare[®] (Colchicine) 0.6 mg Capsules

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 page 21 and enclosed Full Prescribing Information and Medication Guide.

This guide provides general information about gout and how it may affect you. It also explains how Mitigare[®] (Colchicine) 0.6 mg Capsules may help prevent flares in adults with gout.¹ To learn more, visit www.mitigare.com or talk with your healthcare provider.

INSIDE:

- **Understanding Gout**
- **Recognizing Gout Symptoms**
- **Living With Gout**
- **Preventing Flares**

Please see Important Safety Information on page 21 and enclosed Full Prescribing Information and Medication Guide.

A photograph of an older couple smiling and embracing in a park. The woman is on the left, wearing a blue shirt, and the man is on the right, wearing a white shirt. They are both looking towards the camera. The background is a soft-focus green landscape with trees and sunlight filtering through the leaves.

Understanding Gout Flares

Gout is a form of inflammatory arthritis that affects approximately 8.3 million Americans and is associated with painful episodes called flares.^{2,3} With the help of a physician, however, many adults who suffer from gout may be able to prevent future flares.¹

Causes & Risks

Gout occurs when there is too much uric acid in the body.⁴ Your body produces uric acid when it breaks down chemicals called purines.³ Purines are found in certain foods (like organ meats, alcohol or fruit juices) and also occur naturally in the body.³ When there are too many purines, uric acid can build up and crystallize in your joints causing gout.⁴ A number of factors can contribute to your risk of developing gout, including³:



**Family
history of
gout**



**Recent
surgery or
trauma**



Obesity



**High-purine
diet**



Age
(men 30-50 &
postmenopausal
women)



**Certain
medications**
(ask your doctor)



**Untreated high
blood pressure**



Diabetes



**Metabolic
syndromes**



**Heart or kidney
diseases**

A male doctor with a beard and glasses, wearing a white lab coat over a blue shirt and tie, is standing and talking to an elderly male patient. The patient is sitting on a white-covered table or bed, wearing a light-colored sweater and blue jeans. The doctor has a stethoscope around his neck. The background is a bright, out-of-focus window with sheer curtains. A semi-transparent white oval is overlaid on the right side of the image, containing the title text.

Recognizing Gout Symptoms

Symptoms

Not everyone has symptoms at first.⁵ But when the amount of uric acid in the body reaches a certain level, a flare can happen.³ Gout usually occurs in the big toe first.³ Symptoms of gout include³:

1

**Intense pain or swelling
in one or more joints**

2

**Redness, warmth
and/or tenderness**

3

**Limited range
of motion**

Diagnosis

To determine if you have gout, your doctor will probably examine you and ask questions about your symptoms and lifestyle. Your doctor may also perform one or more of the following tests^{6,7}:



**Joint
fluid test**



**Blood
test**



X-ray



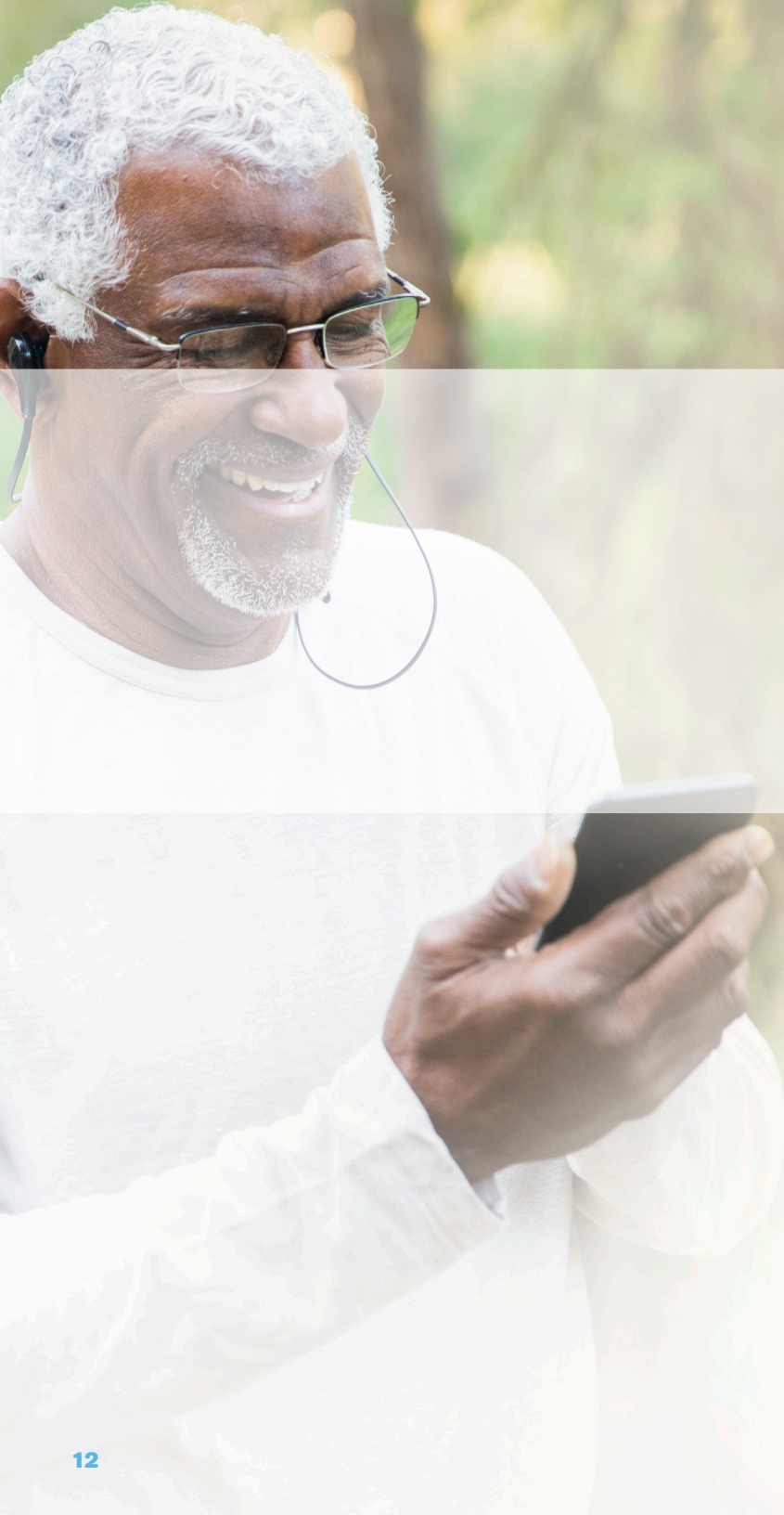
**Musculo-
skeletal
ultrasound**



**Dual
energy
CT scan**



**Urine
test**



Living With Gout

Visiting your doctor and setting up a gout treatment plan is the first step to preventing future flares. However, lifestyle changes may also help you live better with the disease.³

Exercise

When you carry extra weight, it's harder for your kidneys to remove excess uric acid.⁸ People who are considered obese are four times more likely to develop gout than people who are of ideal body weight.⁹

If you are overweight, gradual weight loss may help lower your uric acid levels and help reduce the risk of gout attacks.⁹ If you want to start an exercise routine, be sure to talk to your doctor first.

Diet

In addition to the medications your doctor prescribes, combining a diet rich in vegetables, low-fat dairy and some fruit with a healthy, active lifestyle can help lower your uric acid levels and reduce your risk of future flares.^{10,11}



**Unfold and tear out this
gout dietary guide and
keep it in a convenient
location for easy reference.**

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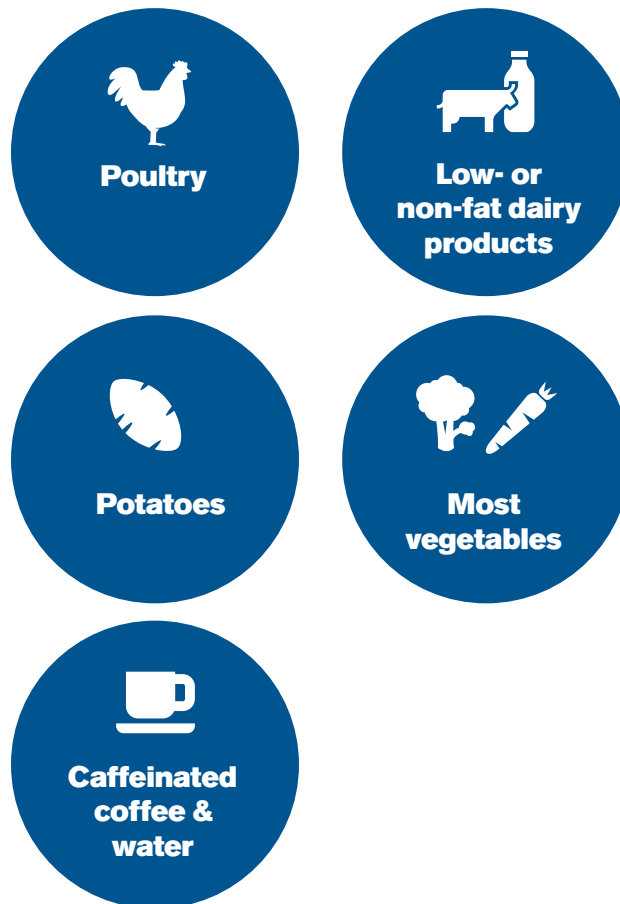
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A Gout Dietary Guide

Your doctor may recommend that you include, limit or avoid certain foods.

Gout-friendly Foods[†]:



* Mayo Clinic website. Healthy Lifestyle/Nutrition and healthy eating. Gout diet: What's allowed, what's not. Available at: <https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/gout-diet/art-20048524>. Accessed January 24, 2019.

† Arthritis Foundation website. 5 Good Foods for Gout. Available at: <https://www.arthritis.org/about-arthritis/types/gout/articles/low-purine-diet.php>. Accessed January 24, 2019.

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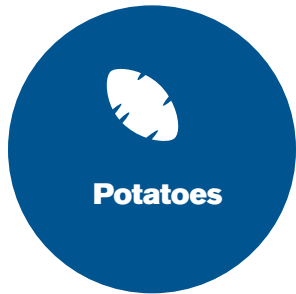
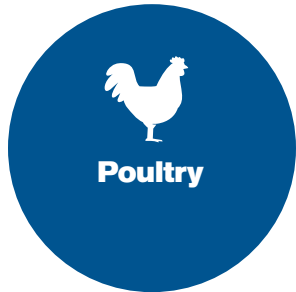
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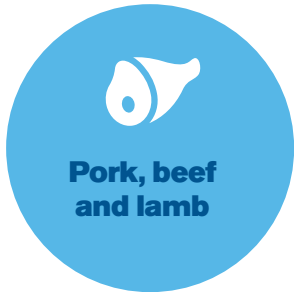
A Gout Dietary Guide

Your doctor may recommend that you include, limit or avoid certain foods.

Gout-friendly Foods[†]:



Consider Limiting[†]:



Consider Avoiding[†]:



* Mayo Clinic website. Healthy Lifestyle/Nutrition and healthy eating. Gout diet: What's allowed, what's not. Available at: <https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/gout-diet/art-20048524>. Accessed January 24, 2019.

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A photograph of an older couple smiling and embracing each other. The woman is on the left, wearing a pink shirt, and the man is on the right, also wearing a pink shirt. They are outdoors with a blurred green background. The image is split vertically by a dotted line, with the couple's faces on the left and text on the right.

Preventing Flares

Mitigare[®] is a medication that can help prevent gout flares.¹ Plant extracts containing colchicine, the active ingredient in Mitigare[®], have been used to prevent gout flares for more than 2000 years.¹²

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 page 21 and enclosed Full Prescribing Information and Medication Guide.

Stay Ahead of Flares with Colchicine

It's important to take preventative measures to stop flares before they happen.⁴ Without medication, your risk of additional flares greatly increases over time.⁴ Using colchicine as part of your regimen may help reduce your risk of repeat flares.¹³ In a six-month study, adults who took colchicine 0.6 mg daily had an 82% reduction in gout flares:¹³



82%

**fewer gout flares with
preventative colchicine
therapy.¹³**

In one study, 43 patients starting allopurinol were randomized to receive colchicine 0.6 mg or placebo for up to 6 months. Over the study period, the mean number of gout attacks in patients receiving colchicine plus allopurinol was 0.52, compared with 2.91 gout attacks among patients receiving placebo.¹³

Important Safety Information

The preventive use of colchicine 0.6 mg was well tolerated by participants in the study.¹³ The most common adverse reactions experienced by patients taking colchicine once or twice a day are gastrointestinal symptoms, including diarrhea, nausea, vomiting and abdominal pain.¹

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[®].

Please see additional Important Safety Information on page 21 and enclosed Full Prescribing Information and Medication Guide.

Ask your doctor about gout flare prevention for adults with Mitigare® (Colchicine) 0.6 mg Capsules today.

If you suspect you have gout, make an appointment with your doctor as soon as possible.³ After your initial examination, your doctor may want to refer you to a rheumatologist (a specialist who focuses on patients with arthritis and other inflammatory joint conditions).

Don't wait—untreated gout can become increasingly painful and result in joint damage.³

**For more about what you should
talk with your doctor about, visit
mitigare.com/doctor-visit-form**



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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.

**Please see enclosed full Prescribing
Information and Medication Guide for
complete product information.**

References:

1. Mitigare® (Colchicine) Capsules [prescribing information]. Columbus, OH: West-Ward Columbus, Inc.; 2018.
2. Zhu Y et al. Prevalence of Gout and Hyperuricemia in the US General Population. The National Health and Nutrition Examination Survey 2007 2008. *Arthritis Rheum.* 2011;63(10):3136–3141.
3. Mayo Clinic. Diseases and Conditions. Gout. Symptoms. <https://www.mayoclinic.org/diseases-conditions/gout/basics/symptoms/CON-20019400>. Accessed November 11, 2018.
4. US National Library of Medicine. PubMed Health. Gout: Overview. <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0073025/>. Accessed November 11, 2018.
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9. Gout & Uric Acid Education Society website. Lifestyle Recommendations. <http://gouteducation.org/medical-professionals/treating-gout/lifestyle/>. Accessed November 11, 2018.
10. Arthritis Foundation website. 5 Good Foods for Gout. Available at: <https://www.arthritis.org/about-arthritis/types/gout/articles/low-purine-diet.php>. Accessed January 24, 2019.
11. Mayo Clinic website. Healthy Lifestyle/Nutrition and healthy eating. Gout diet: What's allowed, what's not. Available at: <https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/gout-diet/art-20048524>. Accessed January 24, 2019.
12. Nuki G, Simkin PA. A concise history of gout and hyperuricemia and their treatment. *Arthritis Res Ther.* 2006;8(Suppl 1):S1. Centers for Disease Control. Gout. <http://www.cdc.gov/arthritis/basics/gout.html>. Accessed November 11, 2018.
13. Borstad GC, Bryant LR, Abel MP, et al. Colchicine prophylaxis of acute flares when initiating allopurinol for chronic gouty arthritis. *J Rheumatol.* 2004;31:2429–2432.

Seeing Blue May Lead to Saving Green

With the True Blue Savings Card, you can receive Mitigare® (Colchicine) 0.6 mg Capsules for as little as

\$0* first 30 days
& **\$5*** refills

* For all eligible patients 18 years or older who are legal residents of the United States or Puerto Rico. First 30 days are as little as \$0 only for eligible patients. Maximum savings of \$65 on the first fill and \$50 on refills. Please see mitigare.com for complete Terms and Conditions.

True. Blue. Mitigare.





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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Visit www.mitigare.com for more information.

Manufactured by: West-Ward Columbus Inc., Columbus, OH 43228
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