

# Mirdametinib

**Care Team Contact Information:** \_\_\_\_\_

**Pharmacy Contact Information:** \_\_\_\_\_

**Diagnosis:** \_\_\_\_\_

- This treatment is often used for people with neurofibromatosis type 1 (NF1) who have plexiform neurofibromas (PN), but it may also be used for other diagnoses.

**Goal of Treatment:** \_\_\_\_\_

- Treatment may continue until it no longer works or until side effects are no longer controlled.

## Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Mirdametinib (MIR-da-MEH-tih-nib): GOMEKLI (go-MEK-lee)	Slows down or stops the growth of tumor cells by blocking a specific protein that helps them survive	Tablets for oral suspension or capsules taken by mouth

**Treatment Administration and Schedule:** Treatment is typically repeated every 28 days. This is called a “cycle.”

Your mirdametinib dose:

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Treatment Name	Cycle 1, Days																					Next Cycle	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22-28	1
Mirdametinib AM dose	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Week-long break	✓
PM dose	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓

**Treatment Administration and Schedule (continued):**

- Mirdametinib comes in 2 different dosage forms, tablets for oral suspension and capsules. The tablets for oral suspension come in 1 mg strength and are grape-flavored. The capsules come in 1 mg and 2 mg strengths. Your care team will decide the dosage form and dose of mirdametinib that is right for you.
- Your dose is based on body surface area—the total surface area of your body. This is calculated using your height and weight. Your dose may change if you have changes in height or weight.
- Your dose may vary, but mirdametinib is typically taken twice a day, about 12 hours apart, for 21 days, followed by 7 days off of treatment, to complete a 28-day treatment cycle. Your healthcare provider will decide how many treatment cycles are right for you.
- Take mirdametinib with or without food.
- Your care team may change your dose, temporarily stop, or permanently stop mirdametinib treatment if you develop certain side effects.
- If you take mirdametinib tablets for oral suspension, either:
  - Swallow each tablet for oral suspension whole with drinking water. If more than 1 tablet is required, swallow 1 tablet at a time.OR
  - Disperse the tablets for oral suspension in drinking water to make a liquid (suspension) before you take or give mirdametinib.
    - Add the prescribed number of tablets to a dosing cup containing approximately 5 mL to 10 mL of drinking water.
    - Gently swirl the water and tablets until the tablets are fully dispersed and an oral suspension is obtained. It takes approximately two to four minutes to fully disperse the tablets. Once the tablets are dispersed, the oral suspension will appear white and cloudy.
    - Administer the oral suspension immediately after preparation from a dosing cup or oral syringe.
    - After administration of the prepared suspension, add approximately 5 mL to 10 mL of drinking water to the dosing cup and gently swirl to resuspend any remaining particles. Administer the suspension to ensure the full dose is taken.
    - Discard the oral suspension if not administered within 30 minutes after preparation.See the “Instructions for Use” that come with your medicine for instructions on how to prepare and take mirdametinib tablets for oral suspension.
- If you take mirdametinib capsules:
  - Swallow each capsule whole with drinking water. If more than 1 capsule is required, swallow 1 capsule at a time.
  - Do not open, break, or chew the capsules.
- If you miss a dose of mirdametinib, skip the missed dose and take your next dose at your regularly scheduled time.
- If you vomit at any time after taking mirdametinib, do not take an additional dose. Take your next dose at your regularly scheduled time.

**Storage and Handling of Mirdametinib**

- Store mirdametinib at room temperature between 68°F to 77°F (20°C to 25°C). Protect from light.
- Keep mirdametinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused mirdametinib.

**Appointments:** Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

## Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent or treat nausea or vomiting, rash, or diarrhea		

## Common Side Effects

Side Effect	Important Information
Skin Problems	<p>Description: Skin rashes are common with mirdametinib in both adults and children and can also be severe. Mirdametinib can also cause hair loss.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Take a warm (not hot) bath or shower every day with mild, unscented soap or body wash.</li> <li>Pat skin dry (instead of rubbing) with a towel.</li> <li>Use unscented lotion or moisturizing cream immediately after shower to prevent cracking.</li> <li>Use lip balm for dry or chapped lips.</li> <li>Avoid activities that put you at risk for cuts, injuries or burns.</li> <li>Rinse cuts and scrapes immediately under running water and remove any debris from the wound. Wash the skin around the wound with soap. To avoid irritation, do not use soap on the wound.</li> <li>Avoid direct sun when possible. Wear a broad-spectrum sunscreen with SPF 30 or higher and reapply every 2 hours.</li> <li>Use unscented, gentle laundry detergent. Some laundry detergents can irritate sensitive skin.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Flat skin rash</li> <li>Raised bumps on the skin</li> <li>Skin bumps that look like acne</li> <li>Skin redness</li> <li>Itchy rash</li> <li>Peeling skin</li> </ul>
Diarrhea	<p>Description: Diarrhea is when you have loose, watery stools. The need to use the bathroom may occur urgently.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Keep track of how many times you go to the bathroom each day.</li> <li>Drink 8 to 10 glasses of water or other fluids every day, unless your doctor tells you otherwise.</li> <li>Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast.</li> <li>Stay away from foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods.</li> <li>Your care team might suggest a medicine for diarrhea.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>4 or more bowel movements than normal in 24 hours</li> <li>Dizziness or lightheadedness while having diarrhea</li> <li>Bloody diarrhea</li> </ul>

Nausea and Vomiting	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. Vomiting is when your body pushes out what's in your stomach through your mouth.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Your care provider may prescribe medicine for these symptoms.</li> <li>Eat smaller, more frequent meals.</li> <li>Avoid fatty, fried, spicy, or highly sweet foods.</li> <li>Eat bland foods at room temperature and drink clear liquids.</li> <li>If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal). Slowly work up to eating solid food.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Vomiting for more than 24 hours</li> <li>Vomiting that's nonstop</li> <li>Signs of dehydration (like feeling very thirsty, having a dry mouth, feeling dizzy, or having dark urine)</li> <li>Blood or coffee-ground-lik appearance in your vomit</li> <li>Bad stomach pain that doesn't go away after vomiting</li> </ul>
Stomach (Abdominal) Pain	<p>Description: Abdominal pain is when you feel discomfort or pain in the belly area.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Severe abdominal pain</li> </ul>
Muscle, Joint, and Bone Pain	<p>Description: You may experience muscle or joint discomfort that makes daily activities harder. Symptoms can include aching, stiffness, swelling, and weakness, which can hinder lifting objects or walking long distances. You may also feel fatigued, making it difficult to stay active.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Track your pain levels, areas of discomfort, and any activities that worsen or improve your symptoms.</li> <li>Engage in gentle exercises like walking, stretching, or yoga to maintain mobility and strength, but consult your care team before starting any new exercise routine.</li> <li>Apply a warm compress to relax stiff muscles or use cold packs to reduce swelling and numb pain in affected areas.</li> <li>Your care team may prescribe or recommend medications, including over-the-counter pain relievers.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Persistent or worsening muscle or joint pain that does not improve with home treatments</li> <li>New symptoms, such as swelling, redness, or warmth in the joints</li> <li>Severe weakness that affects your ability to perform daily activities</li> <li>Side effects from pain relief medications that you are unable to manage</li> </ul>
Fatigue	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you.</li> <li>Ask your family and friends for help with daily tasks and emotional support.</li> <li>Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good.</li> <li>Make a regular sleep schedule and limit naps during the day so you can sleep better at night, aiming for 7 to 8 hours of sleep.</li> <li>Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Tiredness that affects your daily life</li> <li>Tiredness all the time and it doesn't get better with rest</li> <li>Dizziness and weakness along with being tired</li> </ul>

Headache	<p>Description: A headache can cause you to feel pain or discomfort in your head, making it hard to concentrate or feel your best.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches.</li> <li>Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches.</li> <li>Your care team may recommend the use of over-the-counter pain relief medications.</li> <li>Apply a cold or warm compress to your forehead or neck to help ease headache pain.</li> <li>Get adequate sleep (7-8 hours per night) and establish a regular sleep schedule.</li> <li>Limit caffeine intake.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>A headache that is severe and does not improve with over-the-counter medications</li> <li>A headache lasts longer than a few days or becomes more frequent</li> <li>Vision changes, confusion, weakness, or difficulty speaking</li> <li>A sudden onset of a severe headache, described as a “thunderclap” headache</li> <li>Fever of 100.4°F (38°C) or higher, stiff neck, or rash</li> </ul>
Heart Problems	<p>Description: Mirdametinib may lower the amount of blood pumped by your heart. Your care team will do tests before you start treatment, every 3 months during your first year of treatment, and then as needed to make sure your heart is working properly.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Monitor your body weight every day.</li> <li>Limit sodium (salt) intake to less than 3 grams each day.</li> <li>Avoid high-sodium foods like canned vegetables and soups, prepared sauces and condiments, frozen dinners, deli meats, and salty foods.</li> <li>Avoid smoking.</li> <li>Limit or avoid drinking alcohol.</li> <li>Maintain a healthy weight.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Cough or wheezing</li> <li>Shortness of breath</li> <li>Swelling of your ankles and feet</li> <li>Tiredness</li> <li>Increased heart rate</li> </ul>

### Select Rare or Serious Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Eye Problems	<ul style="list-style-type: none"> <li>Blurred vision</li> <li>Loss of vision</li> <li>Other changes to your vision</li> </ul>

**Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.**  
**If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.**

**Intimacy, Fertility, Pregnancy, and Breastfeeding**

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **cause fertility problems in females**, which may affect your ability to have children. Talk to your care team if you have concerns about fertility.
- Treatment may **harm an unborn baby**.
  - If you might get pregnant, take a pregnancy test before starting treatment.
  - Use an effective method of birth control during treatment and for 6 weeks after you last dose.
  - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partners could be pregnant, use an effective method of birth control—such as condoms—during treatment and for 3 months after your last dose.
- **Do NOT breastfeed** during treatment and for 1 week after your last dose.

**Additional Information**

- **Tell your care team about all the medicines you take.**  
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **The most common severe changes in laboratory test results are:**
  - Children: Decreased white blood cells and increased creatinine phosphokinase (CPK)
  - Adults: Increased CPK
- **This Patient Education Sheet may not describe all possible side effects.**  
Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

**Notes**

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Scan the QR code below to access this education sheet.



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