

## Mirdametinib (Gomekli)

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### About This Medicine

MIRDAMETINIB (MIR da ME ti nib) treats neurofibromatosis, a condition that causes tumors to grow along the nerves. It works by blocking a protein that causes tumor cells to grow and multiply. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Nausea and vomiting (throwing up)
- Tiredness
- Diarrhea (loose bowel movements)
- Increase in creatine phosphokinase (CPK), which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- Muscle, bone and/or joint pain
- Rash

**Note:** Each of the side effects above was reported in greater than 25% of people treated with mirdametinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- Blurred vision or other changes in eyesight such as blockage of small veins in the retina (thin membrane that covers the back of the eye separates from the eyeball) and retinal detachment
- Changes in your heart's ability to pump blood properly
- Severe rash – you may have a pimplelike rash, or a rash with fluid-filled bumps, or red, itchy patches of skin.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

## Important Information

- Hair loss can happen with mirdametininib. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.

## How to Take Your Medicine

- **Capsules:** Swallow the medicine whole with or without food. If you need to take more than one capsule for a dose, swallow one capsule at a time. Do not open, break, or chew capsules.
- **Tablets for oral suspension:** Tablets can be swallowed whole with or without food. If you need to take more than one tablet for a dose, swallow one tablet at a time.
- If you have trouble swallowing, add the number of prescribed 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. Swirl for 2 to 4 minutes to fully disperse the tablets. Once the tablets are fully dispersed, the oral suspension will look white and cloudy. Swallow immediately. Add another 5 mL to 10 mL of water to the cup and gently swirl. Swallow immediately to make sure you have taken the entire dose. Throw away the suspension after 30 minutes of preparation if not used.
- **Missed dose:** If you vomit or miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Protect it from light. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).



- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your care team and they can help you get in touch with programs in your local area.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

## Food and Medicine Interactions

- There are no known interactions of mirdametininib with food.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with mirdametininib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Blurred vision or other changes in eyesight
- Flashes of light and/or dark areas in your field of vision, colored dots, or halos
- Tiredness and/or extreme weakness that interferes with your daily activities
- Trouble breathing
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Swelling of the legs, feet or ankles
- Weight gain of 5 pounds in one week (fluid retention)
- Pain that does not go away, or is not relieved by prescribed medicines
- Unexplained muscle pain, tenderness, or weakness



- A new rash and/or itching or a rash that is not relieved by prescribed medicines

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 6 weeks after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 3 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 week after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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