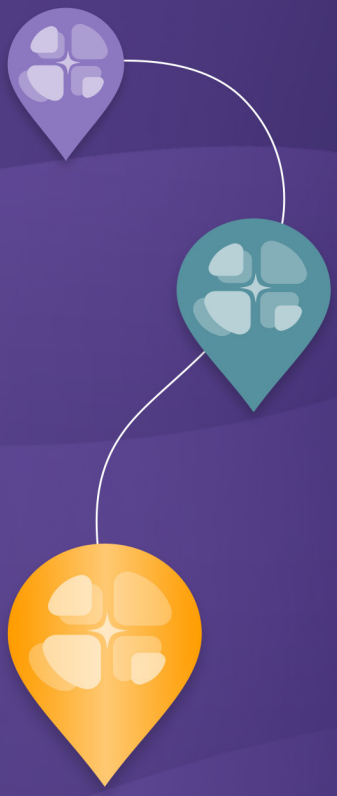
GOMEKLI®
(mirdametinib)
1 mg tablets for oral suspension
1 mg and 2 mg capsules



Helping your patients start and stay on GOMEKLI

A guide for healthcare providers

GOMEKLI (mirdametinib) is indicated for the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.

Important Safety Information

Warnings and Precautions associated with GOMEKLI include Ocular Toxicity, Left Ventricular Dysfunction, Dermatologic Adverse Reactions, and Embryo-Fetal Toxicity.

Adverse Reactions (>25%) in both adult and pediatric patients include rash, diarrhea, musculoskeletal pain, vomiting, and nausea, as well as fatigue in adult patients and abdominal pain, headache, paronychia, and left ventricular dysfunction in pediatric patients.

Please see Important Safety Information on pages 10-11, and click here for full Prescribing Information, including Patient Information and Instructions for Use.

Supporting your patients through every phase of treatment

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This tool was designed to help you optimize patient and caregiver interactions—both before treatment begins and throughout the course of care. Think of it as a roadmap that guides you through each key phase of treatment.

1. Getting patients started on treatment
2. Supporting adherence to treatment as prescribed
3. Helping patients stay on track over time

Within each section, you'll find practical guidance to support your practice and your patients at every step of the treatment journey, such as:

- Strategies for effective patient conversations
- How to help patients set realistic treatment goals
- Reminders for key milestones, including follow-up visits or required testing

Use the teal hyperlinks throughout the brochure to access resources on the GOMEKLI website.

When you see "Resource to share" with a hyperlinked asset, this is intended for use with patients and caregivers to support your conversations.

1 Getting patients started on treatment

- Determine if your patient is appropriate for therapy
- Set treatment goals
- Present an overview of GOMEKLI
- Initiate required tests

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2 Supporting adherence to treatment as prescribed

- Set patient and caregiver expectations
- Collaborate with other specialties and set up referrals
- Stress the importance of staying engaged

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3 Helping patients stay on track over time

- Schedule routine follow-ups
- Implement a flexible care model
- Revisit shared treatment goals

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Phase 1: Getting patients started on treatment

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Determine if your patient is appropriate for therapy

The first step toward a positive treatment experience is having a conversation with the patient/caregiver to determine if GOMEKLI may be the right option. Encourage them to tell you about the different ways life has changed due to NF1-PN.

Factors to consider:

- Are their PNs symptomatic (causing pain, changes in appearance, impaired mobility)?
- Do they have PNs not amenable to complete resection due to size, location, and/or infiltration of surrounding nerves and vasculature?

This GOMEKLI Broadcast Video highlights factors to consider when determining treatment.

Set treatment goals

Whether it's shrinking their PNs, alleviating symptoms, or simply feeling better, knowing what the patient is looking for can help you come up with a treatment plan that works for them.

In this Peer Opinion Video, NF1 experts discuss how to set up a positive treatment experience.

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Present an overview of GOMEKLI

When discussing GOMEKLI as a treatment option, it's helpful to review results from the phase 2b, single-arm ReNeu trial to help patients understand what potential benefits and adverse reactions they may experience during treatment.[1] It's also important to review GOMEKLI dosing and administration.

*The **GOMEKLI Presentation Flip Chart** can be used to provide an in-depth look at GOMEKLI treatment. One side is patient-facing and the other includes talking points to help you have effective patient conversations. You can request a flip chart from your GOMEKLI sales representative.*

Resource to share
The GOMEKLI Patient Brochure can be shared with patients to help guide initial treatment conversations.

Initiate required tests

Once you and the patient have decided that GOMEKLI may be an appropriate option, you'll need to order some tests prior to the start of treatment, including[1,2]:

- A pregnancy test, as GOMEKLI can cause fetal harm when administered to a patient who is pregnant
- Blood and urine tests
- A comprehensive ophthalmic assessment
- An echocardiogram to assess ejection fraction

Resource to share
This GOMEKLI 101 Video highlights what tests will be needed before and during GOMEKLI treatment.

Phase 2: Supporting adherence to treatment as prescribed

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Set patient and caregiver expectations

At the start of treatment, it's critical that patients have a clear understanding of what the first few months on GOMEKLI may look like. It is possible that they will experience adverse reactions before their PNs change, so you'll want them to be prepared and understand that there are strategies in place if adverse reactions occur.[1-4]

The GOMEKLI Dosing and Adverse Reaction Management Guide for HCPs includes strategies for managing adverse reactions—including dermatologic reactions—that occur during treatment.

Resource to share

This GOMEKLI 101 Video about side effect management strategies can be shared with patients who are getting started on treatment.

Collaborate with other specialties and set up referrals

Coordinating with specialists in other fields can help you manage the adverse reactions that are commonly associated with GOMEKLI.

Proactively setting up referrals with your colleagues can help ensure that your patients won't have to wait too long to get appointments should the need arise.

Please see Important Safety Information on pages 10–11, and click here for full Prescribing Information, including Patient Information and Instructions for Use.

Stress the importance of staying engaged

Remind patients that in order to get the most out of treatment, they have to take their medication as prescribed and remain adherent with their dosing.

Once a patient enrolls in SpringWorks CareConnections®, they'll receive a **Patient Starter Kit**, which includes tools to help them stay on top of their treatment schedule.

A **dry-erase dosing calendar** to help track each dose

A **pillbox** that can help make taking GOMEKLI a part of their daily routine

Resource to share

With this form, patients can enroll in SpringWorks CareConnections, a free, personalized support program for those taking GOMEKLI.

Another helpful tool is the **GOMEKLI Digital Companion**. It's a free resource for people taking GOMEKLI, available on the Medisafe medication management app. After downloading the app and creating a profile, patients can set up their GOMEKLI dosing calendar and add medication reminders.

Resource to share

*Patients can download the Medisafe app to start using the **GOMEKLI Digital Companion**.*

Phase 3: Helping patients stay on track over time

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Schedule routine follow-ups

Consistent follow-up visits can help patients stay on track with their treatment. Encourage them to keep appointments even when they feel fine, as these visits are your opportunity to check their progress and make sure their treatment is going well.

It may be helpful to remind patients that in order to experience the potential benefits of GOMEKLI, they have to take their medication on schedule and as directed.

Resource to share

*The **Personalized Treatment Journal** is a place where patients can keep notes on how they're feeling while taking GOMEKLI.*

Patients should also have realistic expectations about the tests they'll need throughout GOMEKLI treatment.[1,2]

Blood tests and urinalysis should be initiated **at regular intervals during treatment,** to assess for abnormalities (ie, changes in serum CPK).

Comprehensive ophthalmic assessments should be conducted **at regular intervals during treatment,** and for new or worsening changes such as blurred vision.

Ejection fraction should be assessed by echocardiogram **every 3 months during the first year,** then as **clinically indicated thereafter**.

CPK=creatine phosphokinase.

Please see Important Safety Information on pages 10-11, and click here for full Prescribing Information, including Patient Information and Instructions for Use.

Implement a flexible care model

For patients who live at a distance, travel may be a barrier to routine follow-ups.

- Working with a local healthcare provider can help so patients don't have to travel a long distance for each appointment[5,6]
- If there are no local specialists where the patient primarily resides, you may want to work to establish a local HCP (eg, PCP) who can monitor them in conjunction with a specialist in another town[5]
- The use of telemedicine can alleviate travel burden and allow you to maintain regular check-ins

In this **Peer Opinion Video**, NF1 experts discuss how they help patients stay on track with treatment over time.

Revisit shared treatment goals

After a patient has been on treatment for some time, encourage them to reflect on when they first started. Bring them back to the symptoms they were experiencing at the outset and the goals you established together.

Resource to share

*GOMEKLI.com features a comprehensive **library of resources** for patients, including downloadable tools, helpful videos, and information about the **GOMEKLI Patient Mentor Program**.*

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Warnings and Precautions

Ocular Toxicity: GOMEKLI can cause ocular toxicity including retinal vein occlusion (RVO), retinal pigment epithelium detachment (RPED), and blurred vision. In the adult pooled safety population, ocular toxicity occurred in 28% of patients treated with GOMEKLI: 21% were Grade 1, 5% were Grade 2 and 1.3% were Grade 3. RVO occurred in 2.7%, RPED occurred in 1.3%, and blurred vision occurred in 9% of adult patients. In the pediatric pooled safety population, ocular toxicity occurred in 19% of patients: 17% were Grade 1 and 1.7% were Grade 2. Conduct comprehensive ophthalmic assessments prior to initiating GOMEKLI, at regular intervals during treatment, and to evaluate any new or worsening visual changes such as blurred vision. Continue, withhold, reduce the dose, or permanently discontinue GOMEKLI as clinically indicated.

Left Ventricular Dysfunction: GOMEKLI can cause left ventricular dysfunction. GOMEKLI has not been studied in patients with a history of clinically significant cardiac disease or LVEF <55% prior to initiation of treatment. In the ReNeu study, decreased LVEF of 10 to <20% occurred in 16% of adult patients treated with GOMEKLI. Five patients (9%) required dose interruption, one patient (1.7%) required a dose reduction, and one patient required permanent discontinuation of GOMEKLI. The median time to first onset of decreased LVEF in adult patients was 70 days. Decreased LVEF of 10 to <20% occurred in 25%, and decreased LVEF of ≥20% occurred in 1.8% of pediatric patients treated with GOMEKLI. One patient (1.8%) required dose interruption of GOMEKLI. The median time to first onset of decreased LVEF in pediatric patients was 132 days. All patients with decreased LVEF were identified during routine echocardiography, and decreased LVEF resolved in 75% of patients. Before initiating GOMEKLI, assess ejection fraction (EF) by echocardiogram. Monitor EF every 3 months during the first year and then as clinically indicated. Withhold, reduce the dose, or permanently discontinue GOMEKLI based on severity of adverse reaction.

Dermatologic Adverse Reactions: GOMEKLI can cause dermatologic adverse reactions including rash. The most frequent rashes included dermatitis acneiform, rash, eczema, maculo-papular rash and pustular rash. In the pooled adult safety population, rash occurred in 92% of patients treated with GOMEKLI (37% were Grade 2 and 8% were Grade 3) and resulted in permanent discontinuation in 11% of patients. In the pooled pediatric safety population, rash occurred in 72% of patients treated with GOMEKLI (22% were Grade 2 and 3.4% were Grade 3) and resulted in permanent discontinuation in 3.4% of patients. Initiate supportive care at first signs of dermatologic adverse reactions. Withhold, reduce the dose, or permanently discontinue GOMEKLI based on severity of adverse reaction.

Embryo-Fetal Toxicity: GOMEKLI can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to the initiation of GOMEKLI. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Also advise patients to use effective contraception during treatment with GOMEKLI and for 6 weeks after the last dose (females) or 3 months after the last dose (males).

Adverse Reactions

The most common adverse reactions (>25%) in adult patients were rash (90%), diarrhea (59%), nausea (52%), musculoskeletal pain (41%), vomiting (38%), and fatigue (29%). Serious adverse reactions occurred in 17% of adult patients who received GOMEKLI. The most common Grade 3 or 4 laboratory abnormality (>2%) was increased creatine phosphokinase.

The most common adverse reactions (>25%) in pediatric patients were rash (73%), diarrhea (55%), musculoskeletal pain (41%), abdominal pain (39%), vomiting (39%), headache (34%), paronychia (32%), left ventricular dysfunction (27%), and nausea (27%). Serious adverse reactions occurred in 14% of pediatric patients who received GOMEKLI. The most common Grade 3 or 4 laboratory abnormalities (>2%) were decreased neutrophil count and increased creatine phosphokinase.

Use in Specific Populations

Verify the pregnancy status of patients of reproductive potential prior to initiating GOMEKLI. Due to the potential for adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with GOMEKLI and for 1 week after the last dose.

Please click here for full Prescribing Information, including Patient Information and Instructions for Use.

References: 1. Moertel CL, Hirbe AC, Shuhaiber HH, et al. ReNeu: a pivotal, phase IIb trial of mirdametinib in adults and children with symptomatic neurofibromatosis type 1-associated plexiform neurofibroma. *J Clin Oncol.* 2025;43(6):716-729. **2.** GOMEKLI. Prescribing Information. SpringWorks Therapeutics, Inc. **3.** Data on file: SpringWorks Therapeutics, Inc. **4.** Hirbe A, Anadkat MJ, Boull C, et al. Addressing skin adverse events during mirdametinib treatment in patients with neurofibromatosis type 1-associated plexiform neurofibromas: guidance from a multidisciplinary group of experts involved in the ReNeu trial. Poster presented at: 29th Annual Meeting of the Society for Neuro-Oncology; November 21-24, 2024; Houston, TX. **5.** Rietman AB, van Helden H, Both PH, et al. Worries and needs of adults and parents of adults with neurofibromatosis type 1. *Am J Med Genet* A. 2018;176(5):1150-1160. **6.** The six core elements of health care transition 3.0. Got Transition. Accessed February 3, 2026. https://gottransition.org/6ce/?side-by-side

Supporting your patients through every phase of GOMEKLI treatment

With the GOMEKLI treatment roadmap, you can guide patients toward a positive treatment experience—every step of the way.

1 Getting patients started on treatment

- Determine if your patient is appropriate for therapy
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- Initiate required tests

2 Supporting adherence to treatment as prescribed

- Set patient and caregiver expectations
- Collaborate with other specialties and set up referrals
- Stress the importance of staying engaged

3 Helping patients stay on track over time

- Schedule routine follow-ups
- Implement a flexible care model
- Revisit shared treatment goals

Visit GOMEKLI.com/hcp to find additional tools for your practice and your patients.

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SpringWorks THERAPEUTICS

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