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

Tests before starting and while staying on GOMEKLI

GOMEKLI is the **FIRST FDA-approved treatment** for **both adults** and **children** 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.[1]

		Months into treatment:					
		Before treatment	3	6	9	12	>12
	**Pregnancy test**	✓	A pregnancy test should be conducted prior to initiating treatment, as GOMEKLI can cause fetal harm when administered to a patient who is pregnant.[1]				
	**Lab work**	✓	Blood tests and urinalysis should be initiated prior to treatment, and at regular intervals during treatment, to assess for abnormalities (ie, changes in serum CPK).[2] *CPK=creatine phosphokinase.*				
	**Ophthalmic assessment**	✓	Comprehensive ophthalmic assessments should be conducted prior to initiating treatment, at regular intervals during treatment, and for new or worsening changes such as blurred vision.[1]				
	**Ejection fraction by echocardiogram**	✓	✓	✓	✓	✓	As clinically indicated thereafter.[1]

Indication and Important Safety Information

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.

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. ***Continued on page 2*** **and click here for full Prescribing Information.**

SpringWorks CareConnections®

provides personalized support services and resources to help your patients get started and stay on track with GOMEKLI

Coverage and access support

- We offer support to help navigate insurance coverage, including prior authorization requirements and appeals processes for GOMEKLI
- Field Access Managers (FAMs) can provide in-person or virtual support to help facilitate access to GOMEKLI by providing you and your office staff with regional payer education and timely responses to questions

Financial Assistance

- **Commercial Copay Program:** Eligible patients with commercial insurance may pay as little as a $0 copay per 21-day supply of GOMEKLI*
- **Patient Assistance Program (PAP):** Patients who are uninsured, underinsured, or lack coverage for GOMEKLI may be eligible to receive medication at no cost†
- **Reimbursement for eligible GOMEKLI treatment-related costs:** SpringWorks CareConnections may also help with eligible out-of-pocket costs incurred by your patients for certain treatment related tests, examinations, and/or specialty visits during treatment with GOMEKLI*

Personalized educational and emotional support

- SpringWorks CareConnections Nurse Advocates serve as a single point of contact for your patients throughout the treatment journey with GOMEKLI and can provide personalized educational and emotional support upon request‡

*Terms and conditions apply. The copay program for GOMEKLI and reimbursement for eligible treatment-related costs are subject to annual benefit maximums. To receive the reimbursement of eligible treatment-related expenses, an Explanation of Benefits (EOB) form must be submitted, along with copies of receipts for any payments made. Full terms and conditions are provided during the enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

†Terms and conditions apply. PAP eligibility criteria and annual household income limits apply. Full terms and conditions are provided during the enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

‡The SpringWorks CareConnections Patient Support Program is not intended to take the place of a healthcare provider, and our team of Nurse Advocates cannot provide medical or clinical advice.

Important Safety Information *(continued)*

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.

To report SUSPECTED ADVERSE REACTIONS, contact SpringWorks Therapeutics Inc. at 1-888-400-7989 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Please see full Prescribing Information here.

References:

1. GOMEKLI. Prescribing Information. SpringWorks Therapeutics, Inc.
2. 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. Published online November 8, 2024. doi.org/10.1200/JCO.24.01034

SpringWorks THERAPEUTICS