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

GOMEKLI: The FIRST and ONLY
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]

ICD-10-CM Diagnosis Codes for NF1-PN

What Is Neurofibromatosis Type 1-Associated Plexiform Neurofibromas (NF1-PN)?

Neurofibromatosis type 1 is a rare, genetic, incurable, neuro-oncology disease that impacts both adult and pediatric patients.[2-5] Plexiform neurofibromas are invasive nerve sheath tumors found in approximately 30%-50% of patients with NF1. Plexiform neurofibroma tumors are unpredictable, can grow anywhere in the body,* and may cause significant morbidities that can be debilitating.[2,3,6-8]

The approval of GOMEKLI provides a meaningful advancement in the treatment of NF1-PN.[1]

Billing and Coding for NF1-PN

There is no defined standard of care for NF1-PN.[9,10] Proper patient chart notes and *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) diagnosis codes are essential to ensure accurate disease identification and support insurance coverage for patients **for whom GOMEKLI may be the appropriate treatment option**.

ICD-10-CM Code[5]	Description
NF1	
Q85.01	Neurofibromatosis, type 1
NF1-associated PNs	
D33.3	Benign neoplasm of cranial nerves
D36.10	Benign neoplasm of peripheral nerves and autonomic nervous system, unspecified
D36.11	Benign neoplasm of peripheral nerves and autonomic nervous system of face, head, and neck
D36.12	Benign neoplasm of peripheral nerves and autonomic nervous system, upper limb, including shoulder
D36.13	Benign neoplasm of peripheral nerves and autonomic nervous system of lower limb, including hip
D36.14	Benign neoplasm of peripheral nerves and autonomic nervous system of thorax
D36.15	Benign neoplasm of peripheral nerves and autonomic nervous system of abdomen
D36.16	Benign neoplasm of peripheral nerves and autonomic nervous system of pelvis
D36.17	Benign neoplasm of peripheral nerves and autonomic nervous system of trunk, unspecified

*Except the central nervous system.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on next page and click here for full Prescribing Information.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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.

INDICATION

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.

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 accompanying full Prescribing Information including Patient Information and Instructions for Use in pocket.

References: 1. GOMEKLI. Prescribing Information. SpringWorks Therapeutics, Inc. **2.** Prada CE, Rangwala FA, Martin LJ, et al. Pediatric plexiform neurofibromas: impact on morbidity and mortality in neurofibromatosis type 1. *J Pediatr*. 2012;160(3):461-467. doi:10.1016/j.jpeds.2011.08.051 **3.** Miller DT, Freedenberg D, Schorry E, Ullrich NJ, Viskochil D, Korf BR; for the Council on Genetics and American College of Medical Genetics and Genomics. Health supervision for children with neurofibromatosis type 1. *Pediatrics*. 2019;143(5):e20190660. doi:10.1542/peds.2019-0660 **4.** Billing and coding: genetic testing for oncology. Centers for Medicare & Medicaid Services. Accessed December 16, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59125&ver=26 **5.** ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services. Updated February 1, 2024. Accessed December 16, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes **6.** Ejerskov C, Farholt S, Nielsen FSK, et al. Clinical characteristics and management of children and adults with neurofibromatosis type 1 and plexiform neurofibromas in Denmark: a nationwide study. *Oncol Ther*. 2023;11(1):97-110. doi:10.1007/s40487-022-00213-4 **7.** Plotkin SR, Bredella MA, Cai W, et al. Quantitative assessment of whole-body tumor burden in adult patients with neurofibromatosis. *PLoS One*. 2012;7(4):e35711. doi:10.1371/journal.pone.0035711 **8.** Nguyen R, Kluwe L, Fuensterer C, Kentsch M, Friedrich RE, Mautner V-F. Plexiform neurofibromas in children with neurofibromatosis type 1: frequency and associated clinical deficits. *J Pediatr*. 2011;159(4):652-655. doi:10.1016/j.peds.2011.04.008 **9.** Armstrong AE, Belzberg AJ, Crawford JR, Hirbe AC, Wang ZJ. Treatment decisions and the use of MEK inhibitors for children with neurofibromatosis type 1-related plexiform neurofibromas. *BMC Cancer*. 2023;23(1):553. doi:10.1186/s12885-023-10996-y **10.** Fisher MJ, Blakeley JO, Weiss BD, et al. Management of neurofibromatosis type 1-associated plexiform neurofibromas. *Neuro Oncol*. 2022;24(11):1827-1844. doi:10.1093/neuonc/noac146

SpringWorks® THERAPEUTICS

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