Monitor serum electrolytes (including potassium, calcium, phosphorous and magnesium) prior to the initiation of treatment, at the beginning of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting KISQALI therapy *[see Dosage and Administration (2.2)]*.

Avoid the use of KISQALI in patients who already have or who are at significant risk of developing QT prolongation, including patients with:

- long QT syndrome
- uncontrolled or significant cardiac disease, including recent myocardial infarction, congestive heart failure, unstable angina, and bradyarrhythmias
- electrolyte abnormalities

Avoid using KISQALI with drugs known to prolong QT interval and/or strong CYP3A inhibitors as this may lead to prolongation of the QTcF interval.

5.4 Increased QT Prolongation With Concomitant Use of Tamoxifen

KISQALI is not indicated for concomitant use with tamoxifen. In MONALEESA-7, the observed mean QTcF increase from baseline was > 10 ms higher in the tamoxifen plus placebo subgroup compared with the non-steroidal aromatase inhibitors (NSAIs) plus placebo subgroup. In the placebo arm, an increase of > 60 ms from baseline occurred in 6/90 (7%) of patients receiving tamoxifen, and in no patients receiving an NSAI. An increase of > 60 ms from baseline in the QTcF interval was observed in 14/87 (16%) of patients in the KISQALI and tamoxifen combination and in 18/245 (7%) of patients receiving KISQALI plus an NSAI *[see Clinical Pharmacology (12.2)]*.

5.5 Hepatobiliary Toxicity

In MONALEESA-2, MONALEESA-7 and MONALEESA-3, increases in transaminases were observed. Across all studies, Grade 3 or 4 increases in alanine aminotransferase (ALT) (11% vs. 2.1%) and aspartate aminotransferase (AST) (8% vs. 2%) were reported in the KISQALI and placebo arms, respectively.

Among the patients who had Grade ≥ 3 ALT/AST elevation, the median time-to-onset was 92 days for the KISQALI plus aromatase inhibitor or fulvestrant treatment group. The median time to resolution to Grade ≤ 2 was 21 days in the KISQALI plus aromatase inhibitor or fulvestrant treatment group. In MONALEESA-2 and MONALEESA-3, concurrent elevations in ALT or AST greater than three times the ULN and total bilirubin greater than two times the ULN, with normal alkaline phosphatase, in the absence of cholestasis occurred in 6 (1%) patients and all patients recovered after discontinuation of KISQALI. No cases occurred in MONALEESA-7.

Perform liver function tests (LFTs) before initiating therapy with KISQALI. Monitor LFTs every 2 weeks for first 2 cycles, at the beginning of each subsequent 4 cycles, and as clinically indicated *[see Dosage and Administration (2.2)]*.

Based on the severity of the transaminase elevations, KISQALI may require dose interruption, reduction, or discontinuation as described in Table 5 (Dose Modification and Management for Hepatobiliary Toxicity) *[see Dosage and Administration (2.2)]*. Recommendations for patients who have elevated AST/ALT Grade ≥ 3 at baseline have not been established.

5.6 Neutropenia

In MONALEESA-2, MONALEESA-7, and MONALEESA-3, neutropenia was the most frequently reported adverse reaction (75%), and a Grade 3/4 decrease in neutrophil count (based on laboratory findings) was reported in 62% of patients receiving KISQALI plus an aromatase inhibitor or fulvestrant. Among the patients who had Grade 2, 3, or 4 neutropenia, the median time to Grade ≥ 2 neutropenia was 17 days. The median time to resolution of Grade ≥ 3 (to normalization or Grade < 3) was 12 days in the KISQALI plus aromatase inhibitor or fulvestrant treatment group. Febrile neutropenia was reported in 1.7% of patients receiving KISQALI plus an aromatase inhibitor or fulvestrant. Treatment discontinuation due to neutropenia was 1%.

Perform complete blood count (CBC) before initiating therapy with KISQALI. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each subsequent 4 cycles, and as clinically indicated.

Based on the severity of the neutropenia, KISQALI may require dose interruption, reduction or discontinuation as described in Table 6 *[see Dosage and Administration (2.2)]*.

5.7 Embryo-Fetal Toxicity

Based on findings from animal studies and the mechanism of action, KISQALI can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of ribociclib to pregnant rats and rabbits during organogenesis caused embryo-fetal toxicities at maternal exposures that were 0.6 and 1.5 times the human clinical exposure,

respectively, based on area under the curve (AUC). Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during therapy with KISQALI and for at least 3 weeks after the last dose *[see Use in Specific Populations (8.1, 8.3), Clinical Pharmacology (12.1)]*.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.1)]*
- Severe Cutaneous Adverse Reactions *[see Warnings and Precautions (5.2)]*
- QT Interval Prolongation *[see Warnings and Precautions (5.3, 5.4)]*
- Hepatobiliary Toxicity *[see Warnings and Precautions (5.5)]*
- Neutropenia *[see Warnings and Precautions (5.6)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The pooled safety population described in the WARNINGS AND PRECAUTIONS reflect exposure to KISQALI in 1065 patients in MONALEESA-2, MONALEESA-7, and MONALEESA-3. Among these patients who received KISQALI, 76% were exposed for 6 months or longer and 62% were exposed for greater than one year. In this pooled safety population, the most common (≥ 20%) adverse reactions, including laboratory abnormalities, were leukocytes decreased (95%), neutrophils decreased (93%), hemoglobin decreased (68%), lymphocytes decreased (66%), aspartate aminotransferase increased (55%), gamma-glutamyl transferase increased (53%), alanine aminotransferase increased (52%), infections (47%), nausea (47%), creatinine increased (42%), fatigue (35%), platelets decreased (34%), diarrhea (33%), vomiting (29%), headache (27%), constipation (25%), alopecia (25%), cough (24%), rash (24%), back pain (24%), and glucose serum decreased (20%).

MONALEESA-2: KISQALI in Combination with Letrozole

Postmenopausal Women with HR-positive, HER2-negative Advanced or Metastatic Breast Cancer for Initial Endocrine-Based Therapy

The safety of KISQALI was evaluated in MONALEESA-2, a clinical study of 668 postmenopausal women receiving KISQALI plus letrozole or placebo plus letrozole *[see Clinical Studies (14)]*. The median duration of exposure to KISQALI plus letrozole was 13 months with 58% of patients exposed for ≥ 12 months.

Serious adverse reactions occurred in 21% of patients who received KISQALI plus letrozole. Serious adverse reactions in ≥1 % of patients receiving KISQALI plus letrozole included abdominal pain (1.5%), vomiting (1.5%), constipation (1.2%), nausea (1.2%), anemia (1.2%), febrile neutropenia (1.2%), dyspnea (1.2%), and alanine aminotransferase increased (1.2%).

Permanent discontinuation of both KISQALI and letrozole due to an adverse reaction occurred in 7% of patients. Permanent discontinuation of KISQALI alone occurred in 7% of patients. Adverse reactions which resulted in permanent discontinuation of both KISQALI and letrozole in ≥ 2% of patients were alanine aminotransferase increased (5%), aspartate aminotransferase increased (3%), and vomiting (2%).

Dosage interruptions of both KISQALI and letrozole due to an adverse reaction occurred in 71% of patients. Adverse reactions which required dosage interruption in ≥ 5% of patients included neutropenia (39%), neutrophils decreased (12%), vomiting (6%), nausea (5%), alanine aminotransferase increased (5%), and leukocytes decreased (5%).

Dose reductions of KISQALI due to an adverse reaction occurred in 45% of patients receiving KISQALI plus letrozole. Adverse reactions which required dose reductions in ≥ 2% of patients included neutropenia (24%), neutrophils decreased (8%), and alanine aminotransferase increased (3%).

Antiemetics and antidiarrheal medications were used to manage symptoms as clinically indicated.

The most common (≥ 20% on the KISQALI arm and ≥ 2% higher than placebo) adverse reactions, including laboratory abnormalities, were neutrophils decreased, leukocytes decreased, hemoglobin decreased, nausea, lymphocytes decreased, alanine aminotransferase increased, aspartate aminotransferase increased, fatigue, diarrhea, alopecia, vomiting, platelets decreased, constipation, headache, and back pain.

Table 8 summarizes the adverse reactions in MONALEESA-2.

Table 8: Adverse Reactions (≥ 10% and ≥ 2% Higher Than Placebo Arm) in MONALEESA-2

Adverse reaction	KISQALI + Letrozole (n = 334)		Placebo + Letrozole (n = 330)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Gastrointestinal disorders				
Nausea[1]	52	2.4	29	0.6
Diarrhea[1]	35	1.2	22	0.9
Vomiting[1]	29	3.6	16	0.9
Constipation[1]	25	1.2	19	0
Stomatitis[1]	12	0.3	7	0
Abdominal pain[1]	11	1.2	8	0
General disorders and administration-site conditions				
Fatigue	37	2.4	30	0.9
Pyrexia[1]	13	0.3	6	0
Edema peripheral[1]	12	0	10	0
Skin and subcutaneous tissue disorders				
Alopecia[1]	33	0	16	0
Rash[1]	17	0.6	8	0
Pruritus[1]	14	0.6	6	0
Nervous system disorders				
Headache[1]	22	0.3	19	0.3
Insomnia[1]	12	0.3	9	0
Musculoskeletal and connective tissue disorders				
Back pain[1]	20	2.1	18	0.3
Metabolism and nutrition disorders				
Decreased appetite[1]	19	1.5	15	0.3
Respiratory, thoracic and mediastinal disorders				
Dyspnea[1]	12	1.2	9	0.6
Infections and infestations				
Urinary tract infections[1]	11	0.6	8	0

Grading according to Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[1]Only includes a Grade 3 adverse reaction.

Clinically relevant adverse reactions in < 10% of patients in MONALEESA-2 receiving KISQALI plus letrozole included interstitial lung disease (0.3%), lung infiltration (0.3%), pneumonitis (0.3%), and pulmonary fibrosis (0.6%). Table 9 summarizes the laboratory abnormalities in MONALEESA-2.

Table 9: Select Laboratory Abnormalities (≥ 10%) in Patients in MONALEESA-2 Who Received KISQALI Plus Letrozole

Laboratory abnormality	KISQALI + Letrozole (n = 334)		Placebo + Letrozole (n = 330)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematology				
Leukocytes decreased	93	34	29	1.5
Neutrophils decreased	93	60	24	1.2
Hemoglobin decreased	57	1.8	26	1.2
Lymphocytes decreased	51	14	22	3.9
Platelets decreased	29	0.9	6	0.3
Chemistry				
Alanine aminotransferase increased	46	10	36	1.2
Aspartate aminotransferase increased	44	7	32	1.5
Creatinine increased	20	0.6	6	0
Phosphorous decreased	13	5	4	0.6
Potassium decreased	11	1.2	7	1.2

MONALEESA-7: KISQALI in Combination with an Aromatase Inhibitor

Pre/perimenopausal Patients with HR-positive, HER2-negative Advanced or Metastatic Breast Cancer for Initial Endocrine-Based Therapy

The safety of KISQALI was evaluated in MONALEESA-7, a clinical study of 672 pre/perimenopausal patients with HR-positive, HER2-negative advanced or metastatic breast cancer receiving either KISQALI plus a NSAI or tamoxifen plus goserelin or placebo plus NSAI or tamoxifen plus goserelin *[see Clinical Studies (14)]*. The median duration of exposure on the KISQALI plus a NSAI arm was 15.2 months with 66% of patients exposed for ≥ 12 months. The safety data reported below are based on 495 pre/perimenopausal patients receiving KISQALI plus NSAI plus goserelin or placebo plus NSAI plus goserelin.

Serious adverse reactions occurred in 17% of patients who received KISQALI plus NSAI plus goserelin. Serious adverse reactions in ≥ 1% of patients receiving KISQALI plus NSAI plus goserelin included drug-induced liver injury (1.6%), abdominal pain (1.2%), dyspnea (1.2%), febrile neutropenia (1.2%), and back pain (1.2%).

Permanent discontinuation of both KISQALI and NSAI due to an adverse reaction occurred in 3% of patients. Permanent discontinuation of KISQALI alone occurred in 3% of patients. Adverse reactions which resulted in permanent discontinuation of both KISQALI and NSAI in ≥ 2% of patients were alanine aminotransferase increased (2%), and aspartate aminotransferase increased (2%).

Dosage interruptions of KISQALI plus NSAI plus goserelin due to an adverse reaction occurred in 73% of patients. Adverse reactions which required dosage interruption in ≥ 5% of patients included neutropenia (41%), neutrophils decreased (26%), and leukocytes decreased (6%).

Dose reductions of KISQALI due to an adverse reaction occurred in 33% of patients receiving KISQALI plus NSAI plus goserelin. Adverse reactions which required dose reductions in ≥ 2 % of patients included neutropenia (17%), neutrophils decreased (5%), and alanine aminotransferase increased (2%).

The most common (≥ 20% on the KISQALI arm and ≥ 2% higher than placebo) adverse reactions, including laboratory abnormalities, were leukocytes decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, gamma-glutamyl transferase increased, aspartate aminotransferase increased, infections, arthralgia, alanine aminotransferase increased, nausea, platelets decreased, and alopecia.

Table 10 summarizes the adverse reactions in MONALEESA-7.

Table 10: Adverse Reactions Occurring in ≥ 10% and ≥ 2% Higher Than Placebo Arm in MONALEESA-7 (NSAI) (All Grades)

Adverse reaction	KISQALI + NSAI + Goserelin (n = 248)		Placebo + NSAI + Goserelin (n = 247)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Infections and infestations				
Infections[1;2]	36	1.6	24	0.4
Musculoskeletal and connective tissue disorders				
Arthralgia[2]	34	0.8	29	1.2
Gastrointestinal disorders				
Nausea[2]	32	0	20	0
Constipation[2]	16	0	12	0
Stomatitis[2]	10	0	8	0.4
Skin and subcutaneous tissue disorders				
Alopecia[2]	21	0	13	0
Rash[2]	17	0.4	9	0
Pruritus[2]	11	0	4	0

16 HOW SUPPLIED/STORAGE AND HANDLING

KISQALI (ribociclib) Tablets

Each film-coated tablet contains 200 mg of ribociclib free base.

Light greyish violet, round, curved with beveled edge, debossed with "RIC" on one side and "NVR" on the other side; available in:

Carton of 3 blister packs (63 tablets total) – each blister pack contains a 7-day supply of 21 tablets (200 mg per tablet) (600 mg daily dose). NDC 0078-0874-63

Carton of 3 blister packs (42 tablets total) – each blister pack contains a 7-day supply of 14 tablets (200 mg per tablet) (400 mg daily dose). NDC 0078-0867-42

Carton of 1 blister pack (21 tablets total) – each blister pack contains a 21-day supply of 21 tablets (200 mg per tablet) (200 mg daily dose). NDC 0078-0860-01

Store at 20ºC to 25°C (68ºF to 77°F). Store in the original package.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Interstitial Lung Disease/Pneumonitis

Advise patients to immediately report new or worsening respiratory symptoms *[see Warnings and Precautions (5.1)]*.

Severe Cutaneous Adverse Reactions

Inform patients of the signs and symptoms of severe cutaneous adverse reactions (e.g., skin pain/burning, rapidly-spreading skin rash, and/or mucosal lesions accompanied by fever or flu-like symptoms). Advise patients to contact their healthcare provider immediately if they develop signs and symptoms of severe cutaneous adverse reactions *[see Warnings and Precautions (5.2)]*.

QT Prolongation

Inform patients of the signs and symptoms of QT prolongation. Advise patients to contact their healthcare provider immediately for signs or symptoms of QT prolongation *[see Warnings and Precautions (5.3, 5.4)]*.

Hepatobiliary Toxicity

Inform patients of the signs and symptoms of hepatobiliary toxicity. Advise patients to contact their healthcare provider immediately for signs or symptoms of hepatobiliary toxicity *[see Warnings and Precautions (5.5)]*.

Neutropenia

Advise patients of the possibility of developing neutropenia and to immediately contact their healthcare provider should they develop a fever, particularly in association with any suggestion of infection *[see Warnings and Precautions (5.6)]*.

Embryo-Fetal Toxicity

- Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females to inform their healthcare provider of a known or suspected pregnancy *[see Warnings and Precautions (5.7), Use in Specific Populations (8.1)]*.
- Advise females of reproductive potential to use effective contraception during KISQALI therapy and for at least 3 weeks after the last dose *[Use in Specific Populations (8.3)]*.

Lactation

Advise lactating women not to breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose *[see Use in Specific Populations (8.2)]*.

Drug Interactions

- Inform patients to avoid grapefruit or grapefruit juice while taking KISQALI *[see Drug Interactions (7.1)]*.
- Inform patients to avoid strong CYP3A inhibitors, strong CYP3A inducers, and drugs known to prolong the QT interval *[see Drug Interactions (7.1, 7.2, 7.4)]*.

Dosing

- Instruct patients to take the doses of KISQALI at approximately the same time every day and to swallow whole (do not chew, crush, or split them prior to swallowing) *[see Dosage and Administration (2.1)]*.
- If patient vomits or misses a dose, advise the patient to take the next prescribed dose at the usual time *[see Dosage and Administration (2.1)]*.
- Advise the patient that KISQALI may be taken with or without food *[see Dosage and Administration (2.1)]*.

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

PATIENT INFORMATION
KISQALI® (kis kah' lee)
(ribociclib)
tablets

What is the most important information I should know about KISQALI?
KISQALI may cause serious side effects, including:

- **Lung problems.** KISQALI may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
  - trouble breathing or shortness of breath
  - cough with or without mucus
  - chest pain
- **Severe skin reactions.** Tell your healthcare provider or get medical help right away if you get severe rash or rash that keeps getting worse, reddened skin, flu-like symptoms, skin pain/burning, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, with or without fever.
- **Heart rhythm problems (QT prolongation).** KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your healthcare provider should check your heart and do blood tests before and during treatment with KISQALI. Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.
- **Liver problems.** KISQALI can cause serious liver problems. Your healthcare provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your healthcare provider right away if you get any of the following signs and symptoms of liver problems:
  - yellowing of your skin or the whites of your eyes (jaundice)
  - dark or brown (tea-colored) urine
  - feeling very tired
  - loss of appetite
  - pain on the upper right side of your stomach area (abdomen)
  - bleeding or bruising more easily than normal
- **Low white blood cell counts (neutropenia).** Low white blood cell counts are very common during treatment with KISQALI and may result in infections that may be severe. Your healthcare provider should check your white blood cell counts before and during treatment with KISQALI. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections, such as fever and chills.

Your healthcare provider may tell you to decrease your dose, temporarily stop or completely stop taking KISQALI if you develop certain serious side effects during treatment with KISQALI.

See **"What are the possible side effects of KISQALI?"** for more information about side effects.

What is KISQALI?

KISQALI is a prescription medicine used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has gotten worse or has spread to other parts of the body (metastatic), in combination with:

- an aromatase inhibitor as the first endocrine-based therapy; or
- fulvestrant as the first endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

It is not known if KISQALI is safe and effective in children.

Before taking KISQALI, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)
- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby.
  - If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with KISQALI.

- Females who are able to become pregnant and who take KISQALI should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI.
- Talk to your healthcare provider about birth control methods that may be right for you during this time.
- If you become pregnant or think you are pregnant, tell your healthcare provider right away.

- are breastfeeding or plan to breastfeed. It is not known if KISQALI passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KISQALI and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take KISQALI?

- Take KISQALI exactly as your healthcare provider tells you.
- Do not change your dose or stop taking KISQALI unless your healthcare provider tells you.
- Take KISQALI each day at about the same time, preferably in the morning.
- Take KISQALI with or without food.
- Swallow KISQALI tablets whole. Do not chew, crush, or split KISQALI tablets before swallowing them.
- Do not take any KISQALI tablets that are broken, cracked, or that look damaged.
- If you miss a dose of KISQALI or vomit after taking a dose of KISQALI, do not take another dose on that day. Take your next dose at your regular time.
- If you take too much KISQALI, call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking KISQALI?

Avoid eating grapefruit and drinking grapefruit juice during treatment with KISQALI since these may increase the amount of KISQALI in your blood.

What are the possible side effects of KISQALI?

KISQALI may cause serious side effects, including:

- See **"What is the most important information I should know about KISQALI?"**

The most common side effects of KISQALI include:

- decreased white blood cell counts
- decreased red blood cell counts
- abnormal liver function tests
- infections
- nausea
- increased kidney function test
- tiredness
- decreased platelet counts
- diarrhea
- vomiting
- headache
- constipation
- hair loss
- cough
- rash
- back pain
- low blood sugar level

KISQALI may cause fertility problems in males, which may affect your ability to father a child. Talk to your healthcare provider if this is a problem for you.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KISQALI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KISQALI?

- Store KISQALI at 68°F to 77°F (20°C to 25°C).
- Keep KISQALI in the original container.

Keep KISQALI and all medicines out of the reach of children.

General information about the safe and effective use of KISQALI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use KISQALI for a condition for which it was not prescribed. Do not give KISQALI to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for more information about KISQALI that is written for health professionals.

What are the ingredients in KISQALI?

Active ingredient: ribociclib

Inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropylcellulose, magnesium stearate, and microcrystalline cellulose. The film-coating contains iron oxide black, iron oxide red, lecithin (soya), polyvinyl alcohol (partially hydrolyzed), talc, titanium dioxide, and xanthan gum.

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For more information, go to www.KISQALI.com or call 1-844-KISQALI (1-844-547-7254).

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: August 2023

T2022-59