CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

220910Orig1s000

<u>LABELING</u>

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RASONQUE safely and effectively. See full prescribing information for RASONQUE.

RASONQUE™ (daraxonrasib) tablets, for oral use
Initial U.S. Approval: 2026

----------INDICATIONS AND USAGE----------
RASONQUE is an inhibitor of the RAS GTPase family, indicated for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy. (1)

----------DOSAGE AND ADMINISTRATION----------
- Recommended dosage: 300 mg orally once daily. (2.2)
- Swallow tablets whole with or without food. (2.2)
- Administer prophylactic and concomitant medications to reduce the risk of dermatologic reactions. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------
Tablets: 100 mg; 150 mg. (3)

----------CONTRAINDICATIONS----------
None. (4)

----------WARNINGS AND PRECAUTIONS----------
- Dermatologic and Soft Tissue Toxicity: RASONQUE can cause dermatologic or soft tissue toxicities, including rash, pruritus, and dry skin. Advise patients to limit sun exposure, use sunscreen, and use emollient creams. Withhold, reduce the dose, or permanently discontinue based on severity. (2.3, 5.1)
- Stomatitis and Oral Disorders: RASONQUE can cause stomatitis, including mouth ulcers and oral mucositis. Withhold, reduce the dose, or permanently discontinue based on severity. (2.3, 5.2)
- Diarrhea: RASONQUE can cause diarrhea. Withhold, reduce the dose, or permanently discontinue based on severity. (2.3, 5.3)
- Gastrointestinal Perforation: Monitor for gastrointestinal perforation. Withhold if suspected. If appropriate, reduce the dose or permanently discontinue if no other potential causes of gastrointestinal perforation are identified. (2.3, 5.4)
- Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening pulmonary symptoms. Withhold if suspected. If appropriate, reduce the dose or permanently discontinue if no other potential causes of ILD/pneumonitis are identified. (2.3, 5.5)
- Embryo-Fetal Toxicity: RASONQUE can cause fetal harm. Advise of the potential risk to the fetus and to use effective contraception. (5.6, 8.1, 8.3)

----------ADVERSE REACTIONS----------
Most common adverse reactions (≥ 20%) were rash, diarrhea, stomatitis, nausea, fatigue, vomiting, abdominal pain, edema, decreased appetite, and hemorrhage. (6.1)

Most common laboratory abnormalities (≥ 20%) were decreased albumin, decreased calcium, decreased hemoglobin, increased aspartate aminotransferase, decreased lymphocytes, decreased platelets, increased alanine aminotransferase, decreased sodium, decreased white blood cells, decreased magnesium, increased alkaline phosphatase, increased creatinine, and decreased potassium. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Revolution Medicines, Inc. at 1-844-2-REVMED (1-844-273-8633) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Strong CYP3A Inhibitors with P-gp Inhibition: Avoid concomitant use. (7.1)
- Strong CYP3A Inhibitors without P-gp Inhibition: Reduce RASONQUE dosage. (2.4)
- Moderate CYP3A Inhibitors with or without P-gp Inhibition: Reduce RASONQUE dosage. (2.4)
- P-gp Inhibitors: Reduce RASONQUE dosage. (2.4)
- Cyclosporine A: Avoid concomitant use. (7.1)
- Strong CYP3A Inducers: Avoid concomitant use. Increase RASONQUE dosage if concomitant use cannot be avoided. (2.4, 7.1)
- Moderate CYP3A Inducers: Increase RASONQUE dosage. (2.4)
- P-gp Substrates: Take at least 4 hours apart from RASONQUE. (7.2)

----------USE IN SPECIFIC POPULATIONS----------
- Lactation: Advise women not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 08/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

RASONQUE is indicated for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy.

2 DOSAGE AND ADMINISTRATION

2.1 Prophylactic and Concomitant Medication

When initiating RASONQUE and throughout treatment, prophylactic and concomitant medications are recommended to reduce the risk of dermatologic reactions *[see Warnings and Precautions (5.1)]*:

- administer a topical corticosteroid (applied to the face and chest) and emollient creams
- advise patients to limit sun exposure and use broad-spectrum sunscreen (SPF 30 or higher)
- consider prophylactic oral antibiotics (e.g., doxycycline or minocycline)

2.2 Recommended Dosage

The recommended dosage of RASONQUE is 300 mg orally once daily until disease progression or unacceptable toxicity.

- Take RASONQUE at the same time each day with or without food.
- Swallow tablets whole. Do not chew, crush, or split tablets.
- If a dose is missed for more than 4 hours, skip the missed dose, and take the next dose at the next regularly scheduled time.
- If vomiting occurs after taking the dose, do not take an additional dose. Resume dosing at the next regularly scheduled time.

2.3 Dosage Modifications for Adverse Reactions

Recommended dosage reductions for adverse reactions are provided in Table 1. Permanently discontinue RASONQUE in patients who are unable to tolerate 150 mg orally once daily.

Table 1: Recommended Dosage Reductions for Adverse Reactions

Dose Reduction Level	Dosage
First dose reduction	200 mg once daily
Second dose reduction	150 mg once daily

Recommended dosage modifications for adverse reactions are provided in Table 2.

Table 2: Recommended Dosage Modifications for Adverse Reactions

Adverse Reaction	Severity[1]	Dosage Modification
Dermatologic Toxicity (rash) *[see Warnings and Precautions (5.1)]*	Grade 2	• Consider withholding RASONQUE until recovery to ≤ Grade 1. • Initiate supportive measures, as necessary.

Adverse Reaction	Severity[1]	Dosage Modification
		• Resume RASONQUE at the same dose level or the next lower dose level.
	Grade 3	• Withhold RASONQUE until recovery to ≤ Grade 1. • Initiate supportive measures, as necessary, and consider consultation with a dermatologist. • Resume RASONQUE at the next lower dose level.
	Grade 4	• Permanently discontinue.
Stomatitis *[see Warnings and Precautions (5.2)]*	Grade 2	• Consider withholding RASONQUE until recovery to ≤ Grade 1. • Initiate supportive measures, as necessary. • Resume RASONQUE at the same dose level or the next lower dose level.
	Grade 3	• Withhold RASONQUE until recovery to ≤ Grade 1. • Initiate supportive measures, as necessary. • Resume RASONQUE at the next lower dose level.
	Grade 4	• Permanently discontinue.
Diarrhea *[see Warnings and Precautions (5.3)]*	Grade 2	• Consider withholding RASONQUE until recovery to ≤ Grade 1. • Initiate antidiarrheal treatment. • Resume RASONQUE at the same dose level or the next lower dose level.
	Grade 3	• Withhold RASONQUE until recovery to ≤ Grade 1. • Initiate antidiarrheal treatment. • Resume RASONQUE at the next lower dose level.
	Grade 4	• Permanently discontinue.
Gastrointestinal Perforation *[see Warnings and Precautions (5.4)]*	Grade 3	• Withhold RASONQUE until recovery to ≤ Grade 1. • If appropriate, resume RASONQUE at the next lower dose level.
	Grade 4	• Permanently discontinue.
Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.5)]*	Grade 2	• Withhold RASONQUE until recovery to ≤ Grade 1. • If appropriate, resume RASONQUE at the next lower dose level.
	Recurrent Grade 2, or Grade 3-4	• Permanently discontinue.
Nausea or Vomiting *[see Adverse Reactions (6.1)]*	Grade 3	• Withhold RASONQUE until recovery to ≤ Grade 1. • Initiate or modify anti-emetic regimen. • Resume RASONQUE at the next lower dose level.
	Grade 4	• Permanently discontinue.
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3	• Withhold RASONQUE until recovery to ≤ Grade 1 or baseline. • Resume RASONQUE at the next lower dose level.
	Grade 4	• Permanently discontinue.

[1] Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0.

2.4 Dosage Modifications for Drug Interactions

Strong CYP3A Inhibitors without P-gp Inhibition
Reduce the dosage of RASONQUE from 300 mg once daily to 150 mg once daily when used concomitantly with a strong CYP3A inhibitor without P-gp inhibition *[see Drug Interactions (7.1)]*.

After the strong CYP3A inhibitor without P-gp inhibition has been discontinued for 5 days or 3 to 5 half-lives, whichever is longer, resume the RASONQUE dosage taken prior to initiating the inhibitor.

Moderate CYP3A Inhibitors with P-gp Inhibition
Reduce the dosage of RASONQUE from 300 mg once daily to 100 mg once daily when used concomitantly with a moderate CYP3A inhibitor with P-gp inhibition *[see Drug Interactions (7.1)]*.

After the moderate CYP3A inhibitor with P-gp inhibition has been discontinued for 3 to 5 half-lives, resume the RASONQUE dosage taken prior to initiating the inhibitor.

Moderate CYP3A Inhibitors without P-gp Inhibition
Reduce the dosage of RASONQUE from 300 mg once daily to 200 mg once daily when used concomitantly with a moderate CYP3A inhibitor without P-gp inhibition *[see Drug Interactions (7.1)]*.

After the moderate CYP3A inhibitor without P-gp inhibition has been discontinued for 3 to 5 half-lives, resume the RASONQUE dosage taken prior to initiating the inhibitor.

P-gp Inhibitors
Reduce the dosage of RASONQUE from 300 mg once daily to 150 mg once daily when used concomitantly with a P-gp inhibitor *[see Drug Interactions (7.1)]*.

After the P-gp inhibitor has been discontinued, resume the RASONQUE dosage taken prior to initiating the inhibitor.

Strong CYP3A Inducers
If a strong CYP3A inducer cannot be avoided, increase the dosage of RASONQUE from 300 mg once daily to 400 mg once daily when used concomitantly with a strong CYP3A inducer *[see Drug Interactions (7.1)]*.

After discontinuing use of the strong CYP3A inducer, resume RASONQUE dosage (7 to 14 days after discontinuing the strong CYP3A inducer) that was taken prior to initiating the inducer.

Moderate CYP3A Inducers
Increase the dosage of RASONQUE from 300 mg once daily to 400 mg once daily when used concomitantly with a moderate CYP3A inducer *[see Drug Interactions (7.1)]*.

After discontinuing use of the moderate CYP3A inducer, resume RASONQUE dosage (7 to 14 days after discontinuing the moderate CYP3A inducer) that was taken prior to initiating the inducer.

3 DOSAGE FORMS AND STRENGTHS

- Tablets: 100 mg, blue, oval, biconvex, film-coated, debossed with “R” on one side and “100 M” on the other side.
- Tablets: 150 mg, blue, oval, biconvex, film-coated, debossed with “R” on one side and “150 M” on the other side.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Dermatologic and Soft Tissue Toxicity

RASONQUE can cause dermatologic toxicity, which may be severe. Clinical manifestations included, but were not limited to, rash, pruritus, paronychia, dry skin, and skin fissures. In clinical trials of patients with pancreatic adenocarcinoma, dermatologic toxicity occurred in 86% of patients treated with RASONQUE, of which 10% were Grade 3. The median time to first onset was 13 days (range: 1 to 106 days). The median time to improvement from Grade 3 to Grade 1 or resolution was 16 days (range: 8 to 218 days). Dermatologic toxicity led to interruption of RASONQUE in 24% of patients, dose reduction in 16% of patients, and dose discontinuation in 0.5% of patients.

Monitor patients who develop dermatologic or soft tissue toxicities while receiving RASONQUE. Initiate prophylactic measures (e.g., topical corticosteroids, emollient creams, sunscreen, oral antibiotics) prior to the first dose of RASONQUE to reduce the risk of moderate to severe dermatologic reactions. Advise patients to limit sun exposure while taking RASONQUE. Initiate supportive measures (e.g., oral corticosteroids) as clinically indicated, and consider dermatologic consultation. Withhold, reduce the dose, or permanently discontinue RASONQUE based on severity *[see Dosage and Administration (2.3)]*.

5.2 Stomatitis and Oral Disorders

RASONQUE can cause stomatitis, including mouth ulcers and oral mucositis. In clinical trials of patients with pancreatic adenocarcinoma, stomatitis occurred in 57% of patients, of which 9% were Grade 3. The median time to first onset was 22 days (range: 1 to 343 days). The median time to improvement from Grade 3 to Grade 1 or resolution was 12 days (range: 1 to 127 days). Stomatitis led to interruption of RASONQUE in 17% of patients and dose reduction in 8% of patients.

Monitor patients for signs and symptoms of stomatitis while receiving RASONQUE. Initiate a steroid-containing mouthwash for treatment of stomatitis and administer other topical treatments (e.g., chlorhexidine mouthwash, 2% lidocaine viscous) as clinically indicated. Withhold, reduce the dose, or permanently discontinue RASONQUE based on severity *[see Dosage and Administration (2.3)]*.

5.3 Diarrhea

RASONQUE can cause diarrhea. In clinical trials of patients with pancreatic adenocarcinoma, diarrhea occurred in 63% of patients, of which 6% were Grade 3. The median time to first onset was 3 days (range: 1 to

260 days). The median time to improvement from Grade 3 to Grade 1 or resolution was 3 days (range: 1 to 21 days). Diarrhea led to interruption of RASONQUE in 8% of patients and dose reduction in 4% of patients.

If diarrhea occurs, administer antidiarrheal treatment as clinically indicated. Withhold, reduce the dose, or permanently discontinue RASONQUE based on severity *[see Dosage and Administration (2.3)]*.

5.4 Gastrointestinal Perforation

RASONQUE can cause gastrointestinal perforation. In clinical trials of patients with pancreatic adenocarcinoma, gastrointestinal perforation occurred in 0.9% of patients treated with RASONQUE, of which 0.5% were Grade 3, one event was Grade 4, and one event was fatal. The median time to first onset was 134 days (range: 17 to 254 days). The median time to improvement from Grade ≥ 3 to resolution was 8 days (range: 7 to 9 days).

Monitor patients for gastrointestinal perforation. Withhold RASONQUE if gastrointestinal perforation is suspected. Reduce the dose or permanently discontinue RASONQUE if no other potential causes of gastrointestinal perforation are identified *[see Dosage and Administration (2.3)]*.

5.5 Interstitial Lung Disease (ILD)/Pneumonitis

RASONQUE can cause interstitial lung disease or pneumonitis. In clinical trials of patients with pancreatic adenocarcinoma, ILD/pneumonitis occurred in 2.4% of patients treated with RASONQUE, of which 0.9% were Grade 3, and one event was fatal. The median time to first onset was 111 days (range: 22 to 242 days). The median time to improvement from Grade 3 to resolution was 12 days (range: 12 to 47 days).

Monitor patients for new or worsening pulmonary symptoms. Withhold RASONQUE if ILD/pneumonitis is suspected. Reduce the dose or permanently discontinue RASONQUE if no other potential causes of ILD/pneumonitis are identified *[see Dosage and Administration (2.3)]*.

5.6 Embryo-Fetal Toxicity

Based on findings in animals, RASONQUE can cause fetal harm when administered to a pregnant woman. In an animal reproduction study, oral administration of daraxonrasib to pregnant female mice during the period of organogenesis resulted in adverse developmental outcomes including mortality, alterations to growth, and structural abnormalities at exposures ≥ 2.5 times the recommended dose based on area under the curve (AUC).

Advise females of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose *[see Use in Specific Populations (8.1), (8.3)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Dermatologic and Soft Tissue Toxicity *[see Warnings and Precautions (5.1)]*
- Stomatitis and Oral Disorders *[see Warnings and Precautions (5.2)]*
- Diarrhea *[see Warnings and Precautions (5.3)]*
- Gastrointestinal Perforation *[see Warnings and Precautions (5.4)]*

- Interstitial Lung Disease (ILD)/Pneumonitis *[see Warnings and Precautions (5.5)]*

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 of RASONQUE described in the WARNINGS AND PRECAUTIONS section reflects exposure to RASONQUE 300 mg once daily in 241 patients with pancreatic adenocarcinoma enrolled in RASolute 302 and 184 patients with pancreatic adenocarcinoma enrolled in the open-label trial RMC-6236-001.

Metastatic Pancreatic Adenocarcinoma

The safety of RASONQUE was evaluated in RASolute 302 *[see Clinical Studies (14)]*. Patients with metastatic pancreatic adenocarcinoma received either RASONQUE 300 mg once daily (N = 241) or physician's choice of standard of care (SOC) chemotherapy regimens (N = 214). Among patients who received RASONQUE, 52% were exposed for 6 months or longer and 2% were exposed for greater than one year.

Serious adverse reactions occurred in 30% of patients treated with RASONQUE. Serious adverse reactions occurring in ≥ 2% of patients treated with RASONQUE were diarrhea (3.7%), pyrexia (3.3%), sepsis (2.9%), fatigue (2.1%), and hemorrhage (2.1%).

Adverse reactions leading to permanent discontinuation of RASONQUE occurred in 2.9% of patients, including two patients who discontinued due to rash (0.8%).

Adverse reactions leading to dose interruptions occurred in 69% of patients who received RASONQUE. Adverse reactions which required dose interruptions in ≥ 5% of patients were rash (27%), stomatitis (20%), fatigue (9%), diarrhea (8%), vomiting (8%), nausea (7%), and pyrexia (6%).

Adverse reactions leading to dose reductions occurred in 37% of patients who received RASONQUE. Adverse reactions which required dose reductions in ≥ 5% of patients were rash (18%), stomatitis (8%), and diarrhea (5%).

The most common (≥ 20%) adverse reactions in patients treated with RASONQUE were rash, diarrhea, stomatitis, nausea, fatigue, vomiting, abdominal pain, edema, decreased appetite, and hemorrhage.

Table 3 and Table 4 summarize adverse reactions and laboratory abnormalities in RASolute 302, respectively.

Table 3: Adverse Reactions (≥ 10%) in Patients Who Received RASONQUE in RASolute 302

Adverse Reaction[1]	**RASONQUE N = 241**		**Physician's Choice SOC Chemotherapy Regimens[2] N = 214**	
	All Grades (%)	**Grade 3 or 4 (%)**	**All Grades (%)**	**Grade 3 or 4 (%)**
Skin and subcutaneous tissue disorders				
Rash[3]	87	13	9	0
Dry skin	14	0	3	0
Pruritus	11	0.4	4	0

Adverse Reaction[1]	RASONQUE N = 241		Physician's Choice SOC Chemotherapy Regimens[2] N = 214	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Gastrointestinal disorders				
Diarrhea[3]	67	7	44	8
Stomatitis[3]	56	12	19	3
Nausea	52	3	42	2
Vomiting	42	1	25	1
Abdominal pain[3]	27	2	26	2
Constipation	16	0.4	21	0.5
General disorders and administration site conditions				
Fatigue[3]	47	5	61	10
Edema[3]	25	0.8	22	0
Pyrexia	19	1	23	0.9
Metabolism and nutrition disorders				
Decreased appetite	24	2	27	0.9
Vascular disorders				
Hemorrhage[3]	22	3	12	4
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[3]	19	0.8	27	1
Infections and infestations				
Paronychia	17	0	0	0
Nervous system disorders				
Neuropathy peripheral[3]	10	0	29	4

[1] Graded per NCI CTCAE Version 5.0.
[2] Chemotherapy: mFOLFIRINOX, gemcitabine and nab-paclitaxel, FOLFOX, or nal-IRI+5-FU/LV.
[3] Includes multiple related terms.

Other clinically important adverse reactions occurring in less than 10% of patients who received RASONQUE in RASolute 302 included renal-limited thrombotic microangiopathy (0.4%).

Table 4: Select Laboratory Abnormalities (≥ 20%) that Worsened from Baseline in Patients Who Received RASONQUE in RASolute 302[1]

Laboratory Abnormality[2]	RASONQUE		Physician's Choice SOC Chemotherapy Regimens	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Chemistry				
Albumin decreased	71	3	51	1
Calcium (corrected) decreased	64	2	47	3
Aspartate aminotransferase increased	51	3	36	2
Alanine aminotransferase increased	36	4	39	0.5
Sodium decreased	36	6	30	5
Magnesium decreased	34	1	22	1

Laboratory Abnormality[2]	RASONQUE		Physician's Choice SOC Chemotherapy Regimens	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Alkaline phosphatase increased	29	2	24	0.5
Creatinine increased	24	0.8	9	0
Potassium decreased	20	3	33	7
Hematology				
Hemoglobin decreased	52	10	68	20
Lymphocyte cell count decreased	49	11	56	19
Platelet count decreased	45	3	58	10
White blood cell count decreased	35	3	58	17

[1] The denominator used to calculate the percentage varied from 234 to 237 in the RASONQUE arm and from 207 to 208 in the SOC chemotherapy arm, based on the number of patients with a baseline value and at least one post-baseline value.
[2] Graded per NCI CTCAE Version 5.0.

7 DRUG INTERACTIONS

7.1 Effects of Other Drugs on RASONQUE

Table 5: Effects of Other Drugs on RASONQUE

Strong or Moderate CYP3A Inhibitors with or without P-gp Inhibition	
Prevention or Management	• Strong CYP3A inhibitors with P-glycoprotein (P-gp) inhibition: Avoid concomitant use. • Strong CYP3A inhibitors without P-gp inhibition: Reduce RASONQUE dosage to 150 mg once daily *[see Dosage and Administration (2.4)]*. • Moderate CYP3A inhibitors with P-gp inhibition: Reduce RASONQUE dosage to 100 mg once daily *[see Dosage and Administration (2.4)]*. • Moderate CYP3A inhibitors without P-gp inhibition: Reduce RASONQUE dosage to 200 mg once daily *[see Dosage and Administration (2.4)]*.
Mechanism and Clinical Effect	Daraxonrasib is a CYP3A and P-gp substrate. Moderate or strong CYP3A inhibitors with or without P-gp inhibition increase daraxonrasib exposure *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions.
P-gp Inhibitors	
Prevention or Management	Reduce RASONQUE dosage to 150 mg once daily *[see Dosage and Administration (2.4)]*.
Mechanism and Clinical Effect	Daraxonrasib is a P-gp substrate. P-gp inhibitors increase daraxonrasib exposure *[see Clinical Pharmacology (12.3)],* which may increase the risk of adverse reactions.
Cyclosporine A	
Prevention or Management	Avoid concomitant use of RASONQUE with systemic cyclosporine A or its derivatives.

Mechanism and Clinical Effect	Cyclosporine A or its derivatives and daraxonrasib bind to cyclophilin A. Coadministration of systemic cyclosporine A or its derivatives and RASONQUE may have the potential to alter daraxonrasib pharmacokinetics, efficacy, and safety.
Strong or Moderate CYP3A Inducers	
Prevention or Management	• Strong CYP3A inducers: Avoid concomitant use. If concomitant use cannot be avoided, increase RASONQUE dosage to 400 mg once daily *[see Dosage and Administration (2.4)]*. • Moderate CYP3A inducers: Increase RASONQUE dosage to 400 mg once daily *[see Dosage and Administration (2.4)]*.
Mechanism and Clinical Effect	Daraxonrasib is a CYP3A substrate. Strong CYP3A inducers reduce daraxonrasib exposure *[see Clinical Pharmacology (12.3)]*, which may reduce the effectiveness of RASONQUE.

7.2 Effects of RASONQUE on Other Drugs

P-gp Substrates

Take a P-gp substrate at least 4 hours apart from RASONQUE.

Daraxonrasib is a P-gp inhibitor. Coadministration with RASONQUE increases exposure of P-gp substrates *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions related to these substrates.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on findings in animals, RASONQUE can cause fetal harm when administered to pregnant women. There are no available data on RASONQUE use in pregnant women to inform a drug-associated risk. In an animal reproduction study, oral administration of daraxonrasib to pregnant female mice during the period of organogenesis resulted in adverse developmental outcomes including mortality, alterations to growth, and structural abnormalities at exposures ≥ 2.5 times the recommended dose based on AUC *(see Data)*. Advise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data
Daraxonrasib was administered orally to pregnant female mice during the period of organogenesis at doses of 25, 50, and 75 mg/kg/day. Daraxonrasib at a dose of ≥ 50 mg/kg/day (≥ 2.5 times the exposure at the recommended dose based on AUC) was associated with post-implantation loss, reduced number of live fetuses, decreased fetal body weights, and malformations including eyes, limbs, palate, gonads, great vessels, kidneys, and bones.

8.2 Lactation

Risk Summary

There are no data on the presence of daraxonrasib or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with RASONQUE and for 1 week after the last dose.

8.3 Females and Males of Reproductive Potential

RASONQUE can cause fetal harm when administered to pregnant women *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating RASONQUE.

Contraception

Females
Advise females of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose.

Males
Advise males with female partners of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose.

8.4 Pediatric Use

The safety and effectiveness of RASONQUE have not been established in pediatric patients.

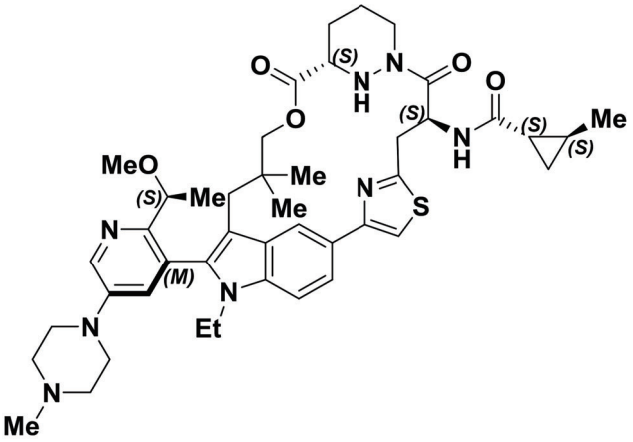
8.5 Geriatric Use

Of the 248 patients with pancreatic adenocarcinoma randomized to the RASONQUE arm in the RASolute 302 study, 54% (134 patients) were ≥ 65 years of age and 18% (45 patients) were ≥ 75 years of age. No overall differences in safety or efficacy were observed between patients who were ≥ 65 years of age and younger patients.

11 DESCRIPTION

Daraxonrasib is an inhibitor of the RAS GTPase family. The molecular formula is $C_{44}H_{58}N_8O_5S$ and the molecular weight is 811.06 g/mol. The chemical name is Cyclopropanecarboxamide, *N*-[(2*R*,14*S*,18*S*)-1-ethyl-18,19,20,21-tetrahydro-2-[2-[(1*S*)-1-methoxyethyl]-5-(4-methyl-1-piperazinyl)-3-pyridinyl]-25,25-dimethyl-

15,22-dioxo-17*H*-5,3-([4,2]-*endo*-thiazolopropano[1,3]-*endo*-pyridazinomethanoxypropano)-1*H*-indol-14-yl]-2-methyl-, (1*S*,2*S*)-. Daraxonrasib has the following chemical structure:



Daraxonrasib is a white to yellow crystalline solid; formulated as a spray-dried dispersion (SDD) and incorporated into a tablet for oral use. Daraxonrasib shows a pH-dependent aqueous solubility across the physiological pH range. Daraxonrasib thermodynamic solubility at 24 hours is greater than 10 mg/mL at pH 1.2, while daraxonrasib solubility is approximately 0.009 mg/mL at pH 6.8.

RASONQUE (daraxonrasib) is supplied as film-coated tablets for oral use containing 150 mg or 100 mg of daraxonrasib. Inactive ingredients in the tablet core are butylated hydroxytoluene, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose acetate succinate, magnesium stearate, mannitol, and microcrystalline cellulose. The tablet film coating contains FD&C blue #2/indigo carmine aluminum lake, glyceryl mono and dicaprylocaprate, polyvinyl alcohol, sodium lauryl sulfate, talc, and titanium dioxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Daraxonrasib is an inhibitor of the RAS GTPase family. Daraxonrasib binds to cyclophilin A, resulting in a binary complex that binds to the active, GTP-bound state of RAS. The tri-complex inhibits RAS signaling by blocking interactions with downstream effectors and promoting GTP hydrolysis to the inactive GDP-bound state of RAS. Daraxonrasib inhibition of wild-type and mutant variants of KRAS, NRAS, and HRAS induces tumor growth suppression and apoptosis. In RAS-dependent models of pancreatic adenocarcinoma, daraxonrasib treatment led to tumor growth inhibition and regression and is associated with antitumor immunity.

12.2 Pharmacodynamics

Exposure-Response Relationships
Daraxonrasib exposure-response relationships and time course of pharmacodynamic response have not been fully characterized.

Based on exposure and safety data from patients with pancreatic adenocarcinoma receiving 10 to 400 mg once daily of daraxonrasib (n = 466), higher daraxonrasib exposure was associated with higher incidence of dose

interruption/reduction/discontinuation, Grade ≥ 3 adverse reactions, Grade ≥ 2 dermatologic reactions, mucositis/stomatitis, nausea/vomiting, and diarrhea.

Cardiac Electrophysiology

At the recommended dosage, a mean increase in the QTc interval > 20 msec was not observed.

12.3 Pharmacokinetics

The pharmacokinetics of daraxonrasib were studied in healthy subjects and patients with advanced solid tumors, including patients with pancreatic adenocarcinoma treated with 300 mg once daily, and are presented as geometric mean (geometric percent coefficient of variation), unless otherwise specified.

Daraxonrasib maximum concentration is 365 ng/mL (50%) and total systemic exposure (AUC) is 3760 ng·h/mL (46%). Daraxonrasib AUC increases in an approximately dose proportional manner whereas C_{max} increases in a less than dose proportional manner over the dose range of 80 mg (0.27 times the recommended dose) to 300 mg. Minimal to no accumulation was observed for AUC.

Absorption

Daraxonrasib median (min, max) time to reach maximum concentration (T_{max}) is approximately 2.2 hours (0.67, 8.0).

Effect of Food
No clinically significant differences in daraxonrasib pharmacokinetics were observed following administration of a high-fat, high-calorie meal (800 to 1000 calories, 50% from fat).

Distribution

Daraxonrasib apparent (oral) volume of distribution during the terminal elimination phase is 1060 L (48%).

Daraxonrasib plasma protein binding is approximately 98% in vitro and is not concentration-dependent. Daraxonrasib blood to plasma ratio is concentration-dependent and ranges from 1.7 to 2.6 in healthy subjects.

Elimination

Daraxonrasib mean (SD) terminal elimination half-life is 9.2 (±2.7) hours with an apparent (oral) clearance (CL/F) of 80.4 L/h (44%).

Metabolism
Daraxonrasib is primarily metabolized by CYP3A.

Excretion
After a single oral dose of radiolabeled daraxonrasib 220 mg to healthy subjects, approximately 93% of the dose was recovered in feces (51% unchanged) and approximately 1% was recovered in urine (1% unchanged).

Specific Populations

No clinically significant differences in the pharmacokinetics of daraxonrasib were observed based on age (19 to 87 years old), sex, race (72% White, 11% Asian, 4% Black or African American), body weight (37 to 171 kg), ECOG PS (0, 1), tumor burden, CLcr 30 to 89 mL/min, or mild (total bilirubin > ULN to 1.5 × ULN or AST > ULN (with bilirubin normal)) or moderate (total bilirubin > 1.5 to 3 × ULN (with any AST level)) hepatic impairment per NCI-ODWG classification. The effects of CLcr < 30 mL/min or severe hepatic impairment (total bilirubin > 3 to 10 × ULN (with any AST level)) on daraxonrasib pharmacokinetics are unknown.

Drug Interaction Studies

Clinical Studies and Model-Informed Approaches

Strong CYP3A Inhibitors with P-gp Inhibition: Daraxonrasib AUC was observed to increase 5.1-fold following concomitant use of itraconazole 200 mg once daily (a strong CYP3A inhibitor with P-gp inhibition).

Strong CYP3A Inhibitors without P-gp Inhibition: Daraxonrasib AUC is predicted to increase 2.0-fold following concomitant use of voriconazole 200 mg twice daily (a strong CYP3A inhibitor without P-gp inhibition).

Moderate CYP3A Inhibitors with P-gp Inhibition: Daraxonrasib AUC is predicted to increase 2.6-fold following concomitant use of verapamil 80 mg three times daily (a moderate CYP3A inhibitor with P-gp inhibition).

Moderate CYP3A Inhibitors without P-gp Inhibition: Daraxonrasib AUC is predicted to increase 1.5-fold following concomitant use of fluconazole 200 mg once daily (a moderate CYP3A inhibitor without P-gp inhibition).

P-gp Inhibitors: Daraxonrasib AUC was observed to increase 1.8-fold following concomitant use of quinidine 300 mg three times daily (a P-gp inhibitor).

Strong CYP3A Inducers: Daraxonrasib AUC was observed to decrease to 50% following concomitant use of phenytoin 100 mg three times daily (a strong CYP3A inducer) and is predicted to decrease to 30% following concomitant use of rifampin 600 mg once daily (a strong CYP3A inducer).

Moderate CYP3A Inducers: Daraxonrasib AUC is predicted to decrease to 50% to 84% following concomitant use of efavirenz 600 mg once daily and modafinil 400 mg once daily (moderate CYP3A inducers).

P-gp Substrates: Free dabigatran C_{max} and AUC are predicted to increase 2.5-fold and 2.1-fold, respectively, following concomitant use of RASONQUE 300 mg once daily. No clinically significant differences in free dabigatran pharmacokinetics are predicted when RASONQUE 300 mg once daily is given 4 hours apart from dabigatran etexilate.

Other Drugs: No clinically significant differences in daraxonrasib pharmacokinetics were observed when used concomitantly with esomeprazole (a proton pump inhibitor).

No clinically significant differences in the pharmacokinetics of the following drugs were observed or predicted when used concomitantly with RASONQUE: midazolam (a sensitive CYP3A substrate), rosuvastatin (a BCRP/OATP1B3 substrate), and pravastatin (an OATP1B3 substrate).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenesis studies have not been conducted with daraxonrasib.

Mutagenesis

Daraxonrasib was not mutagenic in an in vitro bacterial reverse mutation (Ames) assay, not clastogenic in an in vitro micronucleus assay in human peripheral blood lymphocytes, and not genotoxic in an in vivo mouse bone marrow micronuclei test.

Impairment of Fertility

No fertility studies have been conducted with daraxonrasib. In general toxicology studies in mice and monkeys, there were no remarkable findings in male or female reproductive organs.

13.2 Animal Toxicology and/or Pharmacology

In a 4-week toxicity study in mice, increased bone remodeling was observed at ≥ 10 mg/kg/day (exposures at or greater than the recommended dose based on AUC) and was partially reversible. The finding was characterized by increased number and size of osteoclasts (metaphyseal cut-back zone and diaphyseal periosteum) and structural bone changes (wider cortical walls, wider Haversian canals, larger osteocytes/lacunae).

14 CLINICAL STUDIES

The efficacy of RASONQUE was evaluated in a global, randomized, open-label, multicenter study (RASolute 302; NCT06625320). Patients were required to have metastatic pancreatic adenocarcinoma with disease progression after receiving one prior line of systemic therapy, which included either a fluoropyrimidine-based or gemcitabine-based regimen, an Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1, investigator-assessed measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST v1.1), and documentation of locally available RAS mutation status (mutant or wild-type).

A total of 500 patients were randomized 1:1 to receive either RASONQUE 300 mg orally once daily (N = 248) or physician's choice of standard of care (SOC) chemotherapy regimens (mFOLFIRINOX, gemcitabine and nab-paclitaxel, FOLFOX, or nal-IRI+5-FU/LV) (N = 252). Patients were treated until disease progression or unacceptable toxicity. The major efficacy outcomes were overall survival (OS) and progression-free survival (PFS) as assessed by blinded independent central review (BICR) in patients with a RAS G12 mutation (RAS G12 population). Additional efficacy outcomes included OS and PFS as assessed by BICR in the overall population and objective response rate (ORR) as assessed by BICR in the RAS G12 population and overall population.

The baseline demographics and disease characteristics were: median age 66 years (range: 30 to 88); 45% Female; 68% White, 11% Asian, 4% Black or African American; 50% ECOG PS 1; and 70% had liver metastases. Of the 500 patients randomized in the study, 92% of patients had KRAS G12 mutations, 5% had

KRAS mutations at locations other than G12 (i.e., G13 and Q61), and 3% of patients did not have a RAS mutation detected by local testing.

RASolute 302 demonstrated a statistically significant improvement in OS, PFS, and ORR for patients treated with RASONQUE compared to SOC chemotherapy in the RAS G12 population and in the overall population.

Efficacy results for the overall population are summarized in Table 6 and Figures 1 and 2.

Table 6: Efficacy Results from RASolute 302 (Overall Population)

Efficacy Parameter	RASONQUE N = 248	Physician's Choice SOC Chemotherapy Regimens[1] N = 252
Overall Survival		
Number of events (%)	79 (32%)	141 (56%)
Median, months (95% CI)	13.2 (10.0, NE)	6.7 (5.8, 8.0)
Hazard Ratio (95% CI)[2]	0.40 (0.30, 0.53)	
p-value[3]	< 0.0001	
Progression-Free Survival[4]		
Number of events (%)	127 (51%)	130 (52%)
Median, months (95% CI)	7.2 (5.7, 7.5)	3.6 (2.9, 4.2)
Hazard Ratio (95% CI)[2]	0.49 (0.38, 0.64)	
p-value[3]	< 0.0001	
Objective Response Rate[4], % (95% CI)	30 (25, 36)	11 (7, 15)
Complete response, %	1.2	0.8
Partial response, %	29	10
p-value[5]	< 0.0001	

CI = confidence interval; NE = not estimable
[1] Chemotherapy: mFOLFIRINOX, gemcitabine and nab-paclitaxel, FOLFOX, or nal-IRI+5-FU/LV.
[2] Based on the stratified Cox proportional hazard model.
[3] Two-sided p-value based on stratified log-rank test.
[4] Assessed by BICR in all randomized patients.
[5] Two-sided p-value based on stratified Cochran-Mantel-Haenszel chi-square test comparing response rate by BICR in patients with measurable disease by BICR at baseline.

In the RAS G12 population (n = 459), median OS was 13.2 months in the RASONQUE arm vs. 6.6 months in the SOC chemotherapy arm [HR: 0.40 (95% CI: 0.30, 0.54), p-value < 0.0001] and median PFS assessed by BICR was 7.3 months in the RASONQUE arm vs. 3.5 months in the SOC chemotherapy arm [HR: 0.45 (95% CI: 0.34, 0.59), p-value < 0.0001]. Additionally, in the RAS G12 population, ORR assessed by BICR in all randomized patients was 32% (95% CI: 26%, 38%) in the RASONQUE arm vs. 11% (95% CI: 7%, 16%) in the SOC chemotherapy arm [p-value < 0.0001].

Figure 1: Kaplan-Meier Curve of Overall Survival in RASolute 302 (Overall Population)

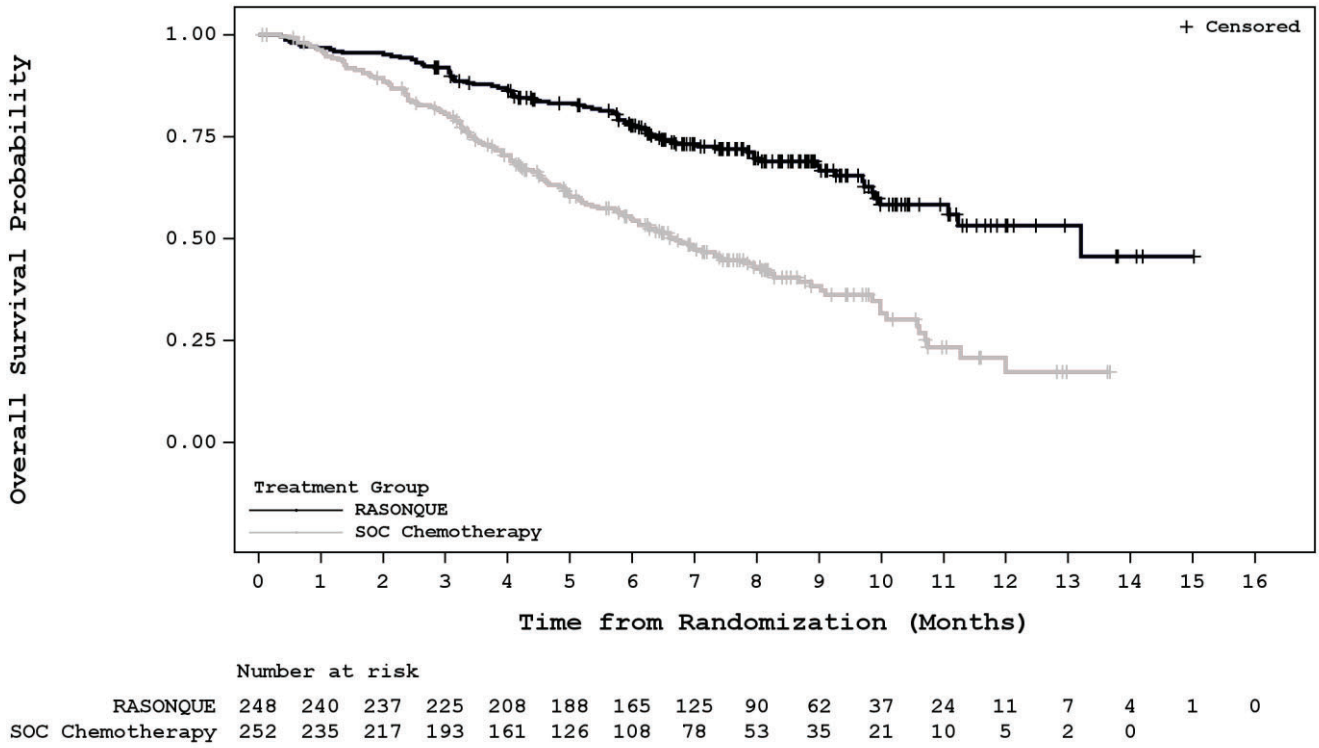
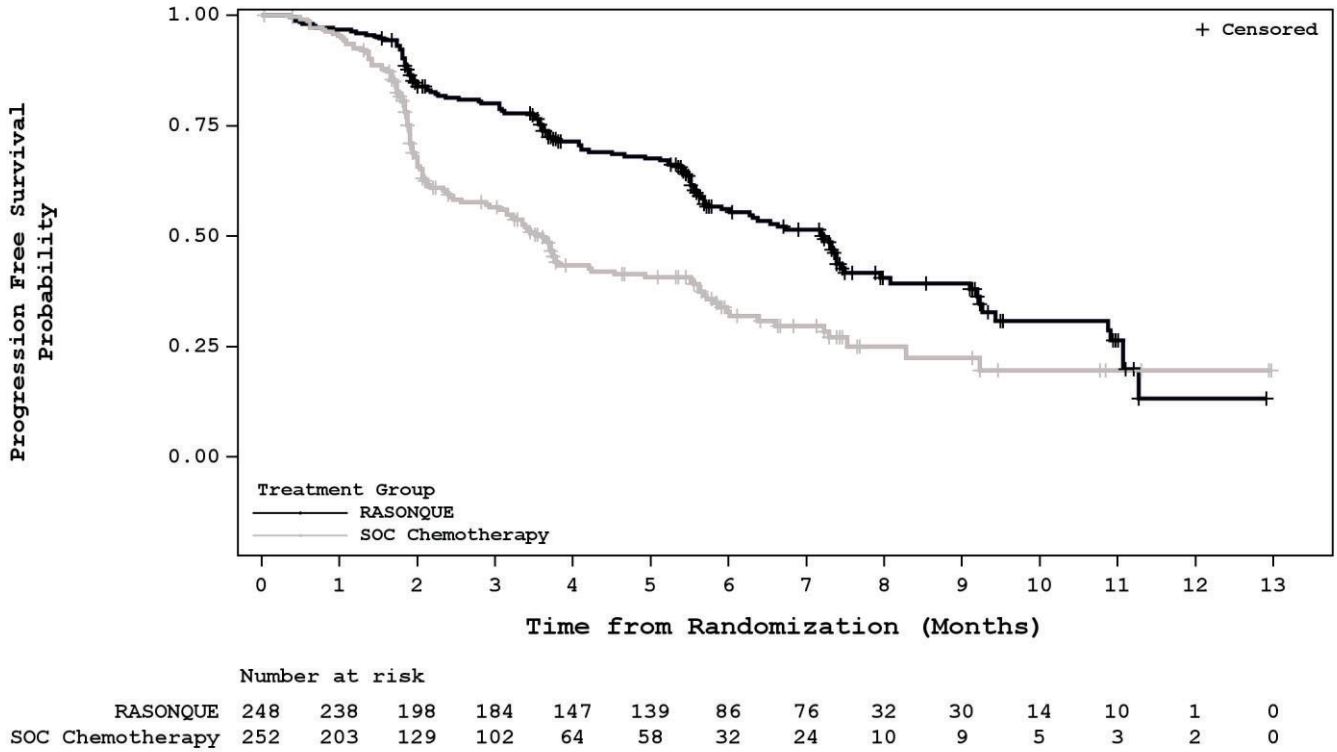


Figure 2: Kaplan-Meier Curve of Progression-Free Survival by BICR in RASolute 302 (Overall Population)



16 HOW SUPPLIED/STORAGE AND HANDLING

RASONQUE tablets are packaged in a bottle containing one desiccant and a child-resistant cap, available as follows:

Strength	Description	Bottle	NDC Number
100 mg	blue, oval, biconvex, film-coated, debossed with "R" on one side and "100 M" on the other side	30 tablets	85219-101-01
150 mg	blue, oval, biconvex, film-coated, debossed with "R" on one side and "150 M" on the other side	30 tablets	85219-104-01

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Dermatologic Reactions
Advise patients of the risk of dermatologic reactions including rash and to use prophylactic measures. Advise patients to limit sun exposure and contact their healthcare provider if they experience dermatologic reactions *[see Dosage and Administration (2.1)* and *Warnings and Precautions (5.1)]*.

Stomatitis
Advise patients of the risk of stomatitis. Advise patients to contact their healthcare provider for new onset or worsening stomatitis *[see Warnings and Precautions (5.2)]*.

Diarrhea
Advise patients to contact their healthcare provider if they experience new onset or worsening diarrhea *[see Warnings and Precautions (5.3)]*.

Gastrointestinal Perforation
Advise patients to contact their healthcare provider immediately if they experience severe abdominal pain or other symptoms of gastrointestinal perforation *[see Warnings and Precautions (5.4)]*.

Interstitial Lung Disease (ILD)/Pneumonitis
Advise patients to contact their healthcare provider immediately if they experience new or worsening respiratory symptoms *[see Warnings and Precautions (5.5)]*.

Embryo-Fetal Toxicity
Advise females to inform their healthcare provider if they are pregnant or become pregnant. Inform females of the potential risk to a fetus *[see Warnings and Precautions (5.6)]*.

Advise females of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose *[see Warnings and Precautions (5.6)* and *Use in Specific Populations (8.3)]*.

Advise males with female partners of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose *[see Warnings and Precautions (5.6)* and *Use in Specific Populations (8.3)]*.

Lactation

Advise women not to breastfeed during treatment with RASONQUE and for 1 week after the last dose *[*see *Use in Specific Populations (8.2)]*.

Drug Interactions

Advise patients to inform their healthcare provider of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, and herbal products *[see Drug Interactions (7.1)]*.

Manufactured for:
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Redwood City, CA 94063 USA
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Pat.: http://www.revmed.com/patents/

MEDICATION GUIDE
RASONQUE™ (RAS-ON-cue)
(daraxonrasib)
tablets

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

- **Skin reactions.** Skin reactions may be severe. To help reduce your risk of skin reactions and protect your skin when starting and during treatment with RASONQUE:
  - use a topical steroid cream on your face and chest
  - use a moisturizing cream on your skin
  - limit your time in the sun and use sunscreen (broad spectrum SPF 30 or higher) and other sun protection measures such as clothing and hats if you must be in the sun
  - take any other medicines if prescribed by your healthcare provider

  Tell your healthcare provider right away if you develop any signs or symptoms of skin reactions, including:
  - rash
  - itching
  - red, swollen, and painful skin around your finger or toenails
  - dry skin
  - cracked skin
- **Swelling or sores in the mouth (stomatitis).** Mouth sores may be severe. Your healthcare provider may prescribe a mouthwash or other medicines to treat your mouth reactions. Tell your healthcare provider right away if you develop trouble eating, talking, swallowing, or develop any new or worsening signs or symptoms in your mouth, including:
  - pain
  - redness
  - swelling
  - ulcers or sores
- **Diarrhea.** Diarrhea may be severe. If you develop diarrhea during treatment with RASONQUE, your healthcare provider may prescribe medicines to treat your diarrhea. Tell your healthcare provider right away if you develop new or worsening diarrhea or if the number of bowel movements you have in a day increases by 6 or more.

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

What is RASONQUE?
RASONQUE is a prescription medicine used to treat adults with a type of pancreatic cancer called pancreatic adenocarcinoma:

- that has spread to other parts of the body, **and**
- who have received at least 1 prior treatment or who cannot receive a combination of cancer treatments.

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

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

- are pregnant or plan to become pregnant. RASONQUE can harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with RASONQUE.
  - Use effective birth control (contraception) during treatment with RASONQUE and for 1 week after the last dose.
  - Tell your healthcare provider right away if you become pregnant during treatment with RASONQUE.

  Males with female partners who are able to become pregnant:
  - Use effective contraception during treatment with RASONQUE and for 1 week after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if RASONQUE passes into your breast milk**. Do not** breastfeed during treatment and for 1 week after your last dose of RASONQUE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RASONQUE can affect the way other medicines work, and other medicines can affect how RASONQUE works, and may increase your risk of side effects.

How should I take RASONQUE?

- Take RASONQUE exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking RASONQUE unless your healthcare provider tells you to.
- Take RASONQUE 1 time each day, at the same time each day.
- Take RASONQUE with or without food.
- Swallow RASONQUE tablets whole. **Do not** chew, crush, or split tablets.
- If you miss a dose, take the dose as soon as you remember. If it has been more than 4 hours, skip the missed dose and take your next dose at your next regularly scheduled time. **Do not** take 2 doses at the same time to make up for a missed dose.
- If you vomit after taking a dose, do not take an extra dose. Take your next dose at your regularly scheduled time.

What are the possible side effects of RASONQUE?
RASONQUE can cause serious side effects, including:

- See **"What is the most important information I should know about RASONQUE?"**
- **Tears in your stomach or intestines (gastrointestinal perforation).** Gastrointestinal perforation may be severe and lead to death. Tell your healthcare provider right away if you develop any of the following signs or symptoms:
  - tenderness or pain in your stomach area (abdomen) that is severe or does not go away
  - nausea, vomiting, or vomiting blood
  - blood in the stool or black stool that looks like tar
  - fever or chills
- **Lung or breathing problems (pneumonitis).** Lung or breathing problems may be severe and lead to death. Tell your healthcare provider right away if you develop any new or worsening breathing problems, including:
  - cough
  - shortness of breath
  - trouble breathing
  - wheezing

The most common side effects of RASONQUE include:

- rash
- diarrhea
- swelling or sores in the mouth
- nausea
- tiredness or weakness
- vomiting
- stomach (abdominal) pain
- swelling in the arms and legs
- decreased appetite
- bleeding

Certain abnormal blood tests are common during treatment with RASONQUE. Your healthcare provider will monitor you for abnormal blood tests and treat you if needed.

Your healthcare provider may decrease your dose, or temporarily or permanently stop treatment with RASONQUE if you develop certain side effects.

These are not all of the possible side effects of RASONQUE.

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 RASONQUE?
Store RASONQUE at room temperature between 68°F to 77°F (20°C to 25°C).
Keep RASONQUE and all medicines out of the reach of children.

General information about the safe and effective use of RASONQUE.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RASONQUE for a condition for which it was not prescribed. Do not give RASONQUE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about RASONQUE that is written for health professionals.

What are the ingredients in RASONQUE?
Active ingredient: daraxonrasib
Inactive ingredients: butylated hydroxytoluene, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose acetate succinate, magnesium stearate, mannitol, and microcrystalline cellulose. The tablet film coating contains FD&C blue #2/indigo carmine aluminum lake, glyceryl mono and dicaprylocaprate, polyvinyl alcohol, sodium lauryl sulfate, talc, and titanium dioxide.

Manufactured for: Revolution Medicines, Inc. Redwood City, CA 94063 USA
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For more information, go to www.RASONQUE.com or call 1-844-2-REVMED (1-844-273-8633).

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 08/2026

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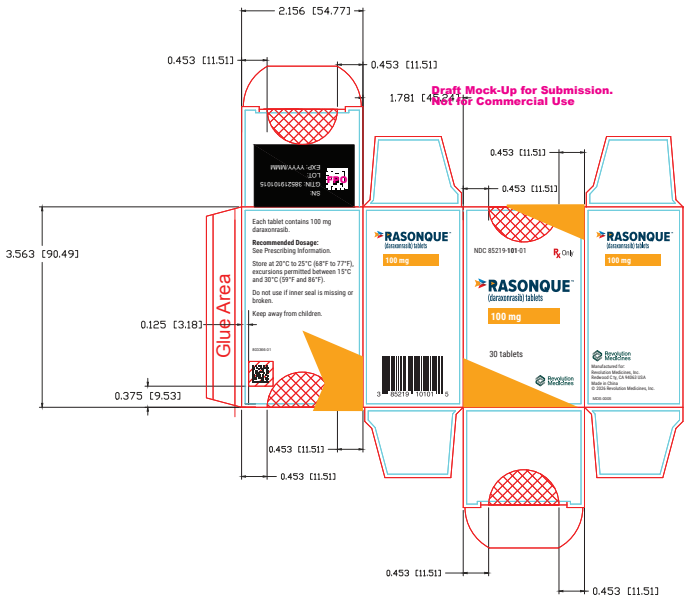

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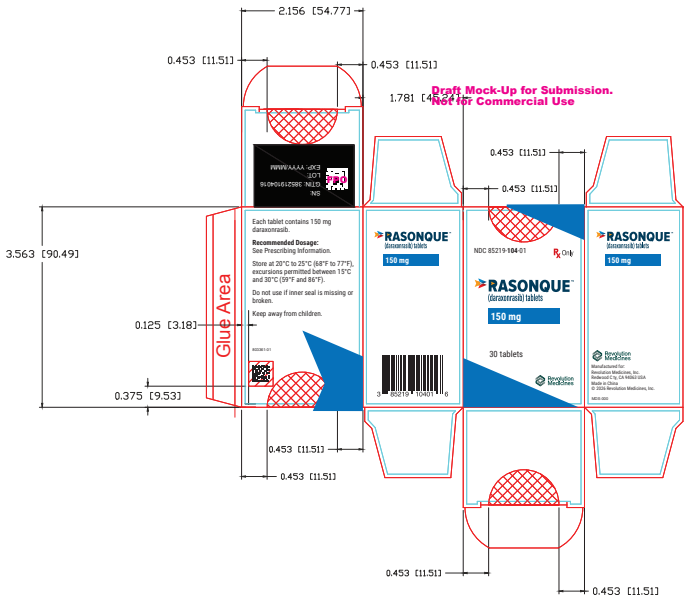

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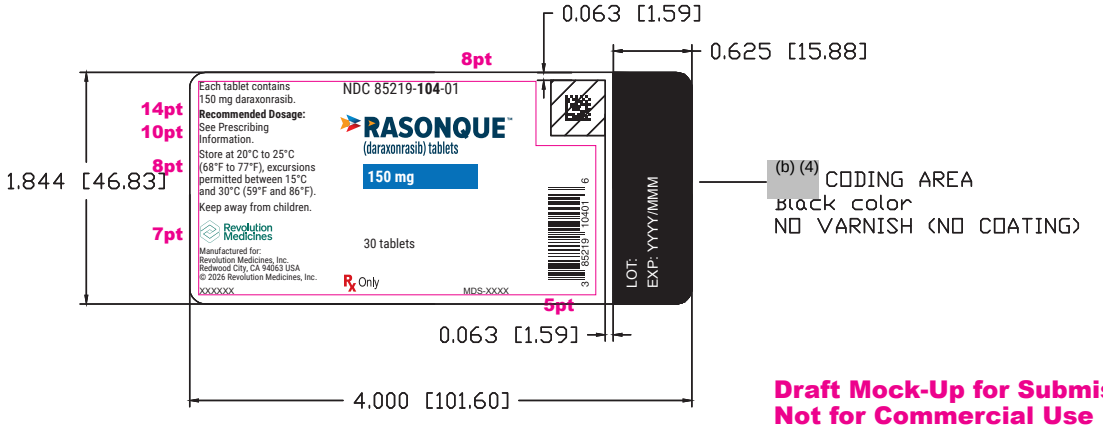

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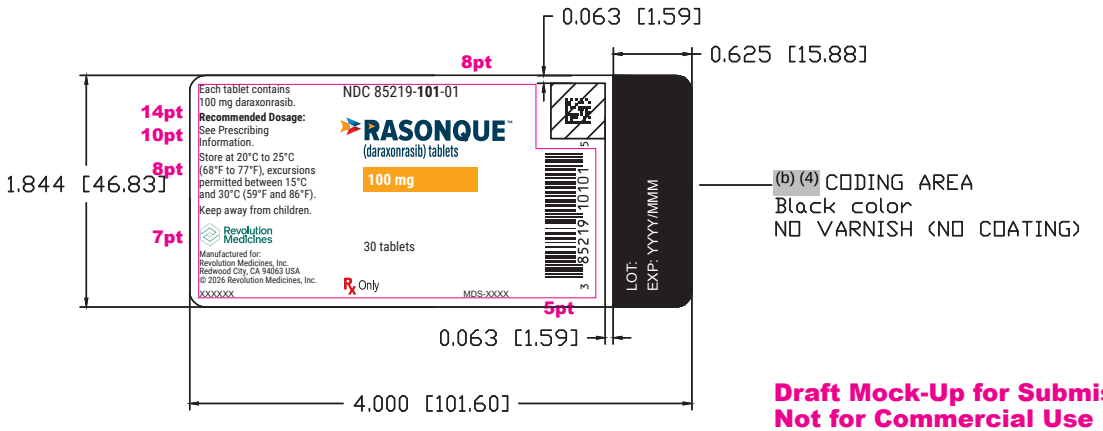

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