What to expect while on treatment

A tool to help you educate your patients about taking INQOVI

INQOVI® (decitabine and cedazuridine) tablets is the only oral hypomethylating agent (HMA) for the treatment of myelodysplastic syndromes (MDS) and CMML. Appropriate patients can take their therapy in the convenience and comfort of their own home.[1]

INDICATIONS

INQOVI is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression

Fatal and serious myelosuppression can occur with INQOVI. Based on laboratory values, new or worsening thrombocytopenia occurred in 82% of patients, with Grade 3 or 4 occurring in 76%. Neutropenia occurred in 73% of patients, with Grade 3 or 4 occurring in 71%. Anemia occurred in 71% of patients, with Grade 3 or 4 occurring in 55%. Febrile neutropenia occurred in 33% of patients, with Grade 3 or 4 occurring in 32%. Myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia) is the most frequent cause of INQOVI dose reduction or interruption, occurring in 36% of patients. Permanent discontinuation due to myelosuppression (febrile neutropenia) occurred in 1% of patients. Myelosuppression and worsening neutropenia may occur more frequently in the first or second treatment cycles and may not necessarily indicate progression of underlying MDS.

Please see additional Important Safety Information throughout and full Prescribing Information in pocket.

INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets

INQOVI is THE ONLY oral HMA for MDS and CMML that patients can take from the convenience of home[1]

Straightforward oral dosing[1]

- **1 tablet, once a day for 5 days per 28-day cycle**
- After 5 days of treatment, patients do not need to take INQOVI for the next 23 days

A complete or partial response may take longer than 4 cycles*

28-day dosing cycle

Week 1	Take 1 tablet once daily for 5 days	2 days rest
Week 2	Rest	
Week 3	Rest	
Week 4	Rest	

Fixed-dose combination tablet containing decitabine (35 mg) and cedazuridine (100 mg)
Tablet shown is not actual size.
Actual tablet size is 7.94 mm x 14.29 mm.

*Premature discontinuation of treatment may have a negative impact on healthcare outcomes.[2]

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression (continued)

Fatal and serious infectious complications can occur with INQOVI. Pneumonia occurred in 21% of patients, with Grade 3 or 4 occurring in 15%. Sepsis occurred in 14% of patients, with Grade 3 or 4 occurring in 11%. Fatal pneumonia occurred in 1% of patients, fatal sepsis in 1%, and fatal septic shock in 1%.

Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor response and toxicity. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose as recommended.

Important dosing reminders[1]

- Tablets should be taken on an empty stomach, at least 2 hours before or 2 hours after a meal
- Do **NOT** substitute INQOVI® (decitabine and cedazuridine) tablets for an IV decitabine product **within a cycle**
- Tablets must be swallowed whole—not cut, crushed, or chewed
- Patients should take INQOVI at the same time each day
- Consider administering antiemetics prior to each dose to minimize nausea and vomiting
- Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate

Storage and Handling[1]

- Store INQOVI tablets in original packaging at room temperature at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F)

Easy-to-use blister pack

DosePak is 7.35 in x 2.45 in.

Please see additional Important Safety Information throughout and full Prescribing Information in pocket.

INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets

Monitoring and dosing modifications

To quickly identify any potential reductions in blood counts at the start of treatment, it is recommended to closely monitor patients during cycle 1 of INQOVI® (decitabine and cedazuridine) tablets treatment. Blood counts may improve with continued treatment.[1,3]

Dose interruptions due to an adverse reaction occurred in **41% of patients** who received INQOVI tablets. **Dose reductions** due to an adverse reaction occurred in **19% of patients** who received INQOVI.[1]

- The most frequent cause of dose reduction or interruption was myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia)[1]

Monitor response[1]

- Obtain complete blood cell counts prior to initiating INQOVI and before each cycle
- Manage toxicity using dose delay, dose modification, growth factors, and anti-infective therapies for treatment or prophylaxis as needed

When to delay or reduce the dose[1]

Delay the next cycle if absolute neutrophil count (ANC) is <1000/µL and platelets are <50,000/µL in the absence of active disease. Monitor complete blood cell counts until ANC is ≥1000/µL and platelets are ≥50,000/µL.

If hematologic recovery does not occur within 2 weeks of achieving remission:

- Delay INQOVI for up to 2 additional weeks, AND
- Resume at a reduced dose by administering INQOVI on days 1 through 4
- Consider further dose reductions (listed on the next page) if myelosuppression persists after first dose reduction
- Maintain or increase dose in subsequent cycles as clinically indicated

When to delay or reduce the dose (continued)[1]

Delay the next cycle for the following nonhematologic adverse reactions and resume at the same or reduced dose once they are resolved:

- Serum creatinine ≥2 mg/dL
- Serum bilirubin ≥2× upper limit of normal (ULN)
- Aspartate aminotransferase or alanine aminotransferase ≥2× ULN
- Active or uncontrolled infection

Recommended dose reductions for myelosuppression*[1]

1st dose reduction	2nd dose reduction	3rd dose reduction
Dosage:	Dosage:	Dosage:
1 day, 2 day, 3 day, 4 day, ~~5 day~~	1 day, 2 day, 3 day, ~~4 day~~, ~~5 day~~	1 day, ~~2 day~~, 3 day, ~~4 day~~, 5 day

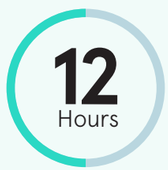
- Manage persistent severe neutropenia and febrile neutropenia with supportive treatment

*Myelosuppression includes thrombocytopenia, neutropenia, anemia, and febrile neutropenia.[1]

If vomiting occurs following dosing[1]:

- No additional dose should be taken that day
- Continue with next scheduled dose

What to do if a dose of INQOVI is missed[1]



Within 12 hours of the time it is usually taken:

- Take the missed dose as soon as possible and resume the normal daily dosing schedule
- Extend the dosing period by 1 day for every missed dose to complete 5 daily doses for each cycle

Please see additional Important Safety Information throughout and full Prescribing Information in pocket.

INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets

Safety

Safety profile similar to IV decitabine[1]

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population

Adverse reactions[a]	INQOVI cycle 1 n=107		IV decitabine cycle 1 n=106		INQOVI all cycles n=208[c]	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
General disorders and administration site conditions						
Fatigue[b]	29	2	25	0	55	5
Hemorrhage[b]	24	2	17	0	43	3
Edema[b]	10	0	11	0	30	0.5
Pyrexia	7	0	7	0	19	1
Gastrointestinal disorders						
Constipation[b]	20	0	23	0	44	0
Mucositis[b]	18	1	24	2	41	4
Nausea	25	0	16	0	40	0.5
Diarrhea[b]	16	0	11	0	37	1
Transaminase increased[b]	12	1	3	0	21	3
Abdominal pain[b]	9	0	7	0	19	1
Vomiting	5	0	5	0	15	0
Musculoskeletal and connective tissue disorders						
Myalgia[b]	9	2	16	1	42	3
Arthralgia[b]	9	1	13	1	40	3
Respiratory, thoracic, and mediastinal disorders						
Dyspnea[b]	17	3	9	3	38	6
Cough[b]	7	0	8	0	28	0
Blood and lymphatic system disorders						
Febrile neutropenia	10	10	13	13	33	32
Skin and subcutaneous tissue disorders						
Rash[b]	12	1	11	1	33	0.5
Nervous system disorders						
Dizziness[b]	16	1	11	0	33	2
Headache[b]	22	0	13	0	30	0
Neuropathy[b]	4	0	8	0	13	0

[a] Please see full Prescribing Information for complete list of adverse events occurring during all cycles.
[b] Includes multiple adverse reaction terms.
[c] Includes adverse reactions that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population (continued)[1]

Adverse reactions[a]	INQOVI cycle 1 n=107		IV decitabine cycle 1 n=106		INQOVI all cycles n=208[c]	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
Metabolism and nutritional disorders						
Decreased appetite	10	1	6	0	24	2
Infections and infestations						
Upper respiratory tract infection[b]	6	0	3	0	23	1
Pneumonia[b]	7	7	7	5	21	15
Sepsis[b]	6	6	2	1	14	11
Cellulitis[b]	4	1	3	2	12	5
Investigations						
Renal impairment[b]	9	0	8	1	18	0
Weight decreased	5	0	3	0	10	1
Injury, poisoning, and procedural complications						
Fall	4	0	1	0	12	1
Psychiatric disorders						
Insomnia	6	0	2	0	12	0.5
Vascular disorders						
Hypotension[b]	4	0	6	1	11	2
Cardiac disorders						
Arrhythmia[b]	3	0	2	0	11	1

[a] Please see full Prescribing Information for complete list of adverse events occurring during all cycles.
[b] Includes multiple adverse reaction terms.
[c] Includes adverse reactions that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

- Safety results were similar to IV decitabine with no unexpected adverse reactions reported in the first 2 cycles[1]
- Incidence of cytopenias was slightly higher in INQOVI® (decitabine and cedazuridine) tablets during cycle 1 compared to IV decitabine[1]

Please see additional Important Safety Information throughout and full Prescribing Information in pocket.

INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets

Important things to remember while patients are treated with INQOVI

INQOVI tablets **can be substituted for IV decitabine, but not within a cycle.**[1]

Patients should be closely monitored during treatment with INQOVI, **especially during the early cycles.**[3]

- Incidence of cytopenias was slightly higher in INQOVI during cycle 1 compared to IV decitabine

A response to INQOVI tablets may not be immediate. It may take up to **4 cycles to see a response.**[1]

Antiemetics (prior to each dose), growth factors, and anti-infective therapies **can be administered for treatment or prophylaxis as appropriate.**[1]

To learn more about treatment with INQOVI® (decitabine and cedazuridine) tablets, visit INQOVI.com/hcp

SELECTED IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

Serious adverse reactions in > 5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%). Fatal adverse reactions included sepsis (1%), septic shock (1%), pneumonia (1%), respiratory failure (1%), and one case each of cerebral hemorrhage and sudden death.

The most common adverse reactions (≥ 20%) were fatigue (55%), constipation (44%), hemorrhage (43%), myalgia (42%), mucositis (41%), arthralgia (40%), nausea (40%), dyspnea (38%), diarrhea (37%), rash (33%), dizziness (33%), febrile neutropenia (33%), edema (30%), headache (30%), cough (28%), decreased appetite (24%), upper respiratory tract infection (23%), pneumonia (21%), and transaminase increased (21%). The most common Grade 3 or 4 laboratory abnormalities (≥ 50%) were leukocytes decreased (81%), platelet count decreased (76%), neutrophil count decreased (71%), and hemoglobin decreased (55%).

USE IN SPECIFIC POPULATIONS

Lactation

Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with INQOVI and for 2 weeks after the last dose.

Renal Impairment

No dosage modification of INQOVI is recommended for patients with mild or moderate renal impairment (creatinine clearance [CLcr] of 30 to 89 mL/min based on Cockcroft-Gault). Due to the potential for increased adverse reactions, monitor patients with moderate renal impairment (CLcr 30 to 59 mL/min) frequently for adverse reactions. INQOVI has not been studied in patients with severe renal impairment (CLcr 15 to 29 mL/min) or end-stage renal disease (ESRD: CLcr <15 mL/min).

References: 1. INQOVI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2022. **2.** Joshi N, Kale H, Corman S, Wert T, Hill K, Zeidan AM. Direct medical costs associated with treatment nonpersistence in patients with higher-risk myelodysplastic syndromes receiving hypomethylating agents: a large retrospective cohort analysis. *Clin Lymphoma Myeloma Leuk*. 2021;21(3):e248-e254. doi:10.1016/j.clml.2020.12.002. **3.** Kim N, Norsworthy KJ, Subramaniam S, et al. FDA approval summary: decitabine and cedazuridine tablets for myelodysplastic syndromes. *Clin Cancer Res*. 2022;28(16):3411-3416. doi: 10.1158/1078-0432.CCR-21-4498. **4.** Zeiden AM, Tsai J-H, Karini M, et al. Patient preferences for benefits, risks, and administration route of hypomethylating agents in myelodysplastic syndromes. *Clin Lymphoma Myeloma Leuk*. 2022;22(9):e853-e866. doi:10.1016/j.clml.2022.04.023.

Please see additional Important Safety Information throughout and full Prescribing Information in pocket.

TAIHO ONCOLOGY

INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets

 06/2023 INQ-PM-US-0500