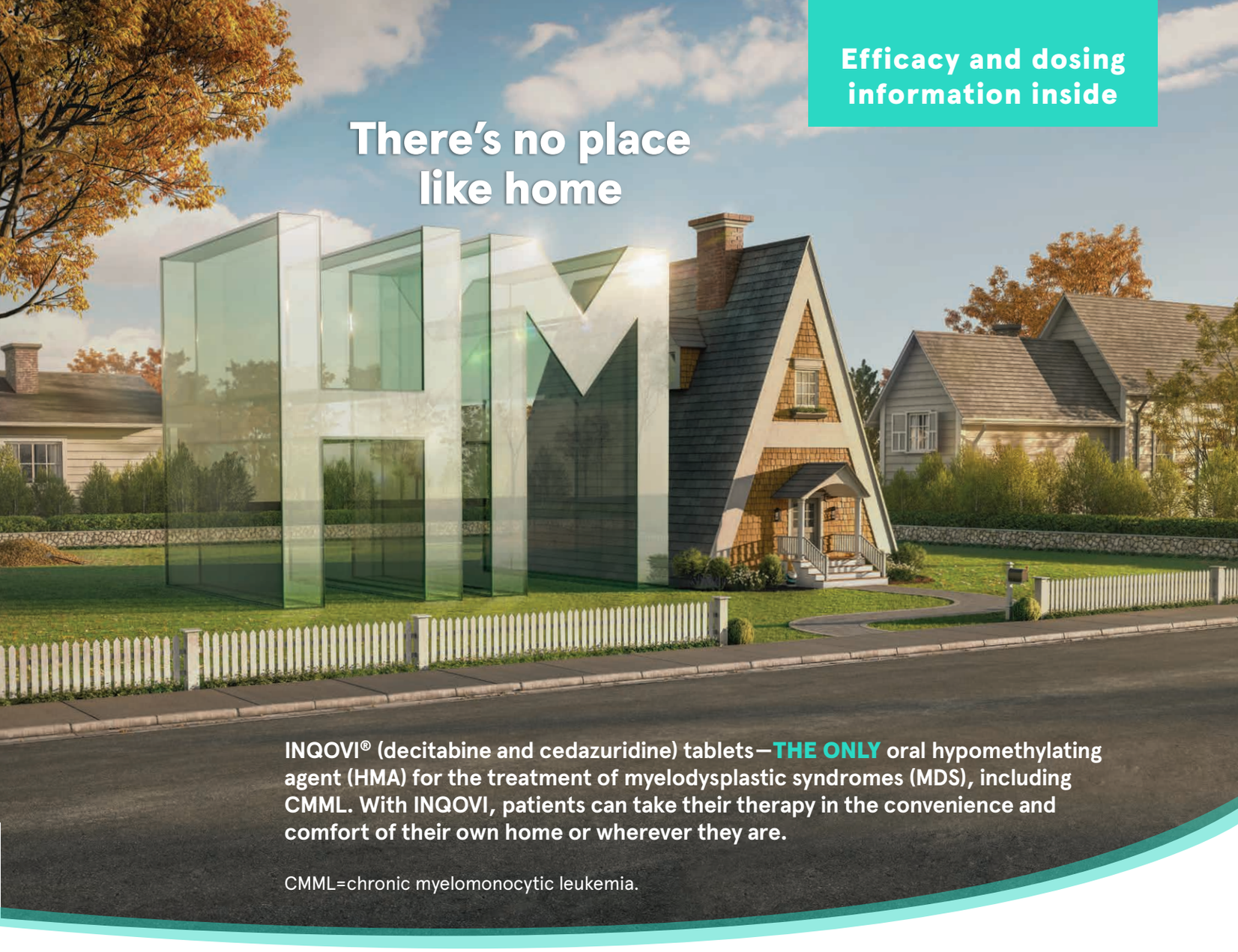


Efficacy and dosing information inside

INQOVI® (decitabine and cedazuridine) tablets—THE ONLY oral hypomethylating agent (HMA) for the treatment of myelodysplastic syndromes (MDS), including CMML. With INQOVI, patients can take their therapy in the convenience and comfort of their own home or wherever they are.

CMML=chronic myelomonocytic leukemia.

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 on back cover and full Prescribing Information in pocket or at INQOVI.com/PI.

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

THE ONLY oral HMA for MDS, including CMML, that

Patients can take from the convenience of home

Oral dosing

- 1 tablet, once a day for 5 days per 28-day cycle
- Fixed-dose combination tablet containing decitabine (35 mg) and cedazuridine (100 mg)
- It is important to remind patients that response to INQOVI® (decitabine and cedazuridine) tablets may not be immediate. Premature discontinuation can limit therapeutic benefits that would otherwise have been reached
- A complete or partial response may take longer than 4 cycles

Tablet shown is not actual size. Actual tablet size is 7.94 mm x 14.29 mm.

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	

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%.

Important dosing reminders

- Patients should avoid eating for 2 hours before and 2 hours after taking INQOVI
- Tablets must be swallowed whole—not cut, crushed, or chewed
- Consider administering antiemetics prior to each dose to minimize nausea and vomiting
- Do NOT substitute INQOVI for an IV decitabine product within a cycle
- Patients should take INQOVI at the same time each day

Storage and handling with INQOVI

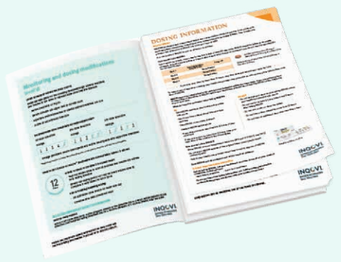
- Store INQOVI tablets in original packaging at room temperature at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F)

DosePak is 7.35 in x 2.45 in.

Additional health resources

Health Journal

A place for patients and caregivers to keep track of their dosing schedule, make note of any side effects, and jot down anything they want to discuss with their healthcare provider.



Dosing Tearpad

A tool to help ensure appropriate dosing and remind patients and caregivers how INQOVI should be taken.

Please see additional Important Safety Information on back cover and full Prescribing Information in pocket or at INQOVI.com/PI.

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

ASCERTAIN trial design

The phase 3 crossover trial was designed to assess systemic decitabine exposure, demethylation activity, and safety between IV decitabine and INQOVI® (decitabine and cedazuridine) tablets. The trial allowed for intrapatient comparison in the first 2 randomized treatment cycles, and then assessment of the long-term efficacy and safety of INQOVI as a single arm.

	Phase 3 N=133
Primary endpoint	5-day area under the curve (AUC) between INQOVI and IV decitabine
Secondary endpoints	Complete response Rate of conversion from transfusion dependence to transfusion independence
Other results	Median duration of treatment: 8.2 months (range: 0.2-19.7) Median follow-up time: 12.6 months (range: 9.3-20.5)

Safety results similar to IV decitabine

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%).

- Incidence of cytopenias was slightly higher in INQOVI during cycle 1 compared to IV decitabine
- These are not the only adverse reactions or laboratory abnormalities seen with INQOVI. Please see full Prescribing Information for complete safety profile

THE ONLY oral HMA with equivalent systemic exposure to IV decitabine

Primary endpoint results

Orally administered INQOVI demonstrated equivalent systemic exposure to IV-administered decitabine

99% **ratio of oral to IV 5-day decitabine AUC**
(90% CI: 93, 106)

- This ratio is the geometric mean of the 5-day cumulative decitabine AUC between INQOVI and IV-administered decitabine when administered once daily for 5 consecutive days

Efficacy results in patients with MDS or CMML in phase 3 crossover trial (N=133)

21% OF PATIENTS
achieved a complete response
(CR, 95% CI: 15, 29)

4.3 MONTHS
median time to CR
(range: 2.1-15.2)

7.5 MONTHS
median duration of CR*
(range: 1.6-17.5)

Transfusion Independence

53% **of the patients treated with INQOVI who were initially transfusion dependent achieved posttreatment RBC and platelet transfusion independence (30/57)†**

63% **of patients who initially were both RBC and platelet transfusion independent remained transfusion independent (48/76)†**

*From start of CR until relapse or death.
†During any consecutive 56-day postbaseline period.
AUC=area under the curve; CI=confidence interval; IV=intravenous; RBC=red blood cell.

Please see Important Safety Information on back cover and full Prescribing Information in pocket or at INQOVI.com/PI.

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

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.

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.

Embryo-Fetal Toxicity

INQOVI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise patients to use effective contraception during treatment and for 6 months (females) or 3 months (males) after last dose.

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).

Please see full Prescribing Information in pocket or at INQOVI.com/PI.

Reference: INQOVI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2022.

TAIHO ONCOLOGY

 05/2022 INQ-PM-US-0191v3

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