Enrollment Process

harliku™
(nitisinone) Tablets

To enroll your patient onto HARLIKU™ (nitisinone) Tablets, you will need to:

1 Download an enrollment form from **harliku.com/hcp/enroll**

2 Fax the completed form to 888-385-8482 or email it to **hello@cyclevita.life**

Indications

HARLIKU™ is indicated for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU).

Important Safety Information

Do not prescribe HARLIKU to patients allergic to nitisinone or any other contained ingredients.

Warnings and Precautions:

Ocular Symptoms and Hyperkeratotic Plaques Due to Elevated Plasma Tyrosine Level:

Ocular signs and symptoms including keratitis, corneal opacities, corneal irritation, corneal ulcers, conjunctivitis, eye pain, and photophobia, have been reported in patients.

• Perform slit-lamp examination prior to treatment and regularly thereafter. Reexamine patients if symptoms develop or tyrosine levels are > 500 micromole/L. Assess plasma tyrosine levels in patients with an abrupt change in neurological status.

• Perform a clinical laboratory assessment, including plasma tyrosine levels, in patients with an abrupt change in neurological status.

Leukopenia and Severe Thrombocytopenia

In clinical trials, patients with hereditary tyrosinemia type 1 (HT-1) treated with another oral formulation of nitisinone and dietary restriction, developed reversible leukopenia, thrombocytopenia, or both. No patients developed infections or bleeding as a result of the episodes of leukopenia and thrombocytopenia. Monitor platelet and white blood cell counts during HARLIKU therapy.

Adverse Reactions:

The most common adverse reactions (≥1%) reported in patients with AKU taking nitisinone in clinical trials are elevated tyrosine levels, thrombocytopenia and keratitis.

Drug Interactions:

• Nitisinone is a moderate CYP2C9 inhibitor and a weak CYP2E1 inducer. Potential clinical impact of Harliku administration with CYP2C9 substrates. Reduce the dosage of the co-administered drugs metabolized by CYP2C9 by half. Additional dosage adjustments may be needed.

• Nitisinone is an inhibitor of OAT1/OAT3. Potential clinical impact of administration with OAT1/OAT3 substrates. Patients should be monitored for potential adverse reactions.

Use in Specific Populations:

Pregnancy: Limited available data with nitisinone use in pregnant women are not sufficient to determine a drug-associated risk of adverse developmental outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.

Lactation: The developmental and health benefits of breastfeeding should be considered against the mother's clinical need for HARLIKU, along with potential adverse effects on the breastfed infant from HARLIKU or from the underlying maternal condition.

Pediatric Use: The safety and effectiveness of HARLIKU have not been established in pediatric patients with AKU.

Geriatric Use: Insufficient data from clinical studies of HARLIKU to determine if patients ≥ 65 years of age respond differently. Elderly patients should be cautious reflecting any decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

For more detailed information, please refer to the full Prescribing Information enclosed and at harliku.com/PI/.

To report SUSPECTED ADVERSE REACTIONS, contact Cycle Pharmaceuticals at 1-855-831-5413, or the FDA at: 1-800-FDA-1088 or www.fda.gov/medwatch.

What Happens Next?

harliku™
(nitisinone) Tablets

After you've sent your completed enrollment form, our support program, Cycle Vita™, will*:

1. Reach out to your patient to welcome them, discuss the support offerings, and assess their need for bridge shipments.

2. Quickly get to work with your patient's insurance provider for a benefit investigation.

3. Share the benefit investigation outcome with you and your patient.

4. Guide your clinic on how to submit prior authorizations** and appeals to the insurance company. Support is also available to help strengthen denied submissions.

5. Provide in-office education for best practice submissions, expectation setting, and other logistics upon your request.

6. Enroll eligible patients in its Co-pay Assistance Program.

7. Route your patients' therapy to the appropriate specialty pharmacy and ensure shipment of medication.

8. Provide continuous clinical support, disease state training, and medication training to your patient to facilitate adherence.

9. Continue to assist in managing prior authorization** renewals and verifying your patient's insurance coverage.

Help your patients step towards a brighter future, let's go!

Download an enrollment form at harliku.com/hcp/enroll

* Some areas of product support are treatment specific and may not be accessible to all patients. Eligibility criteria may apply to ensure compliance with all applicable federal and state requirements, and benefits may be limited to commercially insured patients only.

** Cycle Vita cannot complete prior authorization (PA), medical language, or submissions for a healthcare provider (HCP). Cycle Vita can be expected to monitor progress of PA between the HCP and the Payor, including submission and follow-up reminders with both parties.

US-HKU-2500111 | January 2026. ©2026 Cycle Pharmaceuticals Limited. All rights reserved. Cycle Vita™ is a trademark of Cycle Pharmaceuticals Limited in the United States. This material is for healthcare providers in the US.

CYCLE VITA™
Support *for life*