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| Reference number(s) |
| 7472-H              |

# Specialty Quantity Limit Harliku

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|--------------|
| Harliku    | nitisinone   |

## Program Description

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

## Covered Quantities

| Medication                        | Standard Limit         |
|-----------------------------------|------------------------|
| Harliku (nitisinone) 2 mg tablets | 30 tablets per 30 days |

## FDA-recommended Dosing

### Recommended Dose

2 mg administered orally, once daily.

## References

1. Harliku [package insert]. Boston, MA: Cycle Pharmaceuticals Ltd.; June 2025.