☐ **URGENT – NEWBORN PRESCRIPTION**
(CHECK HERE IF THIS IS A PRESCRIPTION FOR A NEWBORN BABY)

NITYR® (nitisinone) Tablets Enrollment Form

Nityr® nitisinone Tablets

CYCLE PHARMA

Phone: +1 (888) 360-8482 (VITA) FAX: +1 (888) 385-8482 (VITA) Website: www.cyclevita.life | www.nityr.us

1. PATIENT INFORMATION

Patient Name (First, Last):	Date of Birth:		Gender:
Street Address:	City:	State:	ZIP:
Email Address:	Cell Phone:	Home Phone:	Preferred Language:
Caregiver Name (if applicable):	Relation to patient:	Caregiver Phone (if different from patient):	

2. INSURANCE INFORMATION *(attach front and back copies of all insurance cards)*

☐ **Patient/Family does NOT have insurance** ☐ **Patient is a NEWBORN**

Primary Insurance Company Name:	Primary Insurance Cardholder Name:	Relation to Patient:
Primary Insurance Policy Number:	Primary Insurance Group Number:	Primary Insurance Phone Number:
Pharmacy Plan Name:	PCN Number:	BIN Number:
Pharmacy Plan Policy Number:	Pharmacy Plan Group Number:	Pharmacy Phone Number:
Secondary Insurance Plan Name:	Secondary Insurance Cardholder Name:	Relation to Patient:
Secondary Insurance Policy Number:	Secondary Insurance Group Number:	Secondary Insurance Phone Number:

3. PRESCRIBER INFORMATION

Prescriber Name (First, Last):	Facility/Clinic Name:		
State Medical License Number:	NPI Number:		
Facility/Clinic Street Address:	City:	State:	ZIP:
Facility Shipping Address: ☐ Same as above	City:	State:	ZIP:
Prescriber Email:	Prescriber Phone Number:	Prescriber FAX:	
Dietitian or Office Contact Name (First, Last):	Dietitian or Office Contact Email:	Dietitian or Office Contact Phone Number:	

4. PATIENT MEDICAL INFORMATION

Primary Diagnosis:

Diagnosis Code: ☐ ICD-10: E70.21 (HT-1) ☐ ICD-10: E70.29 (AKU) ☐ Other:

Patient Weight: _____ ☐ kg ☐ lbs

Patient is currently on a tyrosine and phenylalanine restricted diet?: ☐ Yes ☐ No
*If no, provide reason:

Liver transplanted?: ☐ Yes ☐ No *If yes, provide transplant date:

Allergies: ☐ NKDA ☐ Known:

Current Medications: ☐ None ☐ Known:

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Patient Name (Printed):	Date of Birth:

5. PRESCRIPTION

☐ **Preferred Specialty Pharmacy:** _____

Patient's Full Name (First, Middle Initial, Last):	Date of Birth:

Ship to: ☐ Prescriber's Office ☐ Hospital Pharmacy ☐ Patient Residence:
☐ First Fill ☐ Always ☐ Never

☐ **"Quick Start"** *(Please check this box if the below statement applies to this patient)*

"Quick Start" is a FREE supply of NITYR® (nitisinone) Tablets that allows eligible patients to begin therapy immediately while Cycle Vita™ secures appropriate benefit verification and authorization. If Quick Start is selected for the patient, an initial 14-day supply of NITYR® (nitisinone) Tablets will be dispensed; 28-day initial supply for patients 6 months and younger. The strength, directions and quantity will match the written prescription below. All further Quick Start deliveries will be supplied in 14-day refills (with a limit of 56 days of FREE supply).

☐ **Ongoing Prescription** *(Check this box for continuous, refillable supply of NITYR® (nitisinone) Tablets).* Please select the prescribed strength below.

☐ **2mg NITYR® (nitisinone) Tablets (NDC: 70709-002-60)**	☐ **5mg NITYR® (nitisinone) Tablets (NDC: 70709-005-60)**	☐ **10mg NITYR® (nitisinone) Tablets (NDC: 70709-000-60)**
Dosage Instructions: _____ AM _____ PM Quantity: _____ Refills: _____ Date: _____ Dispense as Written: x _____	Dosage Instructions: _____ AM _____ PM Quantity: _____ Refills: _____ Date: _____ Dispense as Written: x _____	Dosage Instructions: _____ AM _____ PM Quantity: _____ Refills: _____ Date: _____ Dispense as Written: x _____

The prescriber is to comply with their state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

6. ADMINSTRATION INSTRUCTIONS

Morning	Patient CAN swallow tablet(s)	Patient CANNOT swallow tablets	
____ **2mg tablet(s) and** ____ **5mg tablet(s) and** ____ **10mg tablet(s) and**	☐ Take tablet(s) with or without food	☐ **Suspend in an oral syringe (SUSPENSION)** Create a suspension using an oral syringe with _____ mL* of water. Follow instructions for use.	☐ **Crush and mix with applesauce** Crush tablet(s)**, mix with applesauce and administer. Follow instructions for use.
Afternoon			
____ **2mg tablet(s) and** ____ **5mg tablet(s) and** ____ **10mg tablet(s) and**		**use 2.6mL for (1) tablet or 5mL for (2) tablets; an oral syringe will be provided*	***a tablet crusher will be provided*

Special Instructions:

Prescriber Declaration: I verify that the patient and prescriber information contained in this enrollment form is complete and accurate to the best of my knowledge and that I have prescribed NITYR® (nitisinone) Tablets based on my professional judgment of medical necessity. I authorize CYCLE Pharmaceuticals or its affiliated companies or subcontractors, including in-network specialty pharmacies, through the Cycle Vita™ – NITYR® (nitisinone) Tablets Program ("the Program") to forward this prescription by facsimile, or by mail to the relevant in-network pharmacy for the above-named patient. I also authorize the Program to perform any steps necessary to obtain reimbursement for NITYR® (nitisinone) Tablets, including but not limited to insurance verification and authorization. I understand that the Program may need additional information, and I agree to provide it as needed for the purposes of reimbursement. I also authorize the Program to perform any steps necessary to obtain reimbursement for NITYR® (nitisinone) Tablets, including but not limited to insurance verification and authorization to facilitate a coverage decision. Prescriber's signature (sign below) (Physician attests this is his/her legal signature. NO STAMPS.)

Prescriber Signature: X_____ Date: _____

Patient Name (Printed):	Date of Birth:

Patient Authorization for Use and Disclosure of Personal Health Information (PHI)

I understand that I must complete this enrollment form before I can receive assistance through the CYCLE Pharmaceuticals, Ltd., Cycle Vita™ – NITYR® (nitisinone) Tablets Program. As part of this process, CYCLE and its agents and contractors (collectively, "CYCLE") will need to obtain, review, use and disclose PHI as described below.

To ensure I have access to the Cycle Vita™ – NITYR® (nitisinone) Tablets Program benefits for which I may qualify AND to ensure my Personal Health Information (PHI) is appropriately protected in compliance with applicable federal laws and regulations.

- I further authorize my healthcare providers (HCPs) and health plans to disclose my PHI as described below to an authorized CYCLE Health Care Professional (HCP) in connection with the Cycle Vita™ – NITYR® (nitisinone) Tablets Program, and I authorize CYCLE to use and disclose the information for the purposes stated in this authorization.
    1. Information to Be Disclosed: Personal Health Information (PHI), including information about me (for example, name, mailing address, financial information, and insurance), my past, current and future medical condition and information provided on this form to include information concerning Adverse Events (AE).
    2. Persons Authorized to Disclose My Information: My HCPs, including any pharmacy that fills my prescription medication, and any health plans or programs that provide me healthcare benefits.
    3. Persons to Whom My Information May Be Disclosed: A qualified HCP, individuals representing CYCLE, including third-party administrators responsible for the administration of the NITYR® (nitisinone) Tablets, appropriate third parties under contract to CYCLE, such as the CYCLE Pharmacovigilance Agency and product manufacturer(s) to properly address any Adverse Event (AE). I understand my PHI will only be shared in accordance with my consent as described within this form.
    4. Purposes for Which the Disclosures Are to Be Made: Disclosures of PHI may be made to CYCLE so that CYCLE may use and disclose the PHI for purposes of completing the enrollment process, verifying my enrollment form and establishing my eligibility for the Cycle Vita™ – NITYR® (nitisinone) Tablets Program and benefits that may include:
        a. Insurance and Reimbursement Assistance: Authorization allows for professional assistance at no charge on Patient's behalf for Claims Settlement, Claims Submission – to health insurers (for payment); communication of relevant claim information to/from HCPs and Insurance carriers.
        b. Reimbursement Support: Financial Assistance, including CYCLE's sponsored Co-Pay Assistance, is available only for eligible patients. Co-Pay assistance allows CYCLE

Patient Name (Printed):	Date of Birth:

Pharmaceuticals LTD. to pay associated Co-Payments due to Insurance providers on behalf of the Patient.

c. Patient Benefits Investigation & Payer Prior-Authorization Support: The Cycle Vita™ – NITYR® (nitisinone) Tablets Program will contact, investigate, and arrange for Patient's eligible coverage with their respective Health Insurer and/or PBM (Pharmacy Benefit Manager), as well as support and appropriately assist with Prior-Authorizations.

d. Patient Education and Information: CYCLE and the Cycle Vita™ – NITYR® (nitisinone) Tablets Program will provide Patients with full education on NITYR® (nitisinone) Tablets administration, relevant disease area information and product information updates; in addition to pertinent updates and information on events for patients. This includes advocacy communication from national and international patient advocacy groups.

e. Access to Manufacturer / CYCLE: This will allow CYCLE to alert Patients receiving Cycle Vita™ – NITYR® (nitisinone) Tablets about relevant product and market updates, product recalls, Adverse Event notifications, and available resources, including adherence tools and other programs to benefit patients with Hereditary Tyrosinemia Type 1.

5. Limits of Protections after Disclosure. I understand that once my PHI has been disclosed hereunder, federal privacy law may no longer restrict its use or disclosure.
6. Option to Refuse. I understand I am not required to sign this Authorization as a condition to receive treatment with CYCLE's products, or payment for health care; enrolling in a health plan; or establishing eligibility for benefits. However, by refusing to authorize disclosure of my PHI to a qualified and authorized CYCLE HCP, I also understand that I am knowingly foregoing possible access to the Cycle Vita™ – NITYR® (nitisinone) Tablets Program benefits.
7. Copy of Authorization and Ability to Cancel Authorization. I understand I will be given a copy of this Authorization after I sign it; and my Authorization shall remain in effect until it expires (i.e. 5 years from the date sign below unless a shorter period is required by the law of my state residence), or unless I revoke Authorization at any time by contacting the Cycle Vita™ – NITYR® (nitisinone) Tablets Program (toll-free), at +1 (888) 360-8482 (VITA) Monday through Friday, from 8:00am to 8:00pm EST, by FAX, at +1 (888) 385-8482 (VITA) or in writing to CYCLE Pharmaceuticals Ltd., PO Box 130059, Boston, MA 02113. I understand my cancellation will not apply to any PHI already used or disclosed by my HCPs based on this Authorization prior to their receipt of the cancellation
8. I understand that my pharmacy, health insurers and third-party vendors may receive payment from CYCLE as the manufacturer in exchange for securely sharing my PHI to an authorized CYCLE's HCP for the sole purpose of providing me access to important patient support as described above.

Patient Name (Printed):	Date of Birth:

PATIENT AUTHORIZATION *(to be completed by Patient)*

I have read and understood the Patient Authorization Information (starting on Page 3) and by signing this form authorize the use and disclosure of my health information as described above.

***Signature NOT required to begin benefit investigation. Authorization may also be collected verbally upon completion of benefit investigation with Cycle Vita™.**

_____

Patient Name (Printed)

_____ _____

Signature of Patient Date

_____ _____

Signature of Patient Representative* Date

*If signed by Patient Representative, please explain authority / relation to act on behalf of patient:

_____

Please read the following statements and mark each box:

☐ I hereby authorize the Cycle Vita™ – NITYR® (nitisinone) Tablets Program to use my PHI to contact me by mail, e-mail, text, phone, or any communication method I request for the purposes as described herein.

☐ Further, I understand that this program guarantees that I will receive Cycle Vita™ – NITYR® (nitisinone) Tablets [NDC: (70709-002-60 / 70709-005-60 / NDC: 70709-000-60)] rather than other products. By signing, I elect to receive the generic product specified within this enrollment form. No substitutions will be made or given.