Consultation Guide

Nityr®
nitisinone
Tablets

JOIN GENERATION LIBERATION

Patients with Tyrosinemia Type 1, know your options. You can use this guide to help you ask the right questions to your doctor and to start the conversation today.

NITYR® (nitisinone) Tablets are a hydroxyphenyl-pyruvate dioxygenase inhibitor indicated for the treatment of adult and pediatric patients with Hereditary Tyrosinemia Type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

Indications
NITYR® (nitisinone) Tablets are a competitive inhibitor of 4-hydroxyphenyl-pyruvate dioxygenase indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

Important Safety Information
Do not take NITYR if you are allergic to nitisinone or any other ingredients. Tell your healthcare provider about any health problems, and if you are pregnant or planning to become pregnant and/or breastfeeding, before starting treatment

Warnings and Precautions:
Increased levels of plasma tyrosine, eye symptoms, developmental delay and skin changes:

- Inadequate restriction of tyrosine and phenylalanine intake can result in elevations of plasma tyrosine.
- Plasma tyrosine levels above 500 micromol/L may lead to ocular signs and symptoms including corneal ulcers, corneal opacities, keratitis, conjunctivitis, eye pain, and photophobia, intellectual disability and developmental delay or painful hyperkeratotic plaques (thickening of the skin) on the soles and palms.
- Your healthcare provider should not adjust NITYR dosage in order to lower the levels of tyrosine in the blood.
- Your healthcare provider will obtain a slit-lamp examination prior to initiating NITYR treatment, regularly during treatment and may reexamine you if you develop symptoms or if your tyrosine levels are above 500 micromol/L.

Changes in blood profile

- You may develop leukopenia (reduction in the number of white blood cells, which form part of the immune system) and severe thrombocytopenia (abnormally low levels of platelets, which help the blood to clot).
- Your healthcare provider will monitor platelet and white blood cell counts, and will adjust your medication accordingly.

Most Common Adverse Reactions: The most common adverse reactions (≥1%) in patients with HT-1 taking nitisinone are elevated tyrosine levels, low platelets (thrombocytopenia) or white cells in the blood (leukopenia), and complaints related to the eyes, including conjunctivitis, corneal opacity, inflammation of the cornea, eye pain and extreme sensitivity to light (photophobia), nosebleed (epistaxis), itching (pruritus), skin inflammation (exfoliative dermatitis), rash (maculopapular rash), dry skin and alopecia.

Drug Interactions: Nitisinone can interfere with the effect of other medicines. Tell your healthcare provider or pharmacist if you are taking, have recently taken or might take any other medicines.

Use in Specific Populations:
Pregnancy: The safety of this medicine has not been studied in pregnancy. Tell your healthcare provider immediately if you become pregnant or planning to become pregnant.
Lactation: The safety of this medicine has not been studied in breastfeeding women. Tell your healthcare provider immediately if you plan on breastfeeding.
Pediatric Use: The safety and effectiveness of nitisinone have been established in pediatric patients for the treatment of HT-1 in combination with dietary restriction of tyrosine and phenylalanine. Use of NITYR in pediatric patients is supported by evidence from one open-label, uncontrolled clinical study conducted with another oral formulation of nitisinone in 207 patients with HT-1 ages 0 to 22 years (median age 9 months)
Geriatric Use: Clinical studies of nitisinone did not include any subjects aged 65 and over. No clinical studies of Nitisinone have been performed in geriatric patients. Your healthcare provider will adjust the dose based on your requirements.

For more detailed information, please refer to the full Prescribing Information.

If you get any side effects, talk to your healthcare provider. This includes possible side effects not listed in this brochure. You may also report side effects directly by calling Cycle Pharmaceuticals at 1-855-831-5413, or the FDA at: 1-800-FDA-1088 or www.fda.gov/medwatch.

Questions to consider asking your doctor

Nityr®
nitisinone
Tablets

Treatment

- What is NITYR and how does it work?
- Is NITYR any different to the NTBC (nitisinone) I am already taking?
- Are the side effects and safety any different to my current NTBC?
- Would my diet or diet plan change?
- How is NITYR taken/given? Would it be different to how I take/give nitisinone at the moment?
- Can NITYR be taken without food?
- Can I take my dose of NITYR once a day?
- How should NITYR be stored or transported?

Product Support

- What product support comes with NITYR? Is it any different to the product support I already have with my current NTBC?
- Is there dietary product support available with NITYR?
- Will there be someone I can contact when I have questions? (i.e., with navigating insurance requirements or staying on top of medication refills.)
- How can I find out if NITYR is covered by my insurance provider?
- Will I have to pay more for NITYR?

Notes:

Still have questions?

If you have any questions about NITYR or need further support, our friendly and familiar team is waiting here at Cycle Vita™, for you, *for life*.

+1 (888) 360-8482 hello@cyclevita.life www.cyclevita.life

CYCLE VITA™
Support *for life*

Please see Important Safety Information on page 1 and the full Prescribing Information at www.nityr.us/PI