

For people 2 years and older with primary hyperoxaluria type 1 (PH1)
and relatively preserved kidney function

Explore the path of possibilities with Rivfloza®

Look forward to the journey ahead with a once-monthly treatment that lowers and keeps urinary oxalate levels under control.



Actor portrayals.

What is Rivfloza®?

Rivfloza® is a prescription medicine used to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.

It is not known if Rivfloza® is safe and effective in children younger than 2 years of age.

Important Safety Information

What are the possible side effects of Rivfloza®?

The most common side effects of Rivfloza® include injection site reactions, such as reddening, pain, bruising, rash, or dimple at the site of injection.

Please click [here](#) for Prescribing Information.

 **rivfloza**®
(nedosiran) injection
80mg, 128mg, 160mg

What is primary hyperoxaluria (PH)?

PH is a rare disease in which the liver does not make enough of a certain protein to prevent oxalate (a natural waste product) from building up in the body.



inherited

Primary Hyperoxaluria



too much



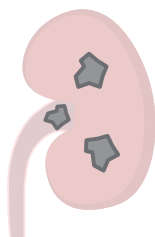
oxalate



urine

- PH is an inherited (genetic) disease, meaning it is caused by a change in a gene that is passed down from both parents to a child
- PH affects both children and adults
- There are 3 types of PH: PH1, PH2, and PH3
 - **PH1 is the most commonly clinically diagnosed type of PH**

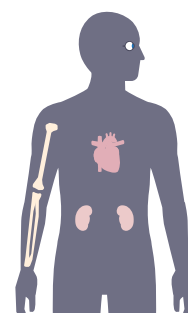
PH1 may affect people differently or change over time



Kidney stones are the most common symptom of PH1 but are not the only symptom of the disease.



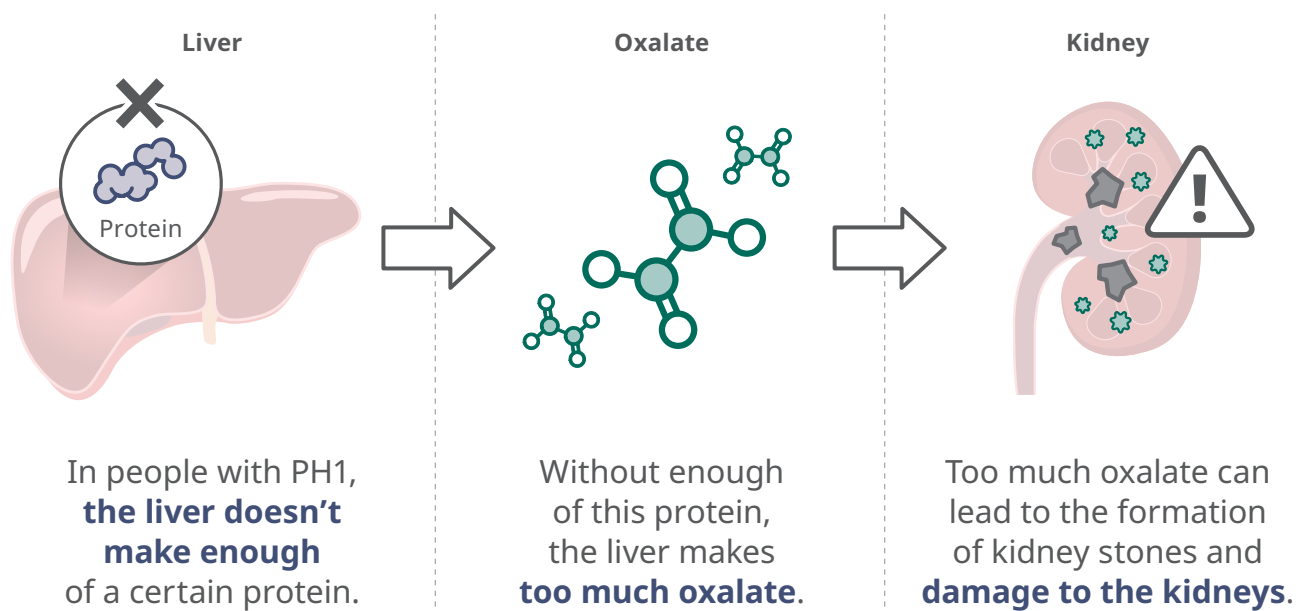
PH1 can cause **kidney damage** that may progress to end-stage kidney disease, requiring dialysis and possible **liver-kidney transplant**.



Over time, PH1 can lead to **systemic oxalosis**, a condition that affects organs throughout the body, including the eyes, heart, skin, and bones.

In PH1, overproduction of oxalate can lead to progressive kidney damage

When too much oxalate is made in the liver, the kidneys are not able to eliminate (remove) enough of it in urine. This causes oxalate to attach to calcium, forming crystals inside the kidneys. These crystals can group together to form kidney stones.



- **Even in the absence of symptoms**, oxalate can continue to build up and cause damage throughout the body in people with PH1
- It is important to **intervene as early as possible** in the disease process and get oxalate levels under control

Treatment challenges

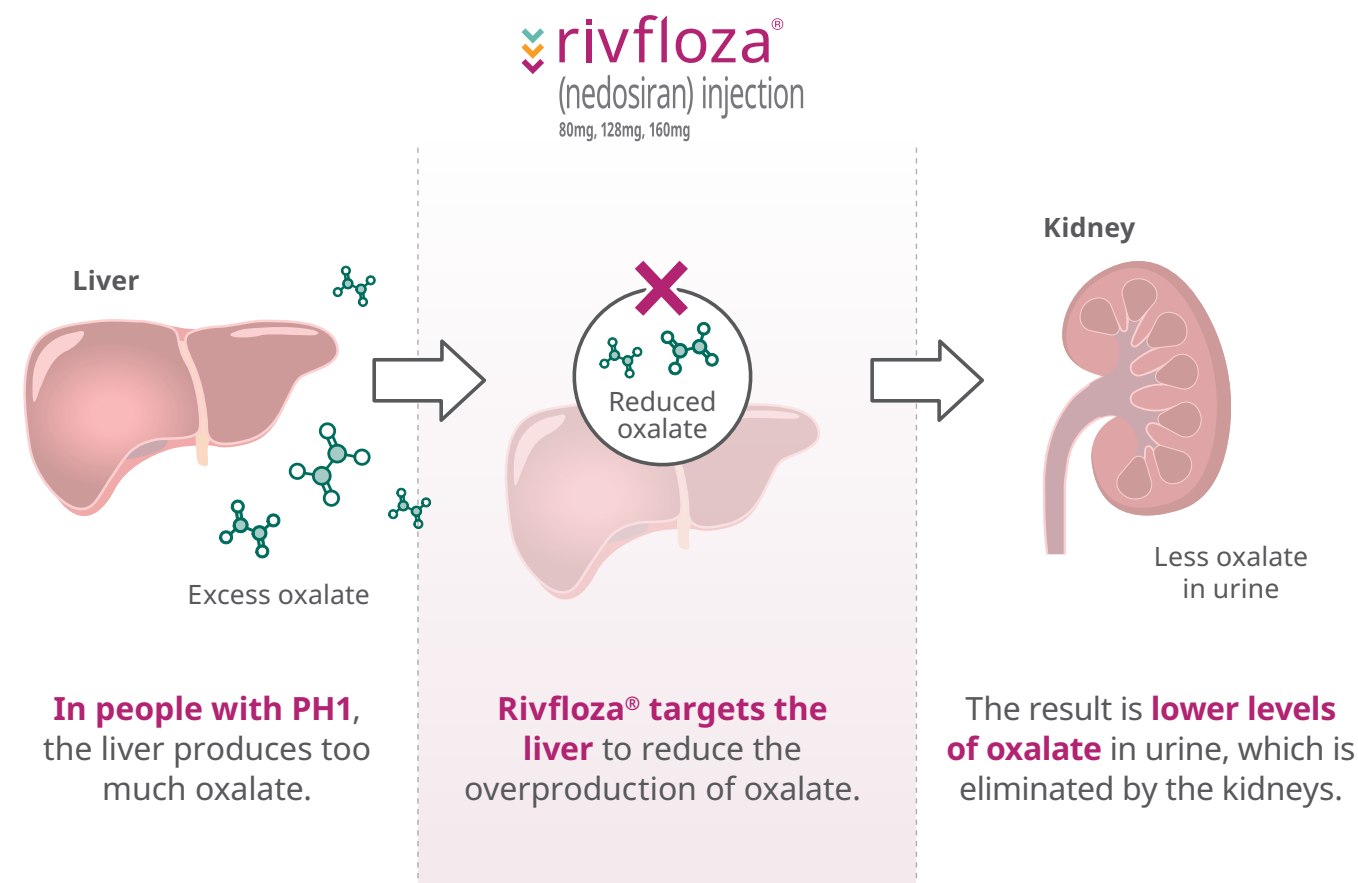


Most standard treatments for PH1 do not address the underlying cause of the disease.

- **Only a subset of people** with PH1 respond to vitamin B6 supplementation
- Hyperhydration (increased daily intake of water) can be **challenging to maintain**

For people 2 years and older with PH1 and relatively preserved kidney function

Rivfloza® helps prevent overproduction of oxalate in the liver



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The only self- or caregiver-administered treatment for patients with PH1





At-home administration


- For people 12 years and older, Rivfloza® (nedosiran) injection may be **self-administered**
- For children 2 to less than 12 years of age, Rivfloza® may be **administered by a caregiver** (after training and guidance from a healthcare provider for the single-dose vial)
- A healthcare provider will show you how to prepare and inject Rivfloza® subcutaneously (which means just under the skin)
- With the Rivfloza® prefilled syringe, the dose is premeasured



Once-a-month dosing

- Rivfloza® is administered once monthly at the recommended age- and weight-based dose as prescribed by your healthcare provider

Age 2 to less than 12 years	Body weight	Dose per month
 Prefilled syringe	110 lbs or more (50 kg or more)	160 mg
	86 to less than 110 lbs (39 to less than 50 kg)	128 mg
 Single-dose vial	Less than 86 lbs (Less than 39 kg)	3.3 mg/kg

Age 12 years and older	Body weight	Dose per month
 Prefilled syringe	110 lbs or more (50 kg or more)	160 mg
	Less than 110 lbs (Less than 50 kg)	128 mg

If you have any questions about taking Rivfloza®, please contact your healthcare provider.

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For people 2 years and older with PH1 and relatively preserved kidney function

Rivfloza[®]'s effectiveness and safety are based on two different trials of PH1 patients with relatively preserved kidney function

	PHYOX [™] 2 Study (Patients ages 6 and older)	PHYOX [™] 8 Study (Patients ages 2 to less than 12)
Design of the study	23 people with PH1 or PH2 treated with Rivfloza [®] ^a 12 people with PH1 or PH2 treated with Placebo (a substance with no active ingredient)	15 people with PH1 treated with Rivfloza [®] No people received Placebo in this study
Length of the study	6 months	
Key Measurements	<ul style="list-style-type: none"> • The percent change in the amount of oxalate in urine from the start of the study • The percentage of patients whose levels of oxalate in the urine were normal or almost normal (elevated slightly above the normal range)^b <p>The amount of oxalate in urine was measured every 30 days</p>	
Long-Term study	13 people with PH1 received an additional 6 months of treatment with Rivfloza [®] in a long-term study (PHYOX [™] 3)	8 people with PH1 received an additional 6 months of treatment with Rivfloza [®] in a long-term study (PHYOX [™] 3)

^aToo few people with PH2 were enrolled in the study to evaluate the effectiveness of Rivfloza[®] in PH2. Therefore, Rivfloza[®] is only approved for use in people with PH1.

^bIn PHYOX[™]2, people who received placebo in the study had higher initial urinary oxalate levels.

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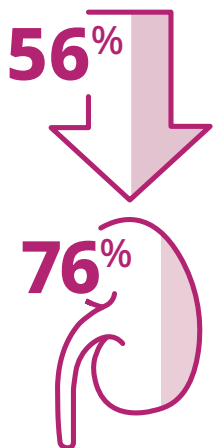
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For people 2 years and older with PH1 and relatively preserved kidney function

Rivfloza[®] (nedosiran) injection reduces oxalate levels in the urine and keeps them under control

In PHYOX[™]2:



People with PH1 treated with Rivfloza[®] achieved an **average difference of 56% in 24-hour urinary oxalate** compared to placebo, measured monthly from 3 months to 6 months.

3 out of 4 people with PH1 treated with Rivfloza[®] had reduced levels of oxalate in their urine, down to **normal or almost normal levels** after 6 months of study.

In PHYOX[™]8:



Children with PH1 treated with Rivfloza[®] achieved a **64% average reduction in spot urinary oxalate:creatinine ratio**, measured at 6 months.

93% of people with PH1 treated with Rivfloza[®] had an **almost-normal urinary oxalate:creatinine ratio** on at least one visit over 6 months.



Across both PHYOX[™]2 and PHYOX[™]8 studies:

All 21 people who received Rivfloza[®] for an additional 6 months **maintained the reduction in urinary oxalate** in the long-term study.

Talk to your healthcare provider about what to expect from treatment.

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For people 2 years and older with PH1 and relatively preserved kidney function

Rivfloza[®] is safe and well-tolerated

No serious treatment-related side effects

in people with PH1 who received Rivfloza[®] in the clinical studies



Actor portrayals.

Most common side effects (occurring in $\geq 20\%$ of patients treated with Rivfloza[®]) were injection site reactions (ISRs)

- In PHYOX[™]2 (patients ages 9-46), 39% of patients experienced ISRs
- In PHYOX[™]8 (patients ages 2-11), 13% of patients experienced ISRs
- These ISRs included reddening, pain, bruising, rash, or dimple at site of injection
- They were generally mild and **did not lead to stopping treatment**

Questions during treatment? Reach out to your healthcare provider.

LEARN MORE AT [Rivfloza.com](https://rivfloza.com)

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NovoCare[®] provides support every step of the way

Once a NovoCare[®] Patient Enrollment Form (PEF) is submitted by your healthcare provider's office, a Case Manager will assist with insurance access and coverage. Case Managers help to ensure proper paperwork and documentation are submitted and provide expert guidance on the range of services available, including:



Benefit verification

Allows a healthcare provider's representative to request benefit verification by completing the PEF.



Appeals assistance

Offers support and information about the appeals process if insurance coverage is denied.



Live support for patients

Ensures every patient is assigned a dedicated Patient Liaison for treatment support.



JumpStart[™]

Provides limited free product to eligible patients experiencing a gap or delay in getting insurance coverage.



Prior authorization (PA) assistance

Helps navigate and streamline the insurance process.



Co-pay assistance

Provides financial assistance to eligible patients.



Injection training

Gives professional live, in-person, or virtual injection training for Rivfloza[®].



Patient Assistance Program (PAP)

Supports eligible patients prescribed Novo Nordisk medications free of charge.

Eligibility requirements may vary.

NovoCare[®] can be reached at (844) 906-5099, Monday-Friday (8 AM-8 PM ET) or through [NovoCare.com](https://www.novocare.com).

Please click [here](#) for Prescribing Information.