

# PRODUCT PROFILE

## **TARPEYO** *Budesonide capsule, delayed release*

### **Manufacturer**

Calliditas Therapeutics AB

### **Indication**

- Tarpeyo is indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.<sup>1</sup>

### **Dosing and Administration**

- The recommended duration of therapy is 9 months, with a dosage of 16 mg administered orally once daily. When discontinuing therapy, reduce the dosage to 8 mg once daily for the last 2 weeks of therapy.<sup>1</sup>
- The delayed release capsules should be swallowed whole in the morning at least 1 hour before a meal. Do not open, crush, or chew.<sup>1</sup>
- If a dose is missed, take the prescribed dose at the next scheduled time. Do not double the next dose.<sup>1</sup>
- Safety and efficacy of treatment with subsequent courses of Tarpeyo have not been established.<sup>1</sup>

### **Storage and Handling**

- Tarpeyo is supplied in 120-count bottles of 4-mg delayed release capsules.<sup>1</sup>
- Store at 20-25 °C (68-77 °F); excursions permitted to 15 to 30 °C (59-86 °F).<sup>1</sup>

### **Safety/Warnings**

- Tarpeyo is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients of Tarpeyo. Serious hypersensitivity reactions including anaphylaxis have occurred with other budesonide formulations.<sup>1</sup>
- When corticosteroids are used chronically, systemic effects such as hypercorticism and adrenal suppression may occur.<sup>1</sup>
- Patients who are on drugs that suppress the immune system are more susceptible to infection than are healthy individuals.<sup>1</sup>
- Tarpeyo is a systemically available corticosteroid and is expected to cause related adverse events. Monitor patients with hypertension, prediabetes, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, or cataracts; with a family history of diabetes or glaucoma; or with any other condition in which corticosteroids may have unwanted effects.
- In clinical studies, the most common adverse events with Tarpeyo (in ≥ 5% of Tarpeyo-treated patients and ≥ 2% higher than noted with placebo) were peripheral edema (17%), hypertension (12%), muscle spasms (12%), acne (11%), headache (10%), upper respiratory tract infection (8%), face edema (8%), weight increased (7%), dyspepsia (7%), dermatitis (6%), arthralgia (6%), and white blood cell count increased (6%).

## Disease State Background

- IgAN, also known as Berger disease, is the most common primary glomerular disease globally; mostly, it impacts children and young adults.<sup>2,3</sup> It is a chronic, immune-mediated kidney disease characterized by IgA-antibody deposition in the glomeruli, which damages the kidneys' filtering ability over time.<sup>2</sup> The exact cause is unknown, but IgAN often follows a respiratory or gastrointestinal infection.<sup>2</sup> Consequences of the disease include reduced life expectancy and progression to end-stage kidney failure with estimates that up to half of patients have kidney failure within 10 to 15 years after diagnosis.<sup>3,4</sup>

## Place in Therapy

- As there is no cure, the Kidney Disease: Improving Global Outcomes guidelines recommend a focus on supportive care (eg, controlling blood pressure and proteinuria) to slow disease progression. More aggressive immunosuppression may be used; in some cases, glucocorticoids may be given.<sup>5</sup> Careful monitoring of kidney function is essential, and many patients eventually require renal replacement therapy in the form of dialysis or kidney transplantation.<sup>5</sup>

## Managed Care Considerations

- Patients with IgAN often have repetitive encounters with physicians due to frequent episodes of gross hematuria, which is often accompanied by upper respiratory tract infections.<sup>3</sup>
- Progression to advanced-stage chronic kidney disease (CKD) can lead to a need for renal dialysis and to comorbidities (eg, depression, insomnia, anorexia, and bone pain and fractures); all of these impact patient quality of life and increase the burden on the health care system.<sup>3</sup>

## Market Insights

- Tarpeyo is the first FDA-approved treatment for IgAN to reduce the loss of kidney function.<sup>7</sup>

## REFERENCES

1. Tarpeyo. Product information. Calliditas Therapeutics AB; 2023. Accessed March 11, 2024. <https://www.tarpeyo.com/prescribinginformation.pdf>
2. Wyatt RJ, Julian BA. IgA nephropathy. *N Engl J Med*. 2013;368(25):2402-2414. doi:10.1056/NEJMr1206793
3. Lai KN, Tang SCW, Schena FP, et al. IgA nephropathy. *Nat Rev Dis Primers*. 2016;2:16001. doi:10.1038/nrdp.2016.1
4. Pitcher D, Braddon F, Hendry B, et al. Long-term outcomes in IgA nephropathy. *Clin J Am Soc Nephrol*. 2023;18(6):727-738. doi:10.2215/CJN.000000000000135
5. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int*. 2021;100(4S):S1-S276. doi:10.1016/j.kint.2021.05.021
6. Lafayette R, Kristensen J, Stone A, et al; NefligArd trial investigators. Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IGA nephropathy (NefligArd): 2-year results from a randomised phase 3 trial. *Lancet*. 2023;402(10405):859-870. doi:10.1016/s0140-6736(23)01554-4
7. Calliditas Therapeutics announces full FDA approval of Tarpeyo, the only FDA-approved treatment for IgA nephropathy to significantly reduce the loss of kidney function. News release. Calliditas. December 20, 2023. Accessed March 13, 2024. <https://www.calliditas.se/en/calliditas-therapeutics-announces-full-fda-approval-of-tarpeyo-the-only-fda-approved-treatment-for-iga-nephropathy-to-significantly-reduce-the-loss-of-kidney-function/>