

JOIN US IN SAN DIEGO AT KIDNEY WEEK FOR A PANEL DISCUSSION ON

Early Intervention in IgA Nephropathy: AN UPDATE ON A POTENTIAL DISEASE-MODIFYING THERAPY

KIDNEY WEEK 2024 | EXHIBITOR SPOTLIGHT

Friday, October 25, 2024

1:00 PM-1:45 PM PT

San Diego Convention Center, San Diego, CA

Exhibit Hall A (Main Entrance at Hall B)

Theater #2

AGENDA

- **Targeting the gut:**
Addressing the origin of IgAN
- **Beyond proteinuria:**
The importance of early biopsy and intervention
- **Straight to the source:**
A potentially disease-modifying approach



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Supported by: Calliditas Therapeutics. The Exhibitor Spotlight is not a Continuing Education (CE) activity.

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THERAPEUTICS

 **TARPEYO**[®]
(budesonide) delayed release capsules - 4 mg

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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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.

WARNINGS AND PRECAUTIONS

Hypercorticism and adrenal axis suppression:

When corticosteroids are used chronically, systemic effects such as hypercorticism and adrenal suppression may occur. Corticosteroids can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to surgery or other stress situations, supplementation with a systemic corticosteroid is recommended. When discontinuing therapy or switching between corticosteroids, monitor for signs of adrenal axis suppression.

Patients with moderate to severe hepatic impairment (Child-Pugh Class B and C, respectively) could be at an increased risk of hypercorticism and adrenal axis suppression due to an increased systemic exposure to oral budesonide. Avoid use in patients with severe hepatic impairment (Child-Pugh Class C). Monitor for increased signs and/or symptoms of hypercorticism in patients with moderate hepatic impairment (Child-Pugh Class B).

Immunosuppression and Increased Risk of Infection: Corticosteroids, including TARPEYO, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens. Corticosteroids can: reduce resistance to new infections, exacerbate existing infections, increase the risk of disseminated infections, increase the risk of reactivation or exacerbation of latent infections, and mask some signs of infection. Corticosteroid-associated infections can sometimes be serious. Monitor for infection and consider TARPEYO withdrawal as needed.

Avoid corticosteroid therapy, including TARPEYO, in patients with active or quiescent tuberculosis or hepatitis B infection; untreated fungal, bacterial, systemic viral, or parasitic infections; ocular herpes simplex; or Kaposi's sarcoma. Avoid exposure to active, easily-transmitted infections (e.g., chickenpox, measles). Corticosteroid therapy may decrease the immune response to some vaccines.

Other corticosteroid effects: TARPEYO is a systemically available corticosteroid and is expected to cause related adverse reactions. Monitor patients with hypertension, prediabetes, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts, or with a family history of diabetes or glaucoma, or with any other condition where corticosteroids may have unwanted effects.

ADVERSE REACTIONS

In clinical studies, the most common adverse reactions with TARPEYO (occurring in $\geq 5\%$ of TARPEYO treated patients, and $\geq 2\%$ higher than 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%).

DRUG INTERACTIONS

Budesonide is a substrate for CYP3A4. Avoid use with potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine. Avoid ingestion of grapefruit juice with TARPEYO. Intake of grapefruit juice, which inhibits CYP3A4 activity, can increase the systemic exposure to budesonide.

USE IN SPECIFIC POPULATIONS

Pregnancy: The available data from published case series, epidemiological studies, and reviews with oral budesonide use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with IgAN. Infants exposed to in-utero corticosteroids, including budesonide, are at risk for hypoadrenalism.

Please see Full Prescribing Information.