

Patient Information
TARPEYO (tar-PAY-oh)
(budesonide)
delayed release capsules

What is TARPEYO?

TARPEYO is a prescription medicine used to reduce the loss of kidney function in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at risk for their disease getting worse.

It is not known if TARPEYO is safe and effective in children.

Do not take TARPEYO if you are allergic to budesonide or any of the ingredients in TARPEYO. See the end of this leaflet for a complete list of ingredients in TARPEYO.

Before taking TARPEYO, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems.
- plan to have surgery.
- have chickenpox or measles or have recently been near anyone with chickenpox or measles.
- have an infection.
- have high blood sugar levels (prediabetes or diabetes).
- have glaucoma or cataracts.
- have a family history of diabetes or glaucoma.
- have or have had tuberculosis.
- have high blood pressure (hypertension).
- have decreased bone mineral density (osteoporosis).
- have stomach ulcers.
- are pregnant or plan to become pregnant. TARPEYO may harm your unborn baby. Talk to your healthcare provider about the possible risk to your unborn baby if you take TARPEYO when you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if TARPEYO passes into your breast milk or if it will affect your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with TARPEYO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TARPEYO and other medicines may affect each other causing side effects.

How should I take TARPEYO?

- Take TARPEYO exactly as your healthcare provider tells you.
- Your healthcare provider will decide how long you should take TARPEYO. Do not stop taking TARPEYO without first talking with your healthcare provider.
- Take your prescribed dose of TARPEYO 1 time each day in the morning, at least 1 hour before a meal.
- Swallow TARPEYO capsules whole. **Do not** open, chew, crush, or break TARPEYO capsules before swallowing.
- If you miss a dose of TARPEYO, take your prescribed dose at your next scheduled time. **Do not** take two doses of TARPEYO at the same time.
- If you take too much TARPEYO, call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking TARPEYO?

Do not eat grapefruit or drink grapefruit juice during your treatment with TARPEYO. Eating grapefruit or drinking grapefruit juice can increase the level of TARPEYO in your blood.

What are the possible side effects of TARPEYO?

TARPEYO may cause serious side effects, including:

- **Effects of having too much corticosteroid medicine in your blood (hypercorticism).** Long-time use of TARPEYO can cause you to have signs and symptoms of too much cortisol, a stress hormone in your blood. Tell your healthcare provider if you have any of the following signs and symptoms of hypercorticism:
 - acne
 - thicker or more hair on your body and face
 - bruise easily
 - a fatty pad or hump between your shoulders (buffalo hump)
 - rounding of your face (moon face)
 - pink or purple stretch marks on the skin of your abdomen, thighs, breasts, or arms
 - ankle swelling
- **Adrenal suppression.** When TARPEYO is taken for a long period of time (chronic use), adrenal suppression can happen. This is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal suppression include:
 - tiredness
 - nausea and vomiting

- weakness
- low blood pressure

Tell your healthcare provider if you are under stress or have any symptoms of adrenal suppression during treatment with TARPEYO.

- **Risk of immunosuppression.** TARPEYO weakens your immune system. Taking medicines that weaken your immune system makes you more likely to get infections. Avoid contact with people who have contagious diseases, such as chickenpox or measles, during treatment with TARPEYO. Tell your healthcare provider right away if you come in contact with anyone who has chickenpox or measles. Consult with your healthcare provider regarding appropriate vaccination scheduling.
- Tell your healthcare provider if you develop any symptoms of infection during treatment with TARPEYO, including:
 - fever
 - feeling tired
 - chills
 - aches
 - pain
 - nausea and vomiting

The most common side effects of TARPEYO include:

- swelling of the lower legs, ankles, and feet
- high blood pressure
- muscle spasms
- acne
- headache
- upper respiratory tract infection
- swelling of the face
- weight increase
- indigestion
- irritation or inflammation of the skin
- joint pain
- increased white blood cell count

These are not all the possible side effects of TARPEYO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TARPEYO?

- Store TARPEYO at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep TARPEYO in a tightly closed container.
- Protect from moisture.

Keep TARPEYO and all medicines out of the reach of children.

General information about the safe and effective use of TARPEYO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TARPEYO for a condition for which it was not prescribed. Do not give TARPEYO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TARPEYO that is written for health professionals.

What are the ingredients in TARPEYO?

Active ingredient: budesonide

Inactive ingredients: sugar spheres (sucrose and starch), hypromellose, polyethylene glycol, citric acid monohydrate, ethyl cellulose, medium chain triglycerides and oleic acid.

The capsules contain: hypromellose and titanium oxide (E171).

The printing ink on the capsules contain: shellac, propylene glycol and black iron oxide (E172).

The enteric coating on the capsules contain: methacrylic acid and methacrylate copolymer, talc and dibutyl sebacate.

Manufactured for and distributed by: Calliditas Therapeutics AB, Stockholm, Sweden

TARPEYO is a registered trademark of Calliditas Therapeutics AB, or its affiliates.

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Patent: <http://www.calliditas.com/patents>

For more information, go to www.TARPEYOTouchpoints.com or call 1-933-444-8277.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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