TARPEYO®
(budesonide) delayed release capsules • 4 mg

Touchpoints®
Support beyond the script

注册表

- 填写此 TARPEYO Touchpoints 注册表，可作为处方使用
- 包含以下事先授权 (PA) 支持文件
- 收到注册表后，Care Navigator 将联系您讨论下一步

covermymeds®
此注册表也可通过
CoverMyMeds
在线获取

支持文件 随注册表一并提交

- ☐ 处方福利保险信息（卡的正面/背面）
- ☐ 肾脏活检文件
- ☐ 最近的实验室结果：UPCR 和 eGFR
- ☐ 包括当前和过去用药列表的临床记录
  - ACE 抑制剂或 ARB，或患者未服用 ACEi/ARB 的原因
  - 显示之前类固醇治疗或患者不适合类固醇的原因的文件（如适用）

将填写好的表格

和支持文件传真至
1-844-854-3251

TARPEYO Touchpoints 在每一步都为您提供帮助每一步都在您身边

电话：1-833-444-8277
服务时间为早上 8点至晚上 8点，美东时间，周一至周五

calliditas THERAPEUTICS

TARPEYO Touchpoints® 注册表

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1-833-444-8277 • 传真：1-844-854-3251 • 早上 8 点到晚上 8 点，美东时间，周一至周五

1 患者信息

* 未填写此项无法启动注册。

* 患者名字	* 患者姓氏	* 出生日期（年月日） / /
* 街道地址	公寓号	* 性别 ☐ 男 ☐ 女
* 城市 / * 州 / * 邮政编码	* 美国居民 ☐ 是 ☐ 否	首选语言 ☐ 英语 ☐ 其他：
* 首选电话号码	备用电话号码	电子邮件
* 备用联系人或授权照顾者姓名（如适用）		* 与患者的关系（如适用）
* 备用 联系人电话（如适用）		

患者授权：

患者签名 _____ * 日期（年月日） / /

☐ * 我已阅读并同意第 3 页上的患者授权书以分享健康信息。

☐ * 我已阅读并同意第 3 页上的患者援助计划的财务资格。

☐ 我同意使用此表格上提供的我的信息来接收与我的药物或 IgA 肾病相关的其他资源（可选）。请参阅第 3 页的选择加入条款。

2 患者保险

***您有保险吗？** ☐ 是 ☐ 否 **如果是：** ☐ **我已附上我的医疗和处方福利保险卡的正反面复印件。**

保险	电话号码	保单编号	团体编号	BIN	PCN	保单持有人姓名 / 出生日期
处方福利 保险名称						姓名 出生日期

3 临床信息

* 选择适当的诊断代码：

☐ N02.B1 反复和持续的 IgAN 伴有肾小球病变
☐ N02.B2 反复和持续的 IgAN 伴有局灶和节段性肾小球病变
☐ N02.B3 反复和持续的 IgAN 伴有弥漫性膜增生性肾小球肾炎
☐ N02.B4 反复和持续的 IgAN 伴有弥漫性膜性肾小球肾炎
☐ N02.B5 反复和持续的 IgAN 伴有弥漫性系膜增生性肾小球肾炎
☐ N02.B6 反复和持续的 IgAN 伴有弥漫性系膜毛细血管性肾小球肾炎
☐ N02.B9 其他反复和持续的 IgAN
☐ 其他：

患者是否进行过肾活检？ ☐ 是 ☐ 否	* 肾活检日期	*UPCR (g/g)： 蛋白尿 (g/ 天)：
*eGFR (mL/ 分)：	* 患者目前是否正在服用 ACEi/ARB？ ☐ 是 ☐ 否	* 患者目前是否正在服用类固醇或是否有过往服用史？ ☐ 是 ☐ 否

☐ 我已随注册表附上所有支持文件，包括肾活检文件、最近的实验室结果（UPCR/ 蛋白尿和 eGFR），以及包括当前和过去用药列表（包括 ACEi/ARB 和以往类固醇使用日期）的临床记录。

4 处方者信息

* 处方者名字	* 处方者姓氏		*MD NPI 编号
* 执业名称			
* 街道地址		房号	州执照编号
* 城市	* 州	* 邮政编码	
* 办公室电话 / * 办公室传真		电子邮件	
* 办公室联系人姓名		办公室联系人职务	
* 办公室联系人电话		办公室联系人电子邮件	

5 * 处方信息

TARPEYO 仅通过 PANTHERx Rare Pharmacy 分销。请在开具电子处方时选择 PANTHERx Specialty Pharmacy。

☐ TARPEYO®（布地奈德）缓释胶囊，4 mg—每天口服 4 粒，持续 30 天 #120 8 次续药			
☐ TARPEYO®（布地奈德）缓释胶囊，4 mg	用法	数量	授权续药次数
☐ **逐渐减量处方：**TARPEYO®（布地奈德）缓释胶囊，4 mg—每天口服 2 粒，持续 14 天 #28 0 次续药			

6 桥接处方信息

填写此可选的额外处方，以便为因保险承保延迟而符合条件的患者免费提供 TARPEYO。

☐ TARPEYO®（布地奈德）缓释胶囊，4 mg—每天口服 4 粒，持续 15 天 #60 3 次续药

处方者授权

我确认上述疗法在医学上是必要的，并且据我所知信息准确无误。我确认我是为上文所述患者开具 TARPEYO 的医生，并已向患者提供了 TARPEYO Touchpoints 计划的描述。为便于传递这些处方，我授权 TARPEYO Touchpoints 及其代表作为我的代理，通过电子方式、传真或邮寄方式将这些处方转发给 PANTHERx（一家专科药房）。

* 处方者签名（无印章） _____ * 日期（年月日） / /

请参阅第 4 页上的重要安全性信息以及随附的完整处方信息。

请仔细阅读以下几页，然后在本页第 1 节中指示的位置签名和填写日期。

患者授权以分享健康信息：

通过签署此授权书以分享健康信息（“授权”），我授权我的医务人员（包括我的药房和医生）、我的健康保险公司及其承包商（统称为“各方”）向 Calliditas Therapeutics US Inc. 及其母公司和附属公司（统称为“Calliditas”）及其及其第三方业务合作伙伴、供应商和其他代理（“代理”）披露关于我的疾病和健康状况、我的医疗治疗、我的药物、我的医疗测试结果和我的健康保险承保情况的信息（“我的信息”），用于本表格中描述的目的。

- *许可用途：*通过在第 2 页签名，我授权各方和 Calliditas（包括其代理）使用和披露我的信息，以提供某些支持服务，包括但不限于：**(1)** 确定我是否有资格参加 TARPEYO Touchpoints® 患者支持计划（“计划”）；**(2)** 管理和改进计划；**(3)** 与我沟通我对计划的体验；**(4)** 向我发送与计划相关的材料；**(5)** 调查我的健康保险覆盖情况；**(6)** 为 TARPEYO® 寻求健康保险覆盖，包括协助获取 TARPEYO 的事先授权；**(7)** 操作和管理计划，以方便报销和处方履行；以及 **(8)** 就我可能报告的任何有关 Calliditas 产品的不良事件进行后续联系。
- *去识别化：*我进一步授权 Calliditas 对我的健康信息进行去识别化，并在本授权到期或撤销之前和之后，将其用于进行研究、教育、商业分析和市场研究，或用于其他商业目的，包括与 Calliditas 可能从其他来源接收到的去识别化信息的链接。
- **信息再披露：**我理解一旦我的信息被披露给 Calliditas，联邦隐私法可能不再保护这些信息免于进一步披露，但 Calliditas 打算仅根据本授权或法律允许的其他方式使用和披露我的信息。
- *向药房支付费用：*我明白，Calliditas 可能会向我的药房付款，以获得我的信息。
- *拒绝权：*我理解，我可以拒绝签署此授权，并且拒签不会影响我获得医疗护理、健康保险承保或福利资格的能力。然而，如果我不签署此授权，Calliditas 无法为我提供支持服务。
- *到期：*我明白，除非适用法律要求更早的到期，或者除非我在那时之前撤销（取回）此授权，否则此授权将在我最后一次 TARPEYO 发货日期后的三 (3) 年到期。
- *撤销：*我理解，我可以随时通过发送书面通知撤销此授权，通知应包括我的姓名、地址和电话号码，发送至 Calliditas，收件人：TARPEYO Touchpoints, 24 Summit Park Dr, Pittsburgh, PA 15275。撤销此授权将终止对本授权的进一步依赖（以及我参与计划的资格），但不会使在接收到和处理撤销通知之前对授权使用或披露我的信息的依赖无效。

通过在第 2 页上签字，我确认我已阅读并理解授权以发布个人健康信息的条款，并同意其条款。我理解，我有权在请求时获得此授权的副本。

选择加入其他资源的条款

通过在第 2 页上勾选框，我授权 Calliditas Therapeutics 通过邮件、电子邮件和 / 或电话联系我，讨论其他可能对我感兴趣的主题，包括疾病状态和产品、促销、服务和研究研究。我理解，我不需要提供此同意作为获得任何 Calliditas 药物或患者支持服务的条件。

患者援助计划的财务资格

我理解，我可以选择同意 Calliditas 执行我的财务信息的电子验证，以验证我的资格并处理我的 TARPEYO Touchpoints 患者援助计划（“PAP”）的申请。通过签署患者授权，我理解我在根据《公平信用报告法》（“FCRA”）提供“书面指示”，授权 Calliditas 从我的信用档案中获取信息，仅用于确定 PAP 的财务资格。
我理解此授权允许 Calliditas 在我参与 PAP 的期间根据需要执行此过程。

我确认我提供的财务和健康计划信息是完整和准确的，尽我所知。
我理解，TARPEYO Touchpoints PAP 包括资格标准，包括财务需求的证明，Calliditas 将评估我是否符合这些标准。
如果我通过 PAP 获得免费产品，我不会提交或导致任何第三方支付者，包括联邦医疗计划如 Medicare 或 Medicaid，或任何私人或其他保险计划，或任何其他人或实体的支付或报销申请此类免费产品。通过 PAP 提供的任何产品的费用将不计入任何 Medicare 真实自付费用。我同意，如果：(1) 我通过其他来源（联邦、州或私人健康计划）获得 PAP 提供的产品承保，或 (2) 我不再符合 PAP 的收入标准，我将立即通知 Calliditas。如果我的健康计划要求，我将通知健康计划我通过 PAP 获得的任何免费产品。我同意通知我的 Medicare 计划，我将在日历年结束前通过 PAP 免费获得我的药物。我理解我必须每年重新申请 PAP。我还理解，Calliditas 有权在任何时候，无需通知修改或停止 PAP 下可能提供的免费产品。

适应症

TARPEYO 适用于降低具有疾病进展高风险的成人原发性免疫球蛋白 A 肾病 (IgAN) 患者的肾功能丧失。

重要安全性信息

禁忌症

TARPEYO 禁用于对布地奈德或 TARPEYO 的任何成分过敏的患者。其他布地奈德制剂也发生过严重过敏反应，包括过敏性休克。

警告和注意事项

高皮质醇症和肾上腺轴抑制：当长期使用皮质类固醇时，可能会出现全身性副作用，例如高皮质醇症和肾上腺抑制。皮质类固醇可减少下丘脑-垂体-肾上腺 (HPA) 轴对压力的反应。在患者进行手术或其他应激情况下，建议补充全身性皮质类固醇。在停止治疗或在不同皮质类固醇之间转换时，需监测肾上腺轴抑制的迹象。

中度至重度肝功能不全的患者（分别为 Child-Pugh B 级和 C 级）可能由于口服布地奈德的全身暴露增加而面临高皮质醇症和肾上腺轴抑制的风险。避免在重度肝功能不全患者（Child-Pugh C 级）中使用。监测中度肝功能不全患者（Child-Pugh B 级）中的高皮质醇症的增加迹象和/或症状。

免疫抑制和感染风险增加：皮质类固醇，包括 TARPEYO，会抑制免疫系统并增加感染任何病原体的风险，包括病毒、细菌、真菌、原生动物或寄生虫病原体。皮质类固醇可以：降低对新感染的抵抗力，加剧现有感染，增加播散性感染的风险，增加潜伏感染再激活或加剧的风险，并掩盖某些感染迹象。皮质类固醇相关感染有时会很严重。监测感染情况并根据需要考虑停用 TARPEYO。

避免在患有活动性或静止性结核病或乙型肝炎感染的患者；未经治疗的真菌、细菌、系统性病毒或寄生虫感染的患者；有眼部单纯疱疹的患者；或卡波西肉瘤的患者中使用皮质类固醇治疗，包括 TARPEYO。避免接触活动性、容易传播的感染（如水痘、麻疹）。皮质类固醇治疗可能会减少对某些疫苗的免疫反应。

其他皮质类固醇的影响：TARPEYO 是一种系统性可用的皮质类固醇，预计会引起相关的不良反应。监测患有高血压、糖尿病前期、糖尿病、骨质疏松症、消化性溃疡、青光眼或白内障的患者，或有糖尿病或青光眼家族史，或有任何其他情况下使用皮质类固醇可能产生不良影响的患者。

不良反应

在临床研究中，TARPEYO 最常见的不良反应（发生率 ⩾5% 的 TARPEYO 治疗患者，且较安慰剂高 ⩾2%）为外周水肿 (17%)、高血压 (12%)、肌肉痉挛 (12%)、痤疮 (11%)、头痛 (10%)、上呼吸道感染 (8%)、面部水肿 (8%)、体重增加 (7%)、消化不良 (7%)、皮炎 (6%)、关节痛 (6%) 和白细胞计数增加 (6%)。

药物相互作用

布地奈德是 CYP3A4 的底物。避免与强效 CYP3A4 抑制剂如酮康唑、伊曲康唑、利托那韦、茚地那韦、沙奎那韦、红霉素和环孢素一起使用。避免在使用 TARPEYO 时摄入葡萄柚汁。摄入葡萄柚汁会抑制 CYP3A4 活性，可能会增加布地奈德的全身暴露。

特殊人群中的使用

妊娠：现有的发表案例系列、流行病学研究和口服布地奈德在孕妇中使用的审查中，未发现与药物相关的主要出生缺陷、流产或其他不良母婴结局的风险。IgAN 相关的母婴风险仍存在。暴露于子宫内皮质类固醇（包括布地奈德）的婴儿面临肾上腺功能不全的风险。

请参阅随附的完整处方信息。

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TARPEYO safely and effectively. See full prescribing information for TARPEYO.

TARPEYO (budesonide) delayed release capsules, for oral use
Initial U.S. Approval: 1997

----------RECENT MAJOR CHANGES----------

Warning and Precautions (5.2) 06/2024

----------INDICATIONS AND USAGE----------

TARPEYO is a corticosteroid indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. (1)

----------DOSAGE AND ADMINISTRATION----------

- The recommended dosage is 16 mg administered orally once daily, in the morning at least 1 hour before a meal. (2)
- Swallow whole. Do not open, crush or chew. (2)
- The recommended duration of therapy is 9 months. When discontinuing, reduce dosage to 8 mg once daily for the last two weeks. (2, 5.1)

----------DOSAGE FORMS AND STRENGTHS----------

Delayed release capsules: 4 mg (3)

----------CONTRAINDICATIONS----------

- Hypersensitivity to budesonide or any of the ingredients in TARPEYO. (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypercorticism and Adrenal Axis Suppression: Follow general warnings concerning corticosteroids, patients with hepatic impairment may be at increased risk. Taper upon discontinuation. (2, 5.1, 8.6, 12.3)
- Immunosuppression and Increased Risk of Infection: Avoid use in patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex. May affect vaccine efficacy. (5.2)
- Other Corticosteroid Effects: Monitor patients with concomitant conditions where corticosteroids may have unwanted effects (e.g., hypertension, diabetes mellitus). (5.3)

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥5%) are peripheral edema, hypertension, muscle spasms, acne, headache, upper respiratory tract infection, face edema, weight increased, dyspepsia, dermatitis, arthralgia, white blood cell count increased. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Calliditas Therapeutics at 1-844-IGA-0011 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

Potent CYP3A4 Inhibitors (e.g. ketoconazole, grapefruit juice): Can increase systemic budesonide concentrations: avoid concomitant use. (7.1)

----------USE IN SPECIFIC POPULATIONS----------

Lactation: Routine monitoring of linear growth in infants is recommended with chronic use of budesonide in the nursing mother. (8.2).

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 06/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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.

2 DOSAGE AND ADMINISTRATION

The recommended treatment duration of therapy is 9 months, with a dosage of 16 mg administered orally once daily *[see Clinical Studies (14.1)]*. When discontinuing therapy, reduce the dosage to 8 mg once daily for the last 2 weeks of therapy *[see Warnings and Precautions (5.1)]*.

The delayed release capsules should be swallowed whole in the morning, at least 1 hour before a meal. Do not open, crush or chew.

If a dose is missed, take the prescribed dose at the next scheduled time. Do not double the next dose.

Safety and efficacy of treatment with subsequent courses of TARPEYO have not been established.

3 DOSAGE FORMS AND STRENGTHS

Delayed release capsule containing 4 mg budesonide. White coated opaque capsules printed with “CAL10 4MG” in black ink.

4 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.

5 WARNINGS AND PRECAUTIONS

5.1 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 *[see Dosing and Administration (2)]* 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 of 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) *[see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)]*.

5.2 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
- Mask some signs of infection

Corticosteroid-associated infections can be mild but can be severe and at times fatal. The rate of infectious complications increases with increasing corticosteroid dosages.

Monitor for the development of infection and consider TARPEYO withdrawal as needed.

Tuberculosis

If TARPEYO is used to treat a condition in patients with latent tuberculosis or tuberculin reactivity, reactivation of tuberculosis may occur. In patients with latent tuberculosis or tuberculin reactivity TARPEYO should be discontinued.

Varicella Zoster and Measles Viral Infections

Varicella and measles can have a serious or even fatal course in non-immune patients taking corticosteroids, including TARPEYO. In corticosteroid-treated patients who have not had these diseases or are non-immune, particular care should be taken to avoid exposure to varicella and measles:

- If a TARPEYO-treated patient is exposed to varicella, prophylaxis with varicella zoster immune globulin may be indicated. If varicella develops, treatment with antiviral agents may be considered.
- If a TARPEYO-treated patient is exposed to measles, prophylaxis with immunoglobulin may be indicated.

Hepatitis B Virus Reactivation

Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including TARPEYO. Reactivation can also occur infrequently in corticosteroid-treated patients who appear to have resolved hepatitis B infection.

Screen patients for hepatitis B infection before initiating immunosuppressive treatment with TARPEYO. For patients who show evidence of hepatitis B infection, recommend consultation with physicians with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.

Fungal Infections

Corticosteroids, including TARPEYO, may exacerbate systemic fungal infections; therefore, avoid TARPEYO use in the presence of such infections.

Amebiasis

Corticosteroids, including TARPEYO, may activate latent amebiasis. Therefore, it is recommended that latent amebiasis or active amebiasis be ruled out before initiating TARPEYO in patients who have spent time in the tropics or patients with unexplained diarrhea.

Strongyloides Infestation

Corticosteroids, including TARPEYO, should be discontinued in patients with known or suspected Strongyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

Cerebral Malaria

Avoid corticosteroids, including TARPEYO, in patients with cerebral malaria.

Ocular Herpes Simplex Virus Infection

Corticosteroids, including TARPEYO, may exacerbate ocular herpes simplex virus infections; therefore, avoid TARPEYO use in the presence of such infections.

Kaposi's Sarcoma

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma.

Immunizations

Corticosteroid therapy, including TARPEYO, may decrease the immune response to some vaccines.

5.3 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.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypercorticism and adrenal axis suppression *[see Warnings and Precautions (5.1)]*
- Risks of immunosuppression *[see Warnings and Precautions (5.2)]*
- Other corticosteroid effects *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of TARPEYO was evaluated in 389 patients in the randomized, double-blind, placebo-controlled study, NeflgArd (NCT: 03643965, Phase 3 clinical study in adults with primary IgAN). The data below reflect TARPEYO exposure in 195 patients with a median duration of 41 weeks, compared with comparable exposure to placebo in 194 patients.

The most common adverse reactions, reported in greater than or equal to 5% of TARPEYO-treated patients and greater than or equal to 2% higher than placebo, in the 9-month treatment period are listed in *Table 1*.

Most adverse reactions that occurred at a greater incidence for TARPEYO compared to placebo were consistent with hypercortisolism and reversible, resolving within 3 months after discontinuation.

Table 1: Reported adverse reactions occurring in greater than or equal to 5% of TARPEYO treated patients, and greater than or equal to 2% higher than Placebo

Adverse Reaction	TARPEYO 16 mg (N=195)	Placebo (N=194)
	n (%)	n (%)
Peripheral edema	33 (17)	10 (5)
Hypertension	23 (12)	6 (3)
Muscle spasms	23 (12)	8 (4)
Acne	22 (11)	2 (1)
Headache	19 (10)	14 (7)
Upper respiratory tract infection	16 (8)	12 (6)
Face edema	15 (8)	1 (0.5)
Weight increased	13 (7)	6 (3)
Dyspepsia	13 (7)	4 (2)
Dermatitis	12 (6)	2 (1)
Arthralgia	12 (6)	4 (2)
White blood cell count increased	11 (6)	1 (0.5)

7 DRUG INTERACTIONS

7.1 Interaction with CYP3A4 Inhibitors

Budesonide is a substrate for CYP3A4. Avoid use with potent CYP3A4 inhibitors; e.g. ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine *[see Clinical Pharmacology (12.3)]*.

Avoid ingestion of grapefruit juice with TARPEYO. Intake of grapefruit juice, which inhibits CYP3A4 activity, can increase the systemic exposure to budesonide *[see Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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 IgA Nephropathy. Infants exposed to in utero corticosteroids, including budesonide, are at risk for hypoadrenalism *(see Clinical Considerations)*. In animal reproduction studies with pregnant rats and rabbits, administration of subcutaneous budesonide during organogenesis at doses approximately 0.3 times or 0.03 times, respectively, the maximum recommended human dose (MRHD), resulted in increased fetal loss, decreased pup weights, and skeletal abnormalities. Maternal toxicity was observed in both rats and rabbits at these dose levels *(see Data)*.

The estimated background risk of major birth defects and miscarriage of the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

IgA nephropathy in pregnancy is associated with adverse maternal outcomes, including increased rates of cesarean section, pregnancy-induced hypertension, pre-eclampsia and preterm delivery, and adverse fetal/neonatal outcomes, including stillbirth and low birth weight.

Fetal/Neonatal Adverse Reactions

Hypoadrenalism may occur in infants born to mothers receiving corticosteroids during pregnancy. Infants should be carefully observed for signs of hypoadrenalism, such as poor feeding, irritability, weakness, and vomiting, and managed accordingly *[see Warnings and Precautions (5.1)]*.

Data

Animal Data

Budesonide was teratogenic and embryo-lethal in rabbits and rats.

In an embryo-fetal development study in pregnant rats dosed subcutaneously with budesonide during the period of organogenesis on gestation days 6 to 15 there were effects on fetal development and survival at subcutaneous doses up to approximately 500 mcg/kg in rats (approximately 0.3 times the maximum recommended human dose (MRHD) on a body surface area basis).

In an embryo-fetal development study in pregnant rabbits dosed during the period of organogenesis on gestation days 6 to 18, there was an increase in maternal abortion, and effects on fetal development and reduction in litter weights at subcutaneous doses from approximately 25 mcg/kg (approximately 0.03 times the MRHD on a body surface area basis).

Maternal toxicity, including reduction in body weight gain, was observed at subcutaneous doses of 5 mcg/kg in rabbits (approximately 0.006 times the maximum recommended human dose on a body surface area basis) and 500 mcg/kg in rats (approximately 0.3 times the maximum recommended human dose on a body surface area basis).

In a peri- and post-natal development study, subcutaneous treatment of pregnant rats with budesonide during the period from Day 15 post coitum to Day 21 post partum, budesonide had no effects on delivery, but did have an effect on growth and development of offspring. In addition, offspring survival was reduced and surviving offspring had decreased mean body weights at birth and during lactation at exposures ≥ 0.012 times the MRHD (on a mg/m^2 basis at maternal subcutaneous doses of 20 mcg/kg/day and higher). These findings occurred in the presence of maternal toxicity.

8.2 Lactation

Risk Summary

Breastfeeding is not expected to result in significant exposure of the infant to TARPEYO. Lactation studies have not been conducted with oral budesonide, including TARPEYO, and no information

is available on the effects of the drug on the breastfed infant or the effects of the drug on milk production. One published study reports that budesonide is present in human milk following maternal inhalation of budesonide *(see Data)*. Routine monitoring of linear growth in infants is recommended with chronic use of budesonide in the nursing mother. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TARPEYO and any potential adverse effects on the breastfed infant from TARPEYO, or from the underlying maternal condition.

Data

One published study reports that budesonide is present in human milk following maternal inhalation of budesonide, which resulted in infant doses approximately 0.3% to 1% of the maternal weight-adjusted dosage and a milk to plasma ratio was approximately 0.5. Budesonide was not detected in plasma, and no adverse events were noted in the breastfed infants following maternal use of inhaled budesonide.

Assuming a daily average milk intake of about 150 mL/kg/day and a milk to plasma ratio of 0.5, the estimated oral dose of budesonide for a 5 kg infant is expected to be less than 2 mcg/day for a maternal dose of 16 mg TARPEYO. Assuming 100% bio-availability in the infant this is about 0.1% of the maternal dose and about 3% of the highest inhaled dose used clinically for asthma in infants.

8.4 Pediatric Use

The safety and efficacy of TARPEYO in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of TARPEYO did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

8.6 Hepatic Impairment

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 budesonide *[see Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)]*. Avoid use in patients with severe hepatic impairments (Child-Pugh Class C). Monitor for increased signs and/or symptoms of hypercorticism in patients with moderate hepatic impairment (Child-Pugh Class B).

10 OVERDOSAGE

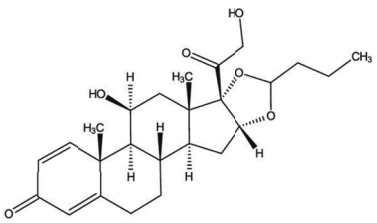
Reports of acute toxicity and/or death following overdosage of corticoids are rare.

In the event of acute overdosage, no specific antidote is available. Treatment consists of supportive and symptomatic therapy.

11 DESCRIPTION

TARPEYO (budesonide) delayed release capsules, for oral administration, contain budesonide, a synthetic corticosteroid, as the active ingredient. Budesonide is designated chemically as 16α, 17α-[(1RS)-Butylidenebis(oxy)]-11β, 21-dihydroxypregna-1,4-diene-3,20-dione.

Budesonide is provided as a mixture of two epimers (22R and 22S). The empirical formula of budesonide is $C_{25}H_{34}O_6$ and its molecular weight is 430.5. Its structural formula is:



Budesonide is a white to off-white, tasteless, odorless powder that is practically insoluble in water, sparingly soluble in alcohol, and freely soluble in chloroform.

The beads in each capsule contain the following inactive ingredients: sugar spheres (sucrose and starch), hypromellose, polyethylene glycol, citric acid monohydrate, ethyl cellulose, medium chain triglycerides and oleic acid. The capsule shells contain hypromellose and titanium oxide (E171); and 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.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Budesonide is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. Mucosal B-cells present in the ileum, including the Peyer's patches, express glucocorticoid receptors and are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy. Through their anti-inflammatory and immunosuppressive effects at the glucocorticoid receptor, corticosteroids can modulate B-cell numbers and activity. It has not been established to what extent TARPEYO's efficacy is mediated via local effects in the ileum vs systemic effects.

12.2 Pharmacodynamics

Treatment with corticosteroids, including TARPEYO, is associated with a suppression of endogenous cortisol concentrations and an impairment of the hypothalamus-pituitary-adrenal (HPA) axis function.

12.3 Pharmacokinetics

Absorption

Following single oral administration of TARPEYO 16 mg to healthy subjects, the average geometric mean C_{max} (CV%) was 4.4 ng/mL (58.3), and $AUC_{0\text{-}24}$ was 24.1 h*ng/mL (49.7). Median T_{lag} (min, max) was 3.1 h (0, 6) while median T_{max} (min, max) was 5.1 h (4.5, 10).

Food Effect

There was no clinically relevant food effect observed on the overall systemic exposure of budesonide when either a moderate or high fat meal was consumed 1 hour after administration of TARPEYO.

Distribution

Approximately 85 to 90% of budesonide binds to plasma proteins in blood over the concentration range of 0.43 to 99 ng/mL. The volume of distribution at steady state reported in the literature is 3 to 4 L/kg.

Metabolism

Budesonide is metabolized by the liver (and to lesser extent the gut), primarily by oxidative pathways via CYP3A4 to two main metabolites, 16α-hydroxyprednisolone and 6β-hydroxybudesonide, which have less than 1% of the corticosteroid activity of budesonide.

Elimination

Budesonide had a high plasma clearance, 0.9 to 1.8 L/min in healthy adults, which is close to the estimated liver blood flow, and, accordingly, suggests that budesonide is a high hepatic clearance drug.

Following single oral administration of TARPEYO 16 mg to healthy subjects, the elimination half-life (t½) for TARPEYO ranged from 5.0 to 6.8 hours.

Excretion

Budesonide was excreted in urine and feces in the form of metabolites. After oral as well as intravenous administration of micronized [^{3}H]-budesonide, approximately 60% of the recovered radioactivity was found in urine. The major metabolites, including 16α-hydroxyprednisolone and 6β-hydroxybudesonide, are mainly renally excreted, intact or in conjugated forms. No unchanged budesonide was detected in urine.

Specific Populations

Age, race, and body weight

The effect of age, race, and body weight on the pharmacokinetics of TARPEYO has not been established.

Sex

Of the 143 healthy volunteers included in the Phase 1 studies, 29% were female. Pharmacokinetics of budesonide was similar between males and females.

Hepatic Impairment

Subjects with moderate hepatic impairment (Child-Pugh class B) had 3.5 times the budesonide AUC compared with healthy volunteers while subjects with mild hepatic impairment (Child-Pugh class A) had approximately 1.4 times the budesonide AUC compared with healthy volunteers.

Patients with severe hepatic impairment (Child-Pugh Class C) have not been studied.

Renal Impairment

Intact budesonide is not excreted renally. The main metabolites of budesonide, which have negligible corticosteroid activity, are largely (60%) excreted in urine.

Drug Interaction Studies

Budesonide is metabolized via CYP3A4. Potent inhibitors of CYP3A4 can increase plasma levels of budesonide.

Thus, clinically relevant drug interactions with potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, cyclosporine, and grapefruit juice, are to be expected. Conversely, induction of CYP3A4 potentially could result in the lowering of budesonide plasma concentrations.

Effects of Other Drugs on Budesonide

Ketoconazole

In an open, non-randomized, cross-over study, 6 healthy subjects were given budesonide 10 mg as a single dose, either alone or concomitantly with the last ketoconazole dose of 3 days treatment with ketoconazole 100 mg twice daily. Co-administration of ketoconazole resulted in 8-fold the AUC of budesonide, compared to budesonide alone.

In an open, randomized, cross-over study 8 healthy subjects were given Entocort EC 3 mg as a single dose, either alone or concomitantly with the last ketoconazole dose of 4 days treatment with ketoconazole 200 mg once daily. Co-administration of ketoconazole resulted in 6.5-fold the AUC of budesonide, compared to budesonide alone.

Grapefruit Juice

In an open, randomized, cross-over study, 8 healthy subjects were given Entocort EC 3 mg, either alone, or concomitantly with 600 mL concentrated grapefruit juice (which inhibits CYP3A4 activity predominantly in the intestinal mucosa), on the last of 4 daily administrations. Concomitant administration of grapefruit juice resulted in doubling the bioavailability of budesonide compared to budesonide alone.

Proton Pump Inhibitors

The pharmacokinetics of TARPEYO have not been evaluated in combination with proton pump inhibitors (PPIs). Since the disintegration of TARPEYO is pH dependent, the release properties and uptake of budesonide may be altered when TARPEYO is taken after treatment with PPIs. In a study assessing intragastric and intraduodenal pH in healthy volunteers after repeated dosing with the PPI omeprazole 40 mg once daily, intragastric and intraduodenal pH did not exceed that required for disintegration of TARPEYO. Beyond the duodenum, PPIs such as omeprazole are unlikely to affect pH.

Oral Contraceptives (CYP3A4 Substrates)

In a parallel study, the pharmacokinetics of budesonide were not significantly different between healthy female subjects who received oral contraceptives containing desogestrel 0.15 mg and ethinyl estradiol 30 µg and healthy female subjects who did not receive oral contraceptives. Budesonide 4.5 mg once daily for one week did not affect the plasma concentrations of ethinyl estradiol, a CYP3A4 substrate. The effect of budesonide 16 mg once daily on the plasma concentrations of desogestrel and ethinyl estradiol was not studied.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies with budesonide were conducted in rats and mice. In a two-year study in Sprague-Dawley rats, budesonide caused a statistically significant increase in the incidence of gliomas in male rats at an oral dose of 50 mcg/kg (approximately 0.03 times the maximum recommended human dose (MRHD) on a body surface area basis). In addition, there were increased incidences of primary hepatocellular tumors in male rats at 25 mcg/kg (approximately 0.015 times the MRHD on a body surface area basis) and above. No tumorigenicity was seen in female rats at oral doses up to 50 mcg/kg (approximately 0.03 times the MRHD on a body surface area basis). In an additional two-year study in male Sprague-Dawley rats, budesonide caused no gliomas at an oral dose of 50 mcg/kg (approximately 0.03 times the MRHD on a body surface area basis). However, it caused a statistically significant increase in the incidence of hepatocellular tumors at an oral dose of 50 mcg/kg (approximately 0.03 times the MRHD of a body surface area basis). The concurrent reference corticosteroids (prednisolone and triamcinolone acetonide) showed similar findings. In a 91-week study in mice, budesonide caused no treatment-related carcinogenicity at oral doses up to 200 mcg/kg (approximately 0.06 times the MRHD on a body surface area basis).

Budesonide was not genotoxic in the Ames test, the mouse lymphoma cell forward gene mutation ($TK^{+/-}$) test, the human lymphocyte chromosome aberration test, the Drosophila melanogaster sex-linked recessive lethal test, the rat hepatocyte UDS test and the mouse micronucleus test.

In rats, budesonide had no effect on fertility at subcutaneous doses up to 80 mcg/kg (approximately 0.05 times the MRHD on a body surface area basis). However, it caused a decrease in prenatal viability and viability in pups at birth and during lactation, along with a decrease in maternal food consumption and body weight gain, at subcutaneous doses of 20 mcg/kg (approximately 0.012 times the MRHD on a body surface area basis) and above. No such effects were noted at 5 mcg/kg (approximately 0.003 times the MRHD on a body surface area basis).

14 CLINICAL STUDIES

14.1 Treatment of IgAN

TARPEYO was shown to reduce the loss of kidney function in adults with primary IgAN at risk of disease progression in the NefIgArd trial. While the effect on kidney function that was seen during the 9-month treatment period persisted following completion of treatment, TARPEYO did not change the long-term rate of decline in kidney function.

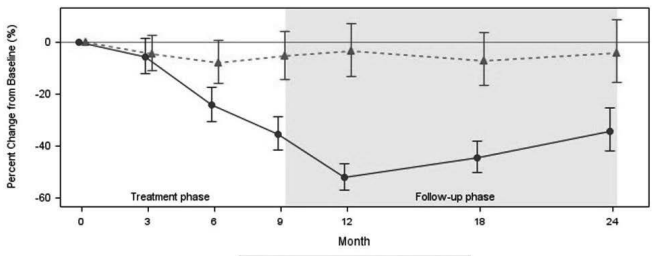
NefIgArd Study: A Phase 3, Double-Blind Placebo-Controlled, Randomized Trial in Adults with Primary IgAN

The effect of TARPEYO on proteinuria and kidney function (estimated glomerular filtration rate, eGFR) was assessed in a randomized, double-blind, phase 3, 2-part, multicenter study (NefIgArd, NCT: 03643965) in adults with biopsy-proven IgAN, eGFR ≥35 mL/min/1.73 m^2, and proteinuria (defined as either ≥1 g/day or urine protein to creatinine ratio (UPCR) ≥0.8 g/g) who were on a stable dose of maximally-tolerated RAS inhibitor therapy. Patients with other glomerulopathies, nephrotic syndrome, or those who had been treated with systemic immunosuppressive medications were excluded. Patients were randomized 1:1 to either TARPEYO 16 mg once daily or placebo and treated for nine months followed by a 2-week taper of either TARPEYO 8 mg once daily or placebo. Patients were then followed off-treatment for 15 months. The primary endpoint for Part A of the study (interim analysis) was the ratio of UPCR (based on 24-hour urine collections) at 9 months compared to baseline based on the first 199 randomized patients who completed the Month 9 visit. The primary endpoint for Part B of the study (final analysis) was a time-weighted average of the log ratio of eGFR at each time point over 2 years relative to baseline.

Of the 364 randomized patients evaluated for efficacy, 66% were male, 76% were Caucasian, 23% were Asian, and 20% were from North America. The median age was 43 years (range 20 to 73 years). At baseline, the mean eGFR was approximately 58 mL/min/1.73 m^2, with 60% of patients having an eGFR <60 mL/min/1.73 m^2. The mean baseline UPCR was 1.5 g/g and 21% of patients had proteinuria >3.5 g/24 hours. Approximately 70% of patients had a history of hypertension and 7% had a history of type 2 diabetes mellitus. At baseline, 98% were treated with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) and <1% of patients were on a sodium-glucose cotransporter 2 (SGLT2) inhibitor. At study entry, the median systolic/diastolic blood pressure was 125/79 mmHg.

The trial met the prespecified Part A primary endpoint based on an interim analysis of 199 randomized patients who had completed the Month 9 visit. The interim analysis showed a 31% reduction in UPCR in patients treated with TARPEYO 16 mg once daily compared to placebo (95% CI: 16% to 42% reduction; p=0.0001). In the final analysis of 364 patients, the percentage change in UPCR observed at 9 months was consistent with the results in the subset of 199 patients included in the interim analysis. The final analysis of the percentage change in UPCR during the treatment and follow-up phase is shown in Figure 1.

Figure 1: LS Mean (95% CI) Percentage Change from Baseline in UPCR (g/g) in NefIgArd Study (Full Analysis Set)



Patients (TARPEYO, Placebo)	(175, 176)	(171, 172)	(170, 167)	(166, 170)	(162, 166)	(157, 160)
TARPEYO % Reduction	5	24	35	52	44	34
Placebo % Reduction	4	8	5	3	7	4
Relative Percent Reduction	1	18	32	50	40	31
95% CI	(-9, 11)	(7, 27)	(22, 41)	(42, 57)	(30, 49)	(18, 43)

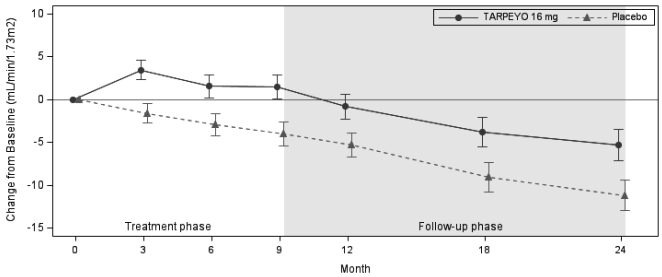
Estimated mean percentage change from baseline in UPCR with 95% confidence intervals estimated from a mixed model repeated measures analysis of log-transformed post-baseline to baseline ratios at 3, 6, 9, 12, 18, and 24 months. Analysis included all UPCR data regardless of use of prohibited medication at any point during the study.

Values reported under the figure are converted to percent reduction from baseline. Relative percent reductions comparing TARPEYO and placebo are estimated from the regression model.
Abbreviations: UPCR, urine protein to creatinine ratio; CI, confidence interval; LS, least squares.

In the final analysis of 364 patients, the trial met the prespecified Part B primary endpoint (p<0.0001).

The mean change from baseline in eGFR and respective 95% CI for each arm at each scheduled visit during the treatment and follow-up phase is shown in Figure 2. The favorable effect of TARPEYO on eGFR was seen by Month 3 (the earliest assessment) and did not appear to increase in magnitude over two years. At Year 2, there was a 5.9 mL/min/1.73 m^2 difference in the mean change from baseline in eGFR between TARPEYO and placebo (95% CI: 3.3 to 8.5 mL/min/1.73 m^2; p<0.0001).

Figure 2: LS Mean (95% CI) Change from Baseline in eGFR (mL/min/1.73 m^2) in NefIgArd Study (Full Analysis Set)



Patients (TARPEYO, Placebo)	(174, 178)	(169, 174)	(171, 167)	(162, 171)	(163, 165)	(161, 165)
TARPEYO LS Mean Change	3.5	1.5	1.5	-0.8	-3.8	-5.3
Placebo LS Mean Change	-1.6	-2.9	-4.0	-5.3	-9.1	-11.2
Difference	5.1	4.5	5.5	4.5	5.3	5.9
95% CI	(3.4, 6.7)	(2.6, 6.3)	(3.5, 7.5)	(2.5, 6.5)	(2.9, 7.8)	(3.3, 8.5)

Estimated least squares mean change from baseline in eGFR (mL/min/1.73 m^2) with 95% confidence intervals estimated from a mixed model repeated measures analysis of post-baseline to baseline differences at 3, 6, 9, 12, 18, and 24 months. Analysis was based on untransformed data and includes all eGFR data regardless of use of prohibited medication at any point during the study. A total of 15 patients in the TARPEYO arm and 20 patients in the placebo arm received rescue medication during the 2-year study.
Abbreviations: eGFR, estimated glomerular filtration rate; CI, confidence interval; LS least squares

The treatment effect based on the change from baseline in eGFR at 2 years was consistent across key subgroups, including key demographic (such as age, sex, race) and baseline disease (such as baseline proteinuria) characteristics.

16 HOW SUPPLIED/STORAGE AND HANDLING

TARPEYO (budesonide) delayed release capsules 4 mg, are white opaque-coated capsules marked with "CAL10 4 MG" in black ink on the body of the capsule. They are supplied as follows:

NDC 81749-004-01: Bottles of 120 capsules. Child-resistant cap.

Store at 20-25°C (68 - 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature].

Keep container tightly closed. Protect from moisture.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Advise patients that TARPEYO may cause hypercorticism and adrenal axis suppression and to follow a taper schedule, as instructed by their healthcare provider if discontinuing therapy *[see Warnings and Precautions (5.1)]*.

TARPEYO causes immunosuppression. Advise patients to avoid exposure to people with chicken pox or measles and, if exposed, to consult their healthcare provider immediately. There is an increased risk of developing a variety of infections, including worsening of existing tuberculosis, fungal, bacterial, viral or parasitic infections, or ocular herpes simplex, and to contact their healthcare provider if they develop any symptoms of infection *[see Warnings and Precautions (5.3)]*. Provide advice regarding vaccination schedules for immunocompromised patients.

Advise patients that TARPEYO delayed release capsules should be swallowed whole and not chewed, crushed or broken and to take TARPEYO in the morning, at least 1 hour before a meal *[See Dosage and Administration (2)]*.

Advise patients to avoid the consumption of grapefruit juice for the duration of their TARPEYO therapy *[See Drug Interactions (7.1)]*.

Manufactured for and distributed by:

Calliditas Therapeutics AB
Stockholm, Sweden

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

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
  - bruise easily
  - rounding of your face (moon face)
  - ankle swelling
  - thicker or more hair on your body and face
  - a fatty pad or hump between your shoulders (buffalo hump)
  - pink or purple stretch marks on the skin of your abdomen, thighs, breasts, or arms

- **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
  - weakness
  - nausea and vomiting
  - 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

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. Revised: 12/2023