



FOR PATIENTS



KINPEYGO® 4 mg
Modified-release hard capsules
budesonide

Information Brochure
for patients who have been prescribed Kinpeygo®

Your doctor has prescribed Kinpeygo® for the treatment of your primary IgA Nephropathy.

In this brochure, you will find additional information about your illness and treatment with Kinpeygo®.

What is the role of the kidneys?

Kidneys are important for keeping our body healthy. Their main task is to filter waste products from our blood. Additionally, they regulate the amount of water and salts in our body, our blood pressure, and the production of certain hormones. Therefore, healthy kidneys are vital.

To fulfill their role, each kidney contains approximately one million tiny filters called 'glomeruli'.

What is IgA Nephropathy?

IgA Nephropathy (or Berger's disease) is a rare autoimmune disease that irreversibly damages the kidney's tiny filters. This will result in a progressive decline in kidney function, ultimately leading to kidney failure and potentially requiring dialysis or transplantation.

IgA Nephropathy at a glance



IgA Nephropathy is a rare autoimmune disease that affects annually approximately 2.5 out of 100,000 people worldwide.¹



IgA Nephropathy most commonly develops in individuals between 16 and 35 years² of age and usually presents no symptoms in the initial stage.¹



Without treatment, IgA Nephropathy can quickly lead to renal dialysis dependency.⁴

IgA Nephropathy affects annually approximately 2.5 per 100,000 individuals worldwide.¹ This kidney disease can develop at any age, but the initial symptoms typically occur between the 16th and 35th years of age.² The severity of this condition can vary from very mild to very severe.

In patients with IgA Nephropathy, the kidneys are damaged by abnormal IgA proteins. IgA proteins play a role in the protection against infections and are primarily produced by immune cells in the intestines. Your IgA proteins are abnormal, causing them to remain 'stuck' in the kidney filters. This triggers an inflammatory reaction in the kidney's filters (glomerulonephritis), ultimately leading to irreversible kidney damage.¹

IgA Nephropathy can arise as a result of another disease (for example, certain liver diseases, intestinal diseases, skin diseases), in which case it is termed secondary IgA Nephropathy. However, most forms of IgA Nephropathy have no identified cause and are referred to as primary IgA Nephropathy.

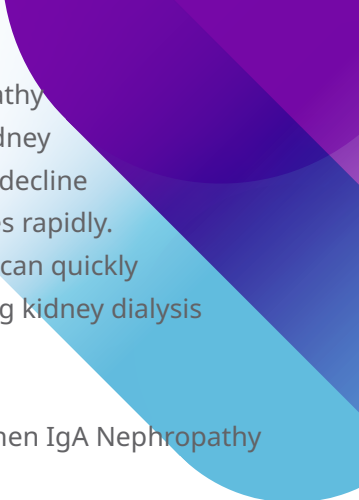
Kinpeygo® is used for the treatment of primary IgA Nephropathy in adults aged 18 years and older.

What are the symptoms of IgA Nephropathy?

Most patients with IgA Nephropathy, especially in the early stages, experience no symptoms at all. The disease is usually detected during routine urine and/or blood tests.

If symptoms do occur, the most common ones are:

- High blood pressure.
- Brownish-red urine due to the presence of blood (hematuria).
- Foamy urine due to the presence of proteins (proteinuria).
- Swelling of the eyes, legs, or feet (edema).



The severity of symptoms resulting from IgA Nephropathy varies from patient to patient. In some patients, the kidney function declines very slowly, or there may even be no decline at all. In other patients, the kidney function deteriorates rapidly. Without treatment, IgA Nephropathy in these patients can quickly lead to a complete loss of kidney function, necessitating kidney dialysis or a kidney transplant.

A kidney biopsy is required to confirm the diagnosis when IgA Nephropathy is suspected.

Why have I been prescribed Kinpeygo®?

You have been prescribed Kinpeygo® because a kidney biopsy confirmed the diagnosis of IgA Nephropathy. Based on medical examinations, your doctor expects that you have an increased risk of rapid deterioration of your kidney function.³

Kinpeygo® is a new treatment specifically for IgA Nephropathy, proven **to slow the loss of kidney function**, thus allowing you to live longer without the need for dialysis or transplantation.

Kinpeygo® contains the active ingredient budesonide, a corticosteroid medication. With a special coating, Kinpeygo® ensures that the active ingredient primarily reaches the intestines locally, reducing the production of IgA proteins. As a result, fewer abnormal IgA proteins will enter the kidneys and accumulate in the kidney filters. In this way, Kinpeygo® addresses the cause of the inflammation that leads to your kidney disease.³

How to take Kinpeygo®?

Always take this medicine exactly as your doctor has told you. Do you have doubts about the correct usage? Then, please contact your doctor or pharmacist.



The recommended dosage of Kinpeygo® is 16 mg (4 capsules of Kinpeygo® 4 mg) once a day.



Take the medication in the morning, at least one hour before a meal.



Swallow the capsule whole with a glass of water.

Do not open, crush, or chew the capsules, as this may affect the medication's effectiveness.

The capsules have a special coating to ensure that the medication is released in the right part of your intestines.

A standard course of treatment with Kinpeygo® lasts for 9 months.

At the end of the 9-month treatment with Kinpeygo®, your doctor will reduce the dose to 8 mg (2 capsules of Kinpeygo® 4 mg) once daily for the last 2 weeks of the treatment. If deemed necessary by your doctor, the dose may then be further reduced to once daily 4 mg (1 capsule of Kinpeygo® 4 mg) for an additional 2 weeks.³

Do not stop taking Kinpeygo® without discussing it with your doctor first. Suddenly stopping the medication can make you ill.

Why is correct intake so important?

As with most chronic treatments that require regular intake, it is important to strictly follow the instructions of your treating physician. Studies show that **optimal results** from a Kinpeygo® treatment are achieved after **9 months of daily intake**.⁵

As with most kidney diseases, unfortunately, recovery of your kidney function is not possible, and only your current kidney function can be preserved against further decline. This is why you are being prescribed this treatment now, and your doctor is not waiting until symptoms develop or worsen.

Protecting your current kidney function as soon as possible is key.

What can I, as a patient, expect from my treatment with Kinpeygo®?

At this stage of your IgA Nephropathy, you may have few or no symptoms. This means that a treatment with Kinpeygo® may also have little or no immediate noticeable effect.

However, significant changes are occurring in your intestines and kidneys. The active ingredient budesonide works locally in the intestines to regulate the inflammation that affects your kidney function. **Studies show a considerable protective effect on your kidney function in the long term**.⁵ If you would like more information on this, you can certainly discuss it with your treating physician.

Like any medication, Kinpeygo® can have side effects, although not everyone will experience them. Some of the most common side effects include rash, acne, low potassium in the blood, high blood pressure, swelling of the arms or legs, and swelling of the face.

If you notice a side effect of this medication, please inform your doctor. For complete information on side effects, we refer you to the patient leaflet which you can find in the Kinpeygo® packaging.

What can I, as a patient, do?

Follow-up visits to your doctor and the regular and correct intake of all your prescribed medications are important aspects of living with IgA Nephropathy.

Furthermore, in addition to your treatment with Kinpeygo®, you can also contribute significantly to improve your health and maintain your quality of life by implementing the following: ⁶



Try to **reduce excess body weight** and exercise regularly.



A **low-salt** diet and the correct intake of your **blood pressure medication** are important to keep your blood pressure perfectly under control.



If you smoke, **quitting completely** is strongly recommended.



Protect yourself from infections. Discuss with your doctor which vaccinations may be useful for you.



Connect with other people with kidney disease to share your experiences.

Reporting of side effects.

If you experience side effects, please contact your doctor or pharmacist. This also applies to possible side effects not listed in the package leaflet. You can also report side effects directly via www.eenbijwerkingmelden.be or email: adr@fagg.be. By reporting side effects, you can help us obtain more information about the safety of this medication.

Where to consult this information electronically?

Scan the QR code or visit **www.kinpeygo.be**

Username: **kinpeygotpatient**

Password: **Kinpeygo123!**



- 1 Lafayette RA, Kelepouris E. Immunoglobulin A Nephropathy: Advances in Understanding of Pathogenesis and Treatment. Am J Nephrol. 2018;47 Suppl 1:43-52. doi: 10.1159/000481636. Epub 2018 May 31. PMID: 29852501.
- 2 IgA nephropathy (Berger disease) - Symptoms and causes - Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/iga-nephropathy/symptoms-causes/syc-20352268>. Accessed April 2024.
- 3 SmPC Kinpeygo Available at: https://www.ema.europa.eu/en/documents/product-information/kinpeygo-epar-product-information_en.pdf.
- 4 Pitcher, D., Braddon, F., Hendry, B., Mercer, A., Osmaston, K., Saleem, M. A., Steenkamp, R., Wong, K., Turner, A. N., Wang, K., Gale, D. P., & Barratt, J. (2023). Long-Term Outcomes in IgA Nephropathy. Clin J Am Soc Nephrol, 18(6), 727-738. <https://doi.org/10.2215/CJN.0000000000000135>.
- 5 Lafayette R, Kristensen J, Stone A, Floege J, Tesar V, Trimarchi H, Zhang H, Eren N, Paliege A, Reich HN, Rovin BH, Barratt J; NefIgArd trial investigators. Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IgA nephropathy (NefIgArd): 2-year results from a randomised phase 3 trial. Lancet. 2023 Sep 9;402(10405):859-870. doi: 10.1016/S0140-6736(23)01554-4. Epub 2023 Aug 14. Erratum in: Lancet. 2023 Sep 9;402(10405):850. doi: 10.1016/S0140-6736(23)01851-2. PMID: 37591292.
- 6 Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. In: Kidney Int 2021;100(4S): 1-276. Available at: [https://www.kidneyinternational.org/article/S0085-2538\(21\)00562-7/fulltext](https://www.kidneyinternational.org/article/S0085-2538(21)00562-7/fulltext), accessed September 2023.