Kinpeygo® 4 mg
modified-release hard capsules
budesonide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kinpeygo® is and what it is used for
2. What you need to know before you take Kinpeygo®
3. How to take Kinpeygo®
4. Possible side effects
5. How to store Kinpeygo®
6. Contents of the pack and other information

1. What Kinpeygo® is and what it is used for

Kinpeygo® contains the active substance budesonide, a corticosteroid medicine which mainly acts locally in the intestine to reduce the inflammation associated with primary immunoglobulin A (IgA) nephropathy.

Kinpeygo® is used to treat primary IgA nephropathy in adults 18 years of age or older.

2. What you need to know before you take Kinpeygo®

Do not take Kinpeygo®:
- If you are allergic to budesonide or any of the other ingredients of this medicine (listed in section 6).
- If you have loss of function of your liver that your doctor has told you is “severe”.

Warnings and precautions
Talk to your doctor or pharmacist before taking Kinpeygo®:
- If you are going to have surgery.
- If you have liver problems.
- If you are taking or have recently taken corticosteroids.
- If you have recently had an infection.
- If you have active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex.
- If you have high blood pressure.
- If you have diabetes – or someone in your family has had diabetes.
- If you have brittle bones (osteoporosis).
- If you have stomach ulcers.
- If you have glaucoma (increased pressure in the eye) or cataracts – or someone in your family has had glaucoma (increased pressure in the eye).

If any of the above apply to you, you may be at increased risk of side effects. Your doctor will decide on the appropriate measures and if it is still all right for you to take this medicine.

Look out for side effects
If you get blurred vision or other sight problems, contact your doctor. See section 4 for more information.

Chickenpox or measles
Illnesses like chickenpox and measles can be more serious if you are taking this medicine. If you have not yet had these illnesses, keep away from people with chicken pox or measles while taking this medicine. Tell your doctor if you think that you have been infected with chicken pox or measles while taking this medicine.

Adrenal function tests
Kinpeygo® could affect the results of adrenal function tests (ACTH stimulation test) ordered by your doctor. Tell your doctors that you are taking Kinpeygo® before you have any tests.

Children and adolescents
Kinpeygo® should not be used in children and adolescents below 18 years of age. The use of this medicine in children younger than 18 years of age has not been studied.

Other medicines and Kinpeygo®
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

This is because Kinpeygo® capsules can affect the way some medicines work and some medicines can have an effect on Kinpeygo® capsules.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Ketoconazole or itraconazole - to treat infections caused by a fungus.
- Medicines for HIV called ‘protease inhibitors’ - such as ritonavir, indinavir and saquinavir.
- Erythromycin - an antibiotic used to treat infections.
- Cyclosporin - used to suppress your immune system.
- Carbamazepine - for epilepsy and nerve pain problems.
- Cardiac glycosides - such as digoxin- medicines used to treat heart conditions.
- Diuretics - to remove excess fluid from the body.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Kinpeygo®.

Kinpeygo® with food and drink
Do not eat grapefruit or drink grapefruit juice while you are taking Kinpeygo®. It can affect the way the medicine works.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine during pregnancy without checking with your doctor first.

Do not take this medicine if you are breast-feeding unless you have checked with your doctor. Budesonide passes in small amounts into the breast milk. Your doctor will help you decide whether you should continue treatment and not breast-feed or if you should stop treatment over the period your baby is being breast-fed.

Driving and using machines
Kinpeygo® is not expected to affect your ability to drive or use any machines.

Kinpeygo® contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Kinpeygo®

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How to take
The recommended dose of Kinpeygo® is 16 mg (**4 capsules** of Kinpeygo® 4 mg) once daily.
Take in the morning, at least 1 hour before a meal.
- Swallow whole with a glass of water.
- Do not open, crush or chew – as this could affect the release of the medicine. The capsules have a special coating, to ensure that the medicine is released in the correct part of your gut.

When treatment is to be discontinued, your doctor will reduce the dose to 8 mg (2 capsules of Kinpeygo® 4 mg) once daily for the last 2 weeks of therapy. If considered necessary by your doctor, the dose may then be reduced to 4 mg once daily (1 capsule of Kinpeygo® 4 mg) for another 2 weeks.

If you take more Kinpeygo® than you should
If you take more Kinpeygo® than you should, talk to a doctor or pharmacist straight away. Take the carton with you.

If you have taken more than you should for a long time, the possible side effects listed in section 4 may appear.

If you forget to take Kinpeygo®
If you miss a dose of Kinpeygo®, wait and take the medicine the next day as usual.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Kinpeygo®
Do not stop taking Kinpeygo® without discussing it with your doctor first. If you suddenly stop taking the medicine, you may become ill.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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Tell your doctor if you notice any of the following side effects with this medicine:

Very common (may affect more than 1 in 10 people)

- Rash or itchy skin
- Acne
- Reduced potassium levels in the blood (hypokalaemia)

Common (may affect up to 1 in 10 people)

- Increased blood pressure
- Swelling of arms or legs – such as ankle swelling
- Swelling of the face
- Cushingoid features such as a rounded face, increased body hair and weight gain
- Indigestion
- Muscle cramps
- Weight gain
- Diabetes mellitus
- Increase in the number of white blood cells (detected by blood tests)

Rare (may affect up to 1 in 1 000 people)

- Blurred vision

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kinpeygo®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the bottle label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kinpeygo® contains

- The active substance is budesonide. Each modified-release hard capsule contains 4 mg of budesonide.

- The other ingredients are:
Capsule content: Sugar spheres (sucrose and corn starch), hypromellose, macrogol, citric acid monohydrate, ethylcellulose, medium chain triglycerides, oleic acid (see also section 2 'Kinpeygo® contains sucrose').
Capsule shell: Hypromellose, macrogol, titanium dioxide (E171), methacrylic acid-methyl methacrylate co-polymers, talc, dibutyl sebacate.
Printing ink: Shellac, black iron oxide (E172).

What Kinpeygo® looks like and contents of the pack
Kinpeygo® 4 mg modified-release hard capsules are 19 mm white coated opaque capsules printed with "CAL10 4MG" in black ink.

The capsules are supplied in a white high-density polyethylene (HDPE) bottle with a white polypropylene (PP) child-resistant closure with an induction seal. Pack sizes: 28 or 120 modified-release hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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HD7 5QH, UK

Manufacturer
STADA Arzneimittel AG
Stadastraße 2-18
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This leaflet was last revised in June 2025

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine.