

RENSON TABLET

Hydrocortisone (10mg and 20mg)

What is in this leaflet

1. What *Renson* is used for
2. How *Renson* works
3. Before you use *Renson*
4. How to use *Renson*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Renson*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Renson* is used for

Renson is used:

- to treat low hydrocortisone levels caused by diseases of the adrenal gland (such as Addison's disease, adrenocortical insufficiency);
 - in the treatment of hypopituitarism (a condition in which the pituitary gland does not produce normal amounts of some or all of its hormones);
 - to treat congenital adrenal hyperplasia which affects your body's natural production of steroids;
 - in conditions where systemic (oral or injectable) glucocorticoid therapy is needed
- Your doctor will tell you for which disease or symptom (s)he has prescribed *Renson* for you.

How *Renson* works

Hydrocortisone or cortisol is a natural glucocorticoid (corticosteroid hormone). It acts by binding to steroid receptors in the cytoplasm. It acts mainly by reducing the local inflammation reaction. It e.g. alleviates inflammation symptoms and eliminates allergic symptoms.

Before you use *Renson*

Some medicines may increase the effects of *Renson* and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

- When you must not use it

Do not use *Renson* tablet if:

- you are allergic to hydrocortisone or any of the other ingredients in this medicine.

- you have thrush, Candida or any other fungal infection.
- you have any other infection.
- you have been vaccinated recently or are going to have any vaccinations.

Pregnancy and lactation

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. Your doctor will decide whether you should take hydrocortisone during this time.

Small amounts of hydrocortisone may pass into breast milk. Please ask your doctor for advice before taking these tablets if you are breast-feeding or intend to breast-feed.

- Before you start to use it

Please tell your doctor or pharmacist before taking *Renson* tablet if you have:

- tuberculosis
- liver and kidney problems
- high blood pressure
- heart problems including recent heart attacks
- diabetes
- osteoporosis (thinning of the bones)
- glaucoma (increased pressure in the eye)
- epilepsy (seizures)
- stomach ulcers or other digestive problems
- muscle weakness with steroids
- existing or previous history of severe mood related disorders
- thyroid problems
- chicken pox, shingles or measles
- a weakened immune system
- Amoebiasis (a type of infection)
- an infestation of a gut worm (strongyloidiasis), it may be activated or become worse by hydrocortisone
- pheochromocytoma (a tumour of the adrenal gland)

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any medicines, including medicines obtained without a prescription. In

particular, do not take this medicine if you are taking any of the following:

- Anticoagulants (used to thin the blood)
- Salicylate such as aspirin (used to relief pain)
- Non-steroidal anti-inflammatory drugs (NSAIDs) (used to treat mild to moderate pain)
- Erythromycin (used to treat bacterial infections)
- Oral contraceptive pill
- Somatropin (a type of growth hormone)
- Potassium-depleting diuretics e.g. acetazolamide, loop diuretics, thiazides (used to treat glaucoma)
- Amphotericin, ketoconazole (used to treat fungal infections)
- Mifepristone (used to assist early termination of pregnancy)
- Diuretics (water tablets)
- Methotrexate (used to treat rheumatoid arthritis)
- Rifabutin and rifampicin (antibiotics used to treat tuberculosis)
- Aminoglutethimide (used in the treatment of cancer)
- Cardiac glycosides (used to treat heart failure and irregular heartbeat)
- Theophylline and sympathomimetics (used to treat asthma and other breathing problem)

How to use *Renson*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Remember to always carry a Steroid Treatment Card. Make sure your doctor or pharmacist gives you this and has filled out the details, including the dose and how long you will have the treatment.

The amount you take each day will depend on your illness.

- When to use it

You should take this medicine by mouth. The amount you take each day will depend on your illness. The number of tablets to be taken will be on the label of your medicine. If you are unsure about the dose you should take, you must talk to your doctor or pharmacist.

- How long to use it

Continue taking *Renson* tablets for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Renson* tablets.

Tell your doctor immediately if you become pregnant while taking this medication.

You should see your doctor if you develop any new infections whilst taking these tablets. Taking hydrocortisone for a long period of time increases your chance of getting infections, which might be worse than normal and may very rarely be fatal.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

If you have been on hydrocortisone tablets for longer than 3 weeks and wish to stop taking them, do not stop suddenly as this could result in a severe drop in blood pressure which could be fatal. Your doctor will advise on how to reduce the number of tablets you are taking.

Do not give *Renson* tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Hydrocortisone may have minor influence on your ability to drive and use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Renson tablets contain lactose

This medicine contains lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects

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

Replacement therapy with *Renson* does not usually cause any adverse effects, and short-term therapy with high doses does not usually result in any adverse effects.

Adverse effects of a long-term *Renson* therapy with high doses include facial rounding, weight gain, blood sugar disorders, and in extremely long-term medication also skin thinning and bone fragility. High-dose therapy may also cause depressed mood and sleeplessness.

If you get any side effects, talk to your doctor or pharmacist. This includes any

possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Biozole

- Storage

Keep out of the reach and sight of children.

Store below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Renson 10 mg tablets are white, oval, flat, bevelled tablets with imprinted "H" on one side and plain on the other side.

Renson 20 mg tablets are white, oval, flat, bevelled tablets with imprinted "H" on one side and a single break line on the other side.

- Ingredients

- Active ingredient(s)
Hydrocortisone

- Inactive ingredients

Lactose monohydrate, maize starch, colloidal silicone dioxide, povidone, microcrystalline cellulose, magnesium stearate

- MAL numbers:

Renson 10mg Tablet:
MAL22076033AZ

Renson 20mg Tablet:
MAL22076034AZ

Manufacturer

Renata Limited
Plot# 1, Section 7, Milk Vita Road,
Mirpur, Dhaka 1216,
Bangladesh.

Product Registration Holder

VitamodeSdnBhd
55, Lorong Sempadan 2,
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