SCHEDULING STATUS

S4

HYDROCORTISONE 10 INNOVATA 10

Hydrocortisone tablets 10 mg

Contains sugar: Lactose monohydrate 78,80 mg

Read all of this leaflet carefully before you start taking HYDROCORTISONE 10 INNOVATA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist
- **HYDROCORTISONE 10 INNOVATA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **HYDROCORTISONE 10 INNOVATA** is and what it is used for

2. What you need to know before you take **HYDROCORTISONE 10 INNOVATA**

3. How to take **HYDROCORTISONE 10 INNOVATA**

4. Possible side effects

5 How to store **HYDROCORTISONE 10 INNOVATA**

6. Contents of the pack and other information

1. What HYDROCORTISONE 10 INNOVATA is and what is it used for:

HYDROCORTISONE 10 INNOVATA belongs to a group of medicines known as corticosteroids.

HYDROCORTISONE 10 INNOVATA is used to replace adrenal hormones in your body, which you may be lacking.

2. **What you need to know before you take HYDROCORTISONE 10 INNOVATA:**

Do not take HYDROCORTISONE 10 INNOVATA if:

- you are allergic to hydrocortisone or to any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- if you have a stomach ulcer.
- if you have osteoporosis.
- if you have any mental disorders.
- if you have an infection and are not receiving treatment for it.
- if you have a viral infection known as shingles or a viral eye infection.
- if you had or have tuberculosis (TB).
- if have been vaccinated recently or are going to have any vaccinations.

Warnings and precautions

Take special care with HYDROCORTISONE 10 INNOVATA:

- if you have liver problems;
- if you have kidney problems;
- if you have high blood pressure;
- if you have heart problems including recent heart attacks;
- if you have diabetes (or a family history of diabetes);

- if you have glaucoma (increased pressure in the eye) or family history of glaucoma;
- if you have HIV infection;
- if you have epilepsy;
- if you have muscle weakness with steroids;
- if you have existing or previous history of severe mood-related disorders;
- if you have thyroid problems;
- if you have chickenpox or measles;
- if you experience an increase of body temperature (fever due to any reason), feeling unwell, undergoing a stressful situation or if you are undergoing any minor surgical procedure inform your doctor or pharmacist as your daily dose may be increased temporarily;
- if you have pheochromocytoma (a tumour of the adrenal gland);
- if you are elderly as side effects can be heightened in this age group.

You should see your doctor if you develop any new infections whilst taking these tablets. Taking **HYDROCORTISONE 10 INNOVATA** for a long period of time increases your chance of getting infections, which might be worse than normal and may very rarely be fatal.

Tell your doctor or health care provider if you have chickenpox or measles. It is important to avoid exposure to people who have chickenpox, measles or shingles, especially if you have not already had these illnesses or are not sure if you have had them. **HYDROCORTISONE 10 INNOVATA** increases the risk of a severe bout of chickenpox. If exposed you must contact your doctor immediately.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are taking or have recently taken (within the last 3 months) **HYDROCORTISONE 10 INNOVATA** and you become ill (particularly important in cases of gastroenteritis or vomiting/diarrhea), suffer stress, get injured or are about to have a surgical procedure you must tell your doctor immediately that you are taking **HYDROCORTISONE 10 INNOVATA**.

Your dose of **HYDROCORTISONE 10 INNOVATA** may need to be increased (or you may have to start taking it again for a short time) to prevent a sharp fall in blood pressure.

If for any other reason your general health is declining although you take your medicine as prescribed; seek medical advice immediately.

Particular care should be taken by patients on long-term treatment as there is an increased risk of side effects. If you have been on **HYDROCORTISONE 10 INNOVATA** 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.

Mental health problems can occur while taking steroids like **HYDROCORTISONE 10 INNOVATA** (see section 4).

• these illnesses can be severe;

• usually they start within a few days or weeks of starting the medicine;

• they are more likely to happen at high doses;

• most of these problems go away if the dose is lowered or the medicine is stopped.

However, if problems do occur they might need treatment.

Talk to a doctor if you (or someone taking this medicine) show any signs of mental health problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or the medicine stopped altogether.

Children and adolescents

If the patient is a child, it is important that the doctor monitors growth and development at intervals during treatment.

Other medicines and HYDROCORTISONE 10 INNOVATA:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines)

Tell your doctor if you are taking any of the following:

- anticoagulants such as warfarin (medicines used to thin the blood);
- salicylates such as aspirin;
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac or naproxen (medicines used to treat mild to moderate pain);
- medicines for diabetes (including insulin);
- erythromycin, telithromycin or clarithromycin (medicines used to treat bacterial infections);
- an oral contraceptive pill;
- somatropin (a type of growth hormone);
- efavirenz, nevirapine or ritonavir (medicines used in the treatment of HIV infections);
- acetazolamide (a medicine used to treat glaucoma);

- amphotericin, ketoconazole, itraconazole, posaconazole or voriconazole (used to treat fungal infections);
- mifepristone (a medicine used to assist medical termination of pregnancy);
- diuretics (water tablets);
- carbenoxolone (a medicine used to treat ulcers);
- methotrexate (a medicine used to treat rheumatoid arthritis);
- St. John's Wort (a herbal medicine used for treating depression);
- medicines used to treat epilepsy such as phenytoin, phenobarbital, carbamazepine and primidone;
- rifabutin and rifampicin (antibiotics used to treat TB);
- aminoglutethimide (a medicine used in the treatment of cancer);
- cardiac glycosides, such as digoxin (used to treat heart failure and irregular heartbeat);
- theophylline and sympathomimetics such as bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline (used to treat asthma and other breathing problems);
- antihypertensives (medicines used to treat high blood pressure).

Pregnancy and breastfeeding and fertility:

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.

Driving and using machines:

HYDROCORTISONE 10 INNOVATA may cause sleepiness, dizziness, changes in vision, tiredness or muscle weakness. If you have any of these symptoms you should not drive or operate machinery.

It is not always possible to predict to what extent **HYDROCORTISONE 10 INNOVATA** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **HYDROCORTISONE 10 INNOVATA** affects them.

HYDROCORTISONE 10 INNOVATA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **HYDROCORTISONE 10 INNOVATA**.

3. How to take HYDROCORTISONE 10 INNOVATA:

Do not share medicines prescribed for you with any other person.

Always take **HYDROCORTISONE 10 INNOVATA** exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

1 to 3 tablets (10 mg to 30 mg) daily.

Your doctor will tell you how long your treatment with **HYDROCORTISONE 10 INNOVATA** will last. If you have the impression that the effect of **HYDROCORTISONE 10 INNOVATA** is too strong or too weak, tell your doctor or pharmacist.

If you take more HYDROCORTISONE 10 INNOVATA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of HYDROCORTISONE 10 INNOVATA:

If you miss a dose, do not take a double dose to make up for forgotten individual doses.

If you stop taking HYDROCORTISONE 10 INNOVATA

Do not stop taking **HYDROCORTISONE 10 INNOVATA** just because you feel better. You should follow your doctor's instructions on stopping this medicine. Your doctor may want you to reduce gradually the number of tablets you take before stopping completely. Never let your tablets run out before receiving the next prescription. It may be dangerous to go without treatment (see Section 2).

Stopping **HYDROCORTISONE 10 INNOVATA** may leave you without enough steroid hormones in your body. This may cause withdrawal symptoms such as fever, muscle and joint pain, blocked/runny nose, swelling of the eye, painful itchy skin rash and weight loss.

4. Possible side effects

HYDROCORTISONE 10 INNOVATA can have side effects.

Not all side-effects reported for this medicine are included in this leaflet.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking HYDROCORTISONE 10 INNOVATA and tell your doctor immediately or go to the nearest hospital immediately or go to the casualty department at your nearest hospital.

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to HYDROCORTISONE 10 INNOVATA. You may need urgent medical attention or hospitalisation.

If any of the following happens, tell your doctor immediately or go to the nearest hospital immediately.

- depressed, including thinking about suicide,
- high (mania) or having moods that go up and down;
- anxious, having problems sleeping, having difficulty in thinking or being confused and losing your memory;
- feeling, seeing or hearing things which do not exist;
- having strange and frightening thoughts, changing how you act or having feelings of being alone.

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Unknown Frequency:

- psychological dependence;
- increased damage to the heart in the event of a heart attack, heart failure, high blood pressure, formation of blood clots, thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies;
- taking **HYDROCORTISONE 10 INNOVATA** can make it easier for you to pick up infections which may very rarely be fatal. Infections such as chickenpox and measles can be made worse or TB may recur. some fungal and viral infections, including herpes, may be activated. Diarrhoea and vomiting, sore throat/cold, flu-like illness caused by a viral infection;

- bleeding ulcers (indicated by stomach pain, bleeding from the back passage, black stools or being sick with blood present), inflammation of the pancreas causing abdominal pain, stomach pain and discomfort, bloated feeling, infection, swelling or ulceration of the gullet (discomfort on swallowing, which can cause chest pain), thrush, indigestion, feeling sick, being sick, tooth erosion;
- tiny blood spots under the skin, reddening of the skin, increased sweating, may suppress reactions to skin tests, itchy rash
- fits (convulsions), worsening of epilepsy, sleepiness, dizziness/spinning sensation, raised pressure within the skull, feeling generally unwell, a spinning sensation, headache;
- muscle weakness or wasting, thinning of bones which makes fractures more likely (osteoporosis), broken bones or fractures, hip or shoulder pain due to poor blood circulation, risk of torn tendons, joint inflammation in the knee and groin (aseptic necrosis) or other joints;
- changes in vision as a result of cataracts (clouding of the lens in the eye) or glaucoma (increased pressure inside the eye), blurred vision, dry eyes, thinning of the surface of the eye, existing eye infections may get worse, eyes that stick out;
- increased or decreased number of white blood cells;
- Hiccups
- irregular or lack of periods;
- development of Cushingoid facies (round or moon-shaped face, buffalo hump), excessive sweating, increased appetite and weight gain, increased

hair on the body and face in women, increased blood sugar levels/ diabetes, loss of calcium and nitrogen (shown on medical tests), salt and water retention (causing swelling and raised blood pressure), low adrenal gland function which reduces the production of steroids in your body (particularly after surgery, an accident or illness); rapid swelling under the skin (in areas such as the face, throat, arms and legs), decreased carbohydrate tolerance, increased or decreased motility and number of sperm cells;

- slow healing of cuts or wounds, thin or delicate skin, redness of the skin/small dilated blood vessels, acne, bruising, itchy rash, stretch marks;
- generally feeling unwell (malaise), tiredness;
- decrease in cholesterol (good cholesterol) in the blood (shown in blood tests), reduction in blood potassium levels, symptoms of which include fainting due to low blood pressure, feeling your heartbeat (palpitations), muscle weakness, tiredness or cramps, feeling sick or being sick, inability to pass stool regularly and properly, frequent passing of urine, excessive thirst and inability to eat properly.

Additional side effects in children and adolescents

- raised pressure within the skull (pseudotumour cerebri, indicated by headaches with vomiting, listlessness and drowsiness) has been reported in children; this usually occurs after treatment is stopped;
- suppression of normal growth in children.

Because of these potential side effects, your doctor may want to monitor you at intervals during your treatment.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **HYDROCORTISONE 10 INNOVATA**.

Innovata Pharmaceutical Contact: regulatory@innovata.co.za

5. How to store HYDROCORTISONE 10 INNOVATA

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

- Store **HYDROCORTISONE 10 INNOVATA** at or below 30 °C. Protect from light and moisture.
- Do not use this medicine after the expiry date shown on the pack.
- Store in the original container
- Do not store in the bathroom
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What HYDROCORTISONE 10 INNOVATA contains:

The active substance is hydrocortisone.

The other ingredients are: Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose (PH-102), povidone (K-30).

What HYDROCORTISONE 10 INNOVATA looks like and contents of the pack

HYDROCORTISONE 10 INNOVATA 10 Tablets:

Oval flat beveled 8 x 5.25 mm, white, with imprinted “H” on one side and plain on other side.

Contents of the pack

HYDROCORTISONE 10 INNOVATA 10:

30’s: Packed in Alu-Opaque PVC blisters containing 10 tablets per blister. 3 blister strips packed in an outer carton with a package insert.

Holder of Certificate of Registration

Innovata Pharmaceuticals Pty Ltd

Crownwood Office Park

100 Northern Parkway

Building D

Ormonde

Johannesburg

2091

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New- 31.03.2026

Registration number

A 59/21.5.1/0080

Access to the corresponding Professional information is contained in the packaging or follow the link for the corresponding Professional Information for HYDROCORTISONE 10 INNOVATA:

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below:

