

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

MACLEODS HYDROCORTISONE INJECTION

Contains hydrocortisone sodium succinate equivalent to 100 mg of hydrocortisone

Contains phosphate buffer as excipient

This medicine contains less than 1 mmol sodium (23 mg) per vial that is to say is essentially 'sodium free'.

Read all of this leaflet carefully before you start taking MACLEODS HYDROCORTISONE INJECTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **MACLEODS HYDROCORTISONE INJECTION** 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 **MACLEODS HYDROCORTISONE INJECTION** is and what it is used for
2. What you need to know before you take MACLEODS HYDROCORTISONE INJECTION
3. How to take **MACLEODS HYDROCORTISONE INJECTION**
4. Possible side effects
5. How to store **MACLEODS HYDROCORTISONE INJECTION**
6. Contents of the pack and other information

VR

1. What **MACLEODS HYDROCORTISONE INJECTION** is and what it is used for

MACLEODS HYDROCORTISONE INJECTION is a corticosteroid medicine, prescribed for many different conditions, including serious illnesses, such as:

- Shock as a result of your adrenal glands not producing enough corticosteroids of their own.
- Systemic lupus erythematosus (rash with fever, arthritis, inflammation of blood vessels, kidney problems and problems affecting the brain).
- If the adrenal glands are not working properly for any reason, so that the body does not make enough of its own steroids naturally.
- Allergic disorders and disorders of the immune system, where antibodies are formed against several different parts of the body.

2. What you need to know before you take **MACLEODS HYDROCORTISONE INJECTION**

Do not take **MACLEODS HYDROCORTISONE INJECTION**:

- If you had an allergic reaction such as skin rash, swelling, or wheezing, or breathing problems after being given **MACLEODS HYDROCORTISONE INJECTION**, or another corticosteroid, tell your doctor or health care professional.
- It is important to tell your doctor if you are pregnant and your doctor will give the appropriate medicine.
- It is important to tell your doctor if you are breastfeeding and your doctor will give the appropriate medicine. High doses may cause your baby's adrenal glands not to work properly.
- **MACLEODS HYDROCORTISONE INJECTION** suppresses growth in infants, children and adolescents and therefore treatment will be limited to the lowest possible dose for the shortest possible time.

You should not be administered **MACLEODS HYDROCORTISONE INJECTION**:

It is important that you tell your doctor or healthcare professional if you suffer from any of the conditions mentioned below, if you are receiving **MACLEODS HYDROCORTISONE INJECTION** or have been prescribed **MACLEODS HYDROCORTISONE INJECTION**:

VR

- If you had an allergic reaction such as skin rash, swelling, or wheezing, or breathing problems after being given **MACLEODS HYDROCORTISONE INJECTION**, or another corticosteroid, tell your doctor or health care professional.
- Any infection that is not being treated with antibiotics or antivirals or if you had a widespread (systemic) fungal infection.
- Herpes simplex virus infection of the eye.
- Any severe psychiatric problems, including severe emotional instability, depression, delusions.
- Latent, healed or active tuberculosis.
- If you have recently had, or are about to have any vaccination.

Warnings and precautions

Take special care with **MACLEODS HYDROCORTISONE INJECTION**

- Gut problems, such as ulcers in your stomach, diverticulitis (inflamed pockets in the bowel wall causing left-sided abdominal pain, constipation or diarrhoea).
- Kidney problems.
- High blood pressure.
- Diabetes mellitus.
- Osteoporosis (brittle bones)
- If you have chicken pox, measles, shingles or a herpes eye infection. If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them
- Traumatic brain injury or stroke
- Myasthenia gravis – a condition causing tired and weak muscles
- Heart problems, including heart failure or infections
- Glaucoma (increased pressure in the eye) or if there is a family history of glaucoma

VR

- Severe depression or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like hydrocortisone, or having a family history of these illnesses
- Liver problems
- Epilepsy (fits)
- Thrombophlebitis - vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins)
- Hypothyroidism – an underactive thyroid
- History of tuberculosis
- Recent heart attack
- Kaposi's sarcoma (a type of skin cancer)
- Pheochromocytoma (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys)
- Muscle problems (pain or weakness) have happened while taking steroid medicines in the past

Caution should be exercised with corticosteroids as they can cause an eye condition (central serous chorioretinopathy) where a collection of fluid forms under the light-sensitive layer of tissue at the back of the inner eye (retina) causing visual impairment and may lead to retinal detachment. Long term therapy of corticosteroids in high doses can cause an abnormal amount of fat deposition on or outside the lining of the spine (epidural lipomatosis).

If hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

Use in children and adolescents

MACLEODS HYDROCORTISONE INJECTION suppresses growth in infants, children and adolescents and therefore treatment will be limited to the lowest possible dose for the shortest possible time.

Use in the elderly

Corticosteroid side-effects may be associated with more serious consequences in old age. Therefore, the patient should be supervised closely by a doctor.

VR

Other medicines and MACLEODS HYDROCORTISONE INJECTION

- Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Tell your doctor or pharmacist if you are taking any of the following medicines:
 - Ciclosporin (used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant) as using ciclosporin together with **MACLEODS HYDROCORTISONE INJECTION** may result in seizures
 - Rifampicin, phenobarbitone, carbamazepine, phenytoin (all used to treat epilepsy), aminoglutethimide (used for treating cancer) as these medicines may reduce the effectiveness of **MACLEODS HYDROCORTISONE INJECTION**.
 - Erythromycin (an antibiotic), clarithromycin, troleandomycin, ketoconazole and itraconazole (used to treat fungal infections), diltiazem, isoniazid and grapefruit juice as used together with **MACLEODS HYDROCORTISONE INJECTION** may result in increased adverse effects.
 - Live vaccines and if you are in close contact with persons or family members who are to be immunized with oral polio vaccines.
 - Salicylates (aspirin containing products) (used to treat mild to moderate pain)
 - Pancuronium (or other medicines called neuromuscular blocking agents which are used in some surgical procedures)
 - Other immunosuppressant agents.
 - Diuretics (sometimes called water tablets)
 - Digoxin (used for heart failure and/or an irregular heart beat)
 - Antidiabetic medicines, oral and insulin as simultaneous use may increase blood glucose levels.
 - Warfarin (used to "thin" the blood)
 - Neostigmine and pyridostigmine (used to treat myasthenia gravis – a muscle condition)
 - Amphotericin B
 - Antihypertensives (medicines for high blood pressure)

If you are taking long term medication(s):

VR

If you are being treated for diabetes, high blood pressure or water retention (oedema), tell your doctor as he/she may need to adjust the dose of the medicines used to treat these conditions.

Before you have any operations, tell your doctor, dentist or anaesthetist that you are being treated with this medicine.

If you require a test to be carried out by your doctor or in hospital, it is important that you tell the doctor or nurse that you are being treated with hydrocortisone. This medicine can affect the results of some tests.

MACLEODS HYDROCORTISONE INJECTION with food and drink and alcohol

While you are receiving **MACLEODS HYDROCORTISONE INJECTION**, your doctor may advise you to limit the amount of salt and to take extra potassium supplements in your diet.

Pregnancy, 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. You should not use **MACLEODS HYDROCORTISONE INJECTION** during pregnancy. Tell your doctor if you are breast-feeding as small amounts of corticosteroid medicines may get into breast milk.

If you continue breast feeding while you are being treated with this medicine, your baby will need extra checks to make sure he or she is not being affected by your medicine.

Driving and using machines

MACLEODS HYDROCORTISONE INJECTION can cause dizziness, confusion, disorientation and fits and, if affected, you must not drive or operate machinery.

3. How to take MACLEODS HYDROCORTISONE INJECTION

MACLEODS HYDROCORTISONE INJECTION is given as an injection through a needle placed into a vein or muscle.

Your doctor, nurse or other healthcare provider will give you this injection.

The dosage is governed more by the severity of the condition and response of the patient, than by age or body mass, but should not be less than 25 mg daily.

You will not be expected to give yourself **MACLEODS HYDROCORTISONE INJECTION**. It will be given to you by a person who is qualified to do so.

Method of administration

MACLEODS HYDROCORTISONE INJECTION is given as an injection through a needle placed into a vein or muscle.

If you take more MACLEODS HYDROCORTISONE INJECTION than you should

Too much **MACLEODS HYDROCORTISONE INJECTION** can cause side effects to occur.

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

4. Possible side effects

MACLEODS HYDROCORTISONE INJECTION can have side effects.

Not all side effects reported for **MACLEODS HYDROCORTISONE INJECTION** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MACLEODS HYDROCORTISONE INJECTION**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **MACLEODS HYDROCORTISONE INJECTION** and tell your doctor 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 **MACLEODS HYDROCORTISONE INJECTION**. You may need urgent medical attention or hospitalisation.

VR

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea (feeling sick),
- Abdominal cramps or stomach pains,
- Headache,
- Dizziness,

VR

- Tiredness,
- Light-headedness,
- Inability to sleep
- Nervousness
- Vomiting
- Increased appetite
- Indigestion - pain or discomfort in the stomach associated with difficulty in digesting food.
- Purpura - A rash of purple spots due to small blood vessels leaking blood into the skin, joints, intestines or organs.
- Thinning of the skin
- Death of tissue (particularly in the bones of the arms and legs)
- Scarring at the injection site
- Presence of infections are unable to be diagnosed
- Cushingoid – caused by increased cortisol and features include facial puffiness and weight gain
Decrease in cortisol production
- Too rapid reduction of corticosteroid dosage after long term treatment can cause adrenal problems, menstrual problems and growth problems in children
- Increase in pressure in the brain, swelling of the optic disc, fits, epidural lipomatosis an abnormal amount of fat is deposited on or outside the lining of the spine. It may press on the spinal cord and nerves.
- Cataract, increased pressure in the eye, thinning of the white part of the eye, worsening of viral or fungal eye diseases, central serous chorioretinopathy (when fluid builds up under the retina in the eye)
- bleeding ulcers in the stomach, swelling of the pancreas, stomach filled with gas, ulcers in the foodpipe, fungal infection in the food pipe, tearing of the intestines, acid-reflux, nausea
- Petechiae (tiny purple, red, or brown spots on the skin), Telangiectasia (dilated or broken blood vessels located near the surface of the skin or mucous membranes), bruising, thinning of the skin

Less frequent side effects:

VR

- Dry cough,
 - Muscle cramps,
 - Flatulence or wind,
 - Diarrhoea,
 - Loss of appetite
 - Confusion, excitement, restlessness, disorientation, false sense of well-being, seeing, feeling or hearing things that are not there, sudden wide mood swings, mistaken feelings of self-importance, or paranoia.
 - Headache, dizziness, lightheadedness, anxiety, vertigo (feeling that the environment is spinning), sweating
 - Sudden blindness
 - Increased blood pressure
 - Increase in liver enzymes (determined by tests)
 - Pimples, wounds taking long to heal
 - Weakness, muscle pain, tearing of a tendons (the tissue attaching muscle to bones)
 - Burning, numbness, pain or tingling near the injection site, allergic reaction at the injection site
 - Feeling irritable, sad, Confusion, excitement, restlessness, disorientation, false sense of well-being, seeing, feeling or hearing things that are not there, sudden wide mood swings, mistaken feelings of self-importance, or paranoia, sleep disturbances, forgetfulness
 - Heart failure
 - High blood pressure
 - Hiccups
 - Muscle disease, muscle weakness, death of bone cells, degeneration of bone tissue, fracture due to weak and brittle bones, growth retardation (when your foetus doesn't develop at a normal rate)
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Should your general health worsen or if you experience any untoward effects while taking

MACLEODS HYDROCORTISONE INJECTION, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **MACLEODS HYDROCORTISONE INJECTION**.

5. How to store MACLEODS HYDROCORTISONE INJECTION

Store at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container.

The solution is stable for 2 hours after reconstitution and must therefore be used immediately. Unused solution must be discarded.

Your doctor will check that the solution contains no particles and is not discoloured before using it.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister/label/carton bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What MACLEODS HYDROCORTISONE INJECTION contains

Each vial contains hydrocortisone sodium succinate equivalent to 100 mg of hydrocortisone.

The other ingredients are:

The other excipient is phosphate buffer.

This medicine contains less than 1 mmol sodium (23 mg) per vial that is to say is essentially 'sodium free'.

VR

What MACLEODS HYDROCORTISONE INJECTION looks like and contents of the pack

MACLEODS HYDROCORTISONE INJECTION is a white powder for parenteral use stored in a clear colourless glass vial sealed with grey bromo butyl rubber stopper and dark blue aluminium flip off seal.

Contents of the pack: Each vial is packed in an outer carton box in packs of 1's or 5's

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

GROUND FLOOR, BLOCK 1,

BASSONIA ESTATE OFFICE PARK (EAST),

1 CUSSONIA DRIVE,

BASSONIA ROCK EXT 12

ALBERTON

GAUTENG

This leaflet was last revised in

18 April 2023

Registration numbers

MACLEODS HYDROCORTISONE INJECTION: 43/21.5/1143

Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://www.macleodspharma.com> or email macleodsrsa@macleodspharma.com or contact 011 682 1169

VR