Front Side

335 mm

300 mm

Grain Direction

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

HIDROTEF 100 mg

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 HIDROTEF 100 mg
- 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.
- **HIDROTEF 100 mg** 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 **HIDROTEF 100 mg** is and what it is used for
2. What you need to know before you take **HIDROTEF 100 mg**
3. How to take **HIDROTEF 100 mg**
4. Possible side effects
5. How to store **HIDROTEF 100 mg**
6. Contents of the pack and other information

1. What HIDROTEF 100 mg is and what it is used for

HIDROTEF 100 mg 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 HIDROTEF 100 mg

Do not take **HIDROTEF 100 mg**:
- If you had an allergic reaction such as skin rash, swelling, or wheezing, or breathing problems after being given **HIDROTEF 100 mg** 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.
- **HIDROTEF 100 mg** 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 **HIDROTEF 100 mg**:
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 **HIDROTEF 100 mg** or have been prescribed **HIDROTEF 100 mg**:
- If you had an allergic reaction such as skin rash, swelling, or wheezing, or breathing problems after being given **HIDROTEF 100 mg**, or another corticosteroid, tell your doctor or health care professional.
- Any infection that is not being treated with antibiotics or antiviral 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 **HIDROTEF 100 mg**
- 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 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
- 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.
Tumour lysis syndrome can occur after treatment of a fast-growing cancer, especially certain leukemias and lymphomas (cancers of the blood) or solid tumours. As the tumour cells die, they break apart and release their contents into the blood. This causes a change in certain chemicals in the blood, which may cause damage to organs, including the kidneys, heart and liver that may lead to muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Use in children and adolescents
HIDROTEF 100 mg 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.

Other medicines and HIDROTEF 100 mg
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 **HIDROTEF 100 mg** 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 **HIDROTEF 100 mg.**
Erythromycin (an antibiotic), clarithromycin, troleandomycin, ketoconazole and itraconazole (used to treat fungal infections), diltiazem, isoniazid and grapefruit juice as used together with **HIDROTEF 100 mg** 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.
Salicylate (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 immune suppressant 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):
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.

HIDROTEF 100 mg with food and drink and alcohol
While you are receiving **HIDROTEF 100 mg**, 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 **HIDROTEF 100 mg** 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
HIDROTEF 100 mg can cause dizziness, confusion, disorientation and fits and, if affected, you must not drive or operate machinery.

3. How to take HIDROTEF 100 mg

HIDROTEF 100 mg 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 **HIDROTEF 100 mg**. It will be given to you by a person who is qualified to do so.

Method of administration
HIDROTEF 100 mg is given as an injection through a needle placed into a vein or muscle.

If you take more HIDROTEF 100 mg than you should
Too much **HIDROTEF 100 mg** 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

HIDROTEF 100 mg can have side effects.
Not all side effects reported for **HIDROTEF 100 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **HIDROTEF 100 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **HIDROTEF 100 mg** 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 **HIDROTEF 100 mg**. You may need urgent medical attention or hospitalisation.
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 **HIDROTEF 100 mg**. 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,
- 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:
- 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 **HIDROTEF 100 mg**, 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 **HIDROTEF 100 mg.**

5. How to store HIDROTEF 100 mg

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 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 HIDROTEF 100 mg 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'.
What HIDROTEF 100 mg looks like and contents of the pack
HIDROTEF 100 mg 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, 5's or 50's.
Not all pack sizes may be marketed.

7. 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

8. This leaflet was last revised in

13 February 2024

9. Registration numbers

HIDROTEF 100 mg: 59/21.5/0169

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

HIDROTEF 100 mg
PM04335731

Back Side

335 mm

300 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

HIDROTEF 100 mg
Bevat natriumhidrokortisoon suksinaat gelykstaande aan 100 mg van hidrokortisoon.
Bevat fosfaatbuffer as bindstof
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per fiesie, dit is so te sê in wese 'natriumvry'

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy HIDROTEF 100 mg begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **HIDROTEF 100 mg** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk
1. Wat **HIDROTEF 100 mg** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **HIDROTEF 100 mg** neem
3. Hoe om **HIDROTEF 100 mg** te neem
4. Moontlike newe-effekte
5. Hoe om **HIDROTEF 100 mg** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat HIDROTEF 100 mg is en waarvoor dit gebruik word

HIDROTEF 100 mg is 'n kortikosteroïed medisyne wat voorgeskryf word vir baie verskillende toestande, insluitend ernstige siektes, soos:
- Skok as gevolg van jou byniere wat nie genoeg kortikosteroïede van hul eie produseer nie.
- Sistemiese lupus eritematosus (uitslag met koors, artritis, ontsteking van bloedvate, nier probleme en probleme wat die brein aantas).
- Indien die byniere om een of ander rede nie behoorlik werk nie, sodat die liggaam nie genoeg van sy eie steroïede natuurlik maak nie.
- Allergiese afwykings en afwykings van die immuunstelsel, waar teenliggaampies teen verskillende dele van die liggaam gevorm word.

2. Wat jy behoort te weet voordat jy HIDROTEF 100 mg neem

Moet nie HIDROTEF 100 mg neem nie:
- Indien jy 'n allergiese reaksie soos veluitslag, swelling of asemgeflui, of probleme met asemhaling gehad het nadat jy **HIDROTEF 100 mg** of 'n ander kortikosteroïed gegee is, vertel jou dokter of professionele gesondheidsorgwerker.
- Dit is belangrik om jou dokter te vertel indien jy swanger is en jou dokter sal die toepaslike medisyne gee.
- Dit is belangrik om jou dokter te vertel indien jy borsvoed en jou dokter sal die toepaslike medisyne gee. Hoë dosisse kan veroorsaak dat jou baba se byniere nie behoorlik werk nie.
- **HIDROTEF 100 mg** onderdruk groei in babas, kinders en adolessante en daarom sal behandeling beperk word tot die laagste moontlike dosis vir die kortste moontlike tyd.

Jy moet nie **HIDROTEF 100 mg** toegedien word nie:
Dit is belangrik dat jy jou dokter of professionele gesondheidsorgwerker vertel indien jy aan enige van die toestande wat hieronder genoem word ly, wanneer jy **HIDROTEF 100 mg** ontvang of as **HIDROTEF 100 mg** voorgeskryf is:
- Indien jy 'n allergiese reaksie soos veluitslag, swelling of asemgeflui, of probleme met asemhaling gehad het nadat jy **HIDROTEF 100 mg**, of 'n ander kortikosteroïed gegee is, vertel jou dokter of professionele gesondheidsorgwerker.
- Enige infeksie wat nie met antibiotika of antivirale middels behandel word nie, of indien jy 'n wydverspreide (sistemiese) swaminfeksie gehad het.
- Herpes simplex-virusinfeksie van die oog.
- Enige ernstige psigiatriese probleme, insluitend ernstige emosionele onstabiliteit, depressie, waanvoorstellings.
- Sluimerende, geneesde of aktiewe tuberkulose.
- Indien jy onlangs enige inenting gehad het of op die punt staan om te ondergaan.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **HIDROTEF 100 mg**
- Derm probleme, soos maagsere, divertikulitis (ontsteekte sakkies in die darmwand wat abdominale pyn aan die linkerkant, hardlywigheid of diarree kan veroorsaak.
- Nier probleme.
- Hoë bloeddruk.
- Diabetes mellitus.
- Osteoporose (bros bene)
- Indien jy waterpokkies, masels, gordelroos of herpes ooginfeksie het. Indien jy vermoed dat jy in kontak was met iemand met waterpokkies, masels of gordelroos en jy het nog nie hierdie siektes gehad nie, of as jy onseker is of jy dit gehad het
- Traumatiese breinbesering of beroerte
- Miastenie gravis – 'n toestand wat moeë en swak spiere veroorsaak
- Hart probleme, insluitend hartversaking of infeksies
- Gloukoom (verhoogde druk in die oog) of as daar 'n familiegeskiedenis van gloukoom is
- Erge depressie of maniese depressie (bipolêre versteuring). Dit sluit in of jy voorheen depressie gehad het, terwyl jy steroïedmedisyne soos hidrokortisoon genoem het, of om 'n familiegeskiedenis van hierdie siektes te hê
- Lewer probleme
- Epilepsie (aanvalle)
- Tromboflebitis –probleme in die are as gevolg van trombose (klonte in die are) wat lei tot aarontsteking (rooi, geswelde en teer are)
- Hipotireose – 'n onderaktiewe skildklier
- Geskiedenis van tuberkulose
- Onlangse hartaanval
- Kaposi se sarkoom (n soort velkanker)
- Feochromositoom (n seldsame gewas van bynierweefsel. Die byniere is bo die niere gelê)
- Spier probleme (pyn of swakheid) het in die verlede plaasgevind tydens die neem van steroïedmedisyne

Wees versigtig met kortikosteroïede, aangesien dit 'n oogtoestand (sentrale serouse chorioretinopatie) kan veroorsaak, waar 'n versameling van vloeistof onder die ligsensitiewe laag van weefsel aan die agterkant van die binneste oog (retina) vorm, wat gesiggestremdheid veroorsaak en kan lei tot retinale loslating. Langtermyn behandeling met kortikosteroïede in hoë dosisse kan 'n abnormale hoeveelheid vetneerslag op of bulte die voering van die ruggraat veroorsaak (epidurale lipomatose).

Indien hidrokortisoon aan 'n vroeggebore baba gegee word, kan monitering van hartfunksie en struktuur nodig wees.
Tumorlise-sindroom kan voorkom na behandeling van 'n vinnig groeiende kanker, veral sekere leukemieë en limfome (bloedkankers) of solide gewasse. Soos die tumorselle doodgaan, breek hulle uitmekaar en stel hul inhoud in die bloed vry. Dit veroorsaak 'n verandering in sekere chemikalieë in die bloed, wat skade aan organe kan veroorsaak, insluitend die niere, hart en lewer wat kan lei tot spierkrampe, spierswakheid, verwarring, onreëlmatige hartklop, visuele verlies of visuele versteurings, en kort van asem. Jou dokter sal jou noukeurig monitor, veral as jy 'n hoë risiko het om tumorlise-sindroom te ontwikkel.

Gebruik in kinders en adolessente
HIDROTEF 100 mg onderdruk groei in babas, kinders en adolessente en daarom sal behandeling beperk word tot die laagste moontlike dosis vir die kortste moontlike tyd.

Gebruik in bejaardes
Kortikosteroïed newe-effekte kan geassosieer word met meer ernstige gevolge in ouer ouderdom. Daarom moet 'n dokter die pasiënt onder noukeurige toesig hou.

Ander medisyne en HIDROTEF 100 mg
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel vir jou dokter of apteker indien jy enige van die volgende medisyne neem:
Siklosporien (word gebruik om toestande te behandel soos ernstige rumatoïede artritis, ernstige peoriase of na 'n orgaan- of beenmurgoorplanting) aangesien die gebruik van siklosporien saam met **HIDROTEF 100 mg** aanvalle tot gevolg kan hê
Rifampisien, fenobarbitoon, karbamasepien, fenitoïen (almal gebruik om epilepsie te behandel), aminoglutetimied (word gebruik vir die behandeling van kanker) aangesien hierdie medisyne die doeltreffendheid van **HIDROTEF 100 mg** kan verminder.
Eritromisien ('n antibiotikum), klaritromisien, troleandomisien, ketokonasool en itrakonasool (word gebruik om swaminfeksies te behandel), diltiasem, lisinopril en pomelosap gebruik saam met **HIDROTEF 100 mg**, kan verhoogde nadelige gevolge tot gevolg hê.
Lewendige entstowwe en as jy in noue kontak is met persone of familielede wat met orale polio-entstowwe ingeënt moet word.
Salisilaat (aspirienbevattende produkte) (word gebruik om ligte tot matige pyn te behandel)
Pankuronium (of ander medisyne bekend as neuromuskulêre blokkeermiddels wat in sommige chirurgiese prosedures gebruik word).
Ander immuunonderdrukkende middels.
Diuretika (soms watertablette genoem)
Digoksien (gebruik vir hartversaking en / of 'n onreëlmatige hartklop)
Anti-diabetiese medisyne, oraal en insulien, aangesien gelyktydige gebruik bloedglukosevlakke kan verhoog.
Warfarien (gebruik om die bloed te "verdun")
Neostigmien en piridostigmien (word gebruik om miasthenie gravis te behandel – 'n spiertoestand)
Amfoterisien B
Anti-hipertensiewe middels (medisyne vir hoë bloeddruk)
Indien jy langtermyn medikasie(s) neem:
Indien jy behandel word vir diabetes, hoë bloeddruk of waterretensie (edeem), vertel jou dokter aangesien hy/sy dalk die dosis van die medisyne wat gebruik word om hierdie toestande te behandel, moet aanpas.
Voordat jy enige operasies ondergaan, vertel jou dokter, tandarts of narkotiseur dat jy met hierdie medisyne behandel word.
Indien daar vereis word dat 'n toets moet uitgevoer word, deur jou dokter of in die hospitaal, is dit belangrik dat jy die dokter of verpleegkundige vertel dat jy met hidrokortisoon behandel word. Hierdie medisyne kan die resultate van sommige toetse beïnvloed.

HIDROTEF 100 mg saam met kos en vloeistof en alkohol
Terwyl jy **HIDROTEF 100 mg** ontvang, kan jou dokter jou adviseer om die hoeveelheid van sout te beperk en om ekstra kalsiumaanvullings in jou dieet te neem.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger is, of beplan om 'n baba te hê, vra asseblief jou dokter of apteker vir advies voordat jy hierdie medisyne neem. Jy moet nie **HIDROTEF 100 mg** gebruik gedurende swangerskap nie. Vertel jou dokter as jy borsvoed, aangesien klein hoeveelhede van kortikosteroïedmedisyne in borsmelk kan beland.

Indien jy aanhou met borsvoeding terwyl jy met hierdie medisyne behandel word, sal jou baba ekstra ondersoeke benodig om seker te maak dat hy of sy nie deur jou medisyne geaffekteer word nie.

Bestuur en gebruik van masjinerie
HIDROTEF 100 mg kan duiseligheid, verwarring, diskriëntasie en aanvalle veroorsaak, en indien geaffekteer, moet jy nie bestuur of masjinerie gebruik nie.

3. Hoe om HIDROTEF 100 mg te neem

HIDROTEF 100 mg word gegee as 'n inspuiting deur 'n naald wat in 'n aar of spier geplaas word. Jou dokter, verpleegkundige of ander gesondheidsorgverskaffer sal hierdie inspuiting aan jou gee. Die dosis word meer behoer deur die erns van die toestand en reaksie van die pasiënt, as deur ouderdom of liggaamsmassa, maar moet nie minder as 25 mg per dag wees nie.

Daar sal nie van jou verwag word om jouself **HIDROTEF 100 mg** te gee nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseerd is om dit te doen.

Metode van toediening
HIDROTEF 100 mg word gegee as 'n inspuiting deur 'n naald wat in 'n aar of spier geplaas word.

Indien jy meer HIDROTEF 100 mg neem as wat jy moet
Te veel **HIDROTEF 100 mg** kan veroorsaak dat newe-effekte voorkom.
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

4. Moontlike newe-effekte

HIDROTEF 100 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir **HIDROTEF 100 mg** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **HIDROTEF 100 mg** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **HIDROTEF 100 mg** te neem en vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat probleme met asemhaling of sluk kan veroorsaak.
- uitslag of gejeuk,
- floute

Hierdie is **almal baie ernstige newe-effekte.** Indien jy dit het, het jy moontlik 'n ernstige reaksie op **HIDROTEF 100 mg** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.
Vertel onmiddellik jou dokter, of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- borskaspyn
- angina
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy agterkom dat dit vinniger klop,
- probleme met asemhaling
- tekens van herhalende infeksies soos koors of seer keel,
- minder urine as wat normaal vir jou is,
- vergeling van die vel en oë, donker urisne en moegheid wat simptome van lewer probleme kan wees.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **HIDROTEF 100 mg** gehad. Jy sal dalk dringende mediese aandag of hospitalisering nodig hê.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- Naarheid (voel siek),
- Abdominale krampe of maagpyn,
- Hoofpyn,
- Duiseligheid
- Moegheid,
- Ligh oofdigheid,
- Onvermoë om te slaap
- Senuweeagtigheid
- Braking
- Verhoogde eetlus
- Slegte spysvertering - pyn of ongemak in die maag wat geassosieer word met probleme om voedsel te verteer.
- Purpura - 'n Uitslag van pers kolletjies as gevolg van klein bloedvatjies wat bloed in die vel, gewrigte, ingewande of organe lek.
- Verdunning van die vel
- Dood van weefsel (veral in die bene van die arms en bene)
- Littekenvorming by die plek van inspuiting
- Traanvoondigheid van infeksies wat nie gediagnoseer kan word nie
- Cushingoid – veroorsaak deur verhoogde kortisol en kenmerke sluit in gesigsapofferigheid en gewigstoename.
  Afname in kortisolprodukale
- Te vinnige vermindering van die kortikosteroïed dosis na langtermyn behandeling kan byvoer probleme, menstruele probleme en groei probleme in kinders veroorsaak
- Toename in druk in die brein, swelling van die optiese skyf, aanvalle, epidurale lipomatose 'n abnormale hoeveelheid van vet word op, of bulte die voering van die ruggraat gedeponeer. Dit kan op die rugmurg en senuwees druk.
- Katarak, verhoogde druk in die oog, verdunning van die wit deel van die oog, versterging van virale- of swam oogsiektes, sentrale serouse chorioretinopatie (wanneer vloeistof onder die retina in die oog opbou)
- bloedende ulkusse in die maag, swelling van die pankreas, maag gevul met winde, ulkusse in die sluikderm, swaminfeksie in die sluikderm, skeuring van die ingewande, suurreflukx, naarheid
- Petegia (klein pers, rooi of bruin kolletjies op die vel), Telangiëktase (verwydde of gebreekte bloedvate geleë naby die oppervlak van die vel of slymvliese), kneusplekke, verdunning van die vel

Minder gereelde newe-effekte:
- Droë hoes,
- Spierkrampe,
- Winderigheid of winde,
- Diarree.
- Verlies aan eetlus
- Verwarring, opgewondenheid, rusteloosheid, disoriëntasie, valse gevoel van welstand, sien, voel of hoor goed wat nie daar is nie, skielike buierigheid, verkeerde gevoelens van eie belang of vervolgingswaansin.
- Hoofpyn, duiseligheid, ligh oofdigheid, angstigheid, vertigo (gevoel dat die omgewing draai), sweet
- Skielike blindheid
- Verhoogde bloeddruk
- Toename in lewerensieme (deur toetse vasgestel)
- Pulsies, wonde wat lank neem om te genees
- Swakheid, spierpyn, skeur van 'n sening (die weefsel wat spiere aan bene heg)
- Brandende, gevoelloosheid, pyn of tintaling naby die inspuitplek, allergiese reaksie by die plek van die inspuiting
- Voel gefrustreerd, hartseer, verwarring, opgewondenheid, rusteloosheid, disoriëntasie, valse gevoel van welstand, sien, voel of hoor goed wat nie daar is nie, skielike buierigheid, verkeerde gevoelens van eie belang, of vervolgingswaansin, slaapstoornisse, vergeestigtigheid
- Hartversaking
- Hoë bloeddruk
- Hik
- Spiersiekte, spierswakheid, dood van beenselle, degenerasie van beenweefsel, fraktuur as gevolg van swak en bros bene, groeivertreging (wanneer jou fetus nie teen 'n normale tempo ontwikkel nie)

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem is nie, stel asseblief jou dokter of apteker in kennis
Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl **HIDROTEF 100 mg** geneem word, kontak asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **HIDROTEF 100 mg.**

5. Hoe om HIDROTEF 100 mg te bewaar

Bewaar by of bande 25 °C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar in die oorspronklike verpakking / houer.
Die oplossing is stabiel vir 2 ure na rekonstitusie en moet dus onmiddellik gebruik word. Ongebruikte oplossing moet weggegooi word.
Jou dokter sal seker maak dat die oplossing geen deeltjies bevat nie en nie verkleur is voordat dit gebruik word nie.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die etiket / karton / bottel aangebring is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van pak en ander inligting

Wat HIDROTEF 100 mg bevat
Elke fiesie bevat natriumhidrokortisoon suksinaat gelykstaande aan 100 mg van hidrokortisoon.
Die ander bestanddele is:
Die ander bindstof is fosfaatbuffer.
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per fiesie, dit is so te sê in wese 'natriumvry'.

Hoe HIDROTEF 100 mg lyk en Inhoud van die pak
HIDROTEF 100 mg is 'n wit poeier vir parenterale gebruik wat geberg word in 'n helder kleurlose glasfiesie, wat gesel is met 'n grys broombutielrubberprop en donkerblou aluminium afkapseël.

Inhoud van die pak:
Elke fiesie word in 'n buitenste kartonboks verpak in pakkies van 1's, 5's of 50's.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. HOUER VAN SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1,
Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1,
Bassonia Rock, Uitbr. 12,
Alberton
Gauteng

8. Hierdie inligtingstuk is laas hersien in

13 Februarie 2024

9. Registrasienommers

HIDROTEF 100 mg: 59/21.5/0169

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

PACKAGING RESEARCH & DEVELOPMENT

MACLEODS

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: HIDROTEF 100 mg (Hydrocortisone Sodium Succinate Injection BP 100 mg)	
2. Country: South Africa - (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 335 (L) x 300 (W)mm
9. Design / Style: Booklet type	10. Item code No.: PM04335731
11. Artwork has been made: Actual Size	12. Pharma code No.: 34048 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. File Name : Z:\HYDROCORTISONE\SA Private Market\Hydrocortisone 100 mg PIL - PM04335731.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
07/01/2025	Vanita Rajool	07/01/25	07/01/25	08/01/25	Gyadav 08/01/25

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04335731		