Front Top

255 mm

230 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
MACLEODS HYDROCORTISONE INJECTION
100 mg powder for injection. For IM or IV use.

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU RECEIVE MACLEODS HYDROCORTISONE INJECTION
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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 MACLEODS HYDROCORTISONE INJECTION CONTAINS
Each vial contains hydrocortisone sodium succinate equivalent to 100 mg of hydrocortisone.
It also contains phosphate buffer as excipient.

WHAT MACLEODS HYDROCORTISONE INJECTION 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.

BEFORE YOU ARE ADMINISTERED MACLEODS HYDROCORTISONE INJECTION
ALLERGIES:
- 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.

PREGNANCY:
- It is important to tell your doctor if you are pregnant and your doctor will give the appropriate medicine.

BREASTFEEDING:
- 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.

CHILDREN:
- **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.

MACLEODS HYDROCORTISONE INJECTION 100 mg
PM04335715

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:
- 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.
- Gut problems, such as ulcers in your stomach, diverticulitis (inflamed pockets in the bowel wall causing left-sided abdominal pain, constipation or diarrhea).
- Kidney problems.
- High blood pressure.
- Diabetes mellitus.
- Osteoporosis.

Take special care with MACLEODS HYDROCORTISONE INJECTION:
If you have:
- Chicken pox.
- Measles.

Receiving MACLEODS HYDROCORTISONE INJECTION with food and drink:
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 and breastfeeding:
MACLEODS HYDROCORTISONE INJECTION will not be administered to you if you are pregnant or breastfeeding.
If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving **MACLEODS HYDROCORTISONE INJECTION.**

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

Taking other medicines with MACLEODS HYDROCORTISONE INJECTION:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

When you are receiving **MACLEODS HYDROCORTISONE INJECTION,** it is especially important to tell your doctor or healthcare professional if you are taking the following:
- Ciclosporin as using ciclosporin together with **MACLEODS HYDROCORTISONE INJECTION** may result in seizures.
- Rifampicin, carbamazepine and phenytoin as these medicines may reduce the effectiveness of **MACLEODS HYDROCORTISONE INJECTION.**
- Erythromycin and ketoconazole 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).
- Pancuronium.
- Other immunosuppressant agents.
- Diuretics.
- Digoxin.
- Antidiabetic medicines, oral and insulin as simultaneous use may increase blood glucose levels.
- Warfarin.
- Neostigmine and pyridostigmine.
- Amphotericin B.
- Antihypertensives (medicines for high blood pressure).

HOW MACLEODS HYDROCORTISONE INJECTION IS ADMINISTERED:
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.

If more MACLEODS HYDROCORTISONE INJECTION is administered:
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.

POSSIBLE SIDE EFFECTS
MACLEODS HYDROCORTISONE INJECTION can have side effects.
Not all the 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 receiving **MACLEODS HYDROCORTISONE INJECTION,** please consult your doctor, pharmacist or healthcare professional for advice.

Check with your doctor as soon as possible if any of the following side effects occur:
- Anaphylactic reaction with hives, shortness of breath, swelling of face, nasal membranes and eyelids, tightness in chest, troubled breathing, wheezing.
- Diabetes mellitus (decreased or blurred vision, frequent urination, increased thirst).
- Burning, numbness, pain or tingling at or near injection site.
- Skin rash or hives.
- Local allergic reaction or infection at the injection site, with redness, swelling and pain.
- 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.
- Sudden blindness.
- Nausea, vomiting, increased appetite, weight gain, trouble in sleeping.
- Darkening or lightening of skin colour, dizziness, lightheadedness, sensation of spinning, flushing of face or cheeks, headache, hiccups, increased joint pain, increased sweating, nosebleeds.

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

STORING AND DISPOSING OF MACLEODS HYDROCORTISONE INJECTION
Store at or below 25 °C. Protect from light.
The solution is stable for 2 hours after reconstitution and must therefore be used immediately. Unused solution must be discarded.
KEEP OUT OF REACH OF CHILDREN.

PRESENTATION OF MACLEODS HYDROCORTISONE INJECTION*
A 7.5 ml clear colourless glass vial sealed with grey bromo butyl rubber stopper and dark blue aluminium flip off seal. Each vial is packed in an outer carton box in packs of 1's, 5's & 50's.

* Not all pack sizes may be marketed.

IDENTIFICATION OF MACLEODS HYDROCORTISONE INJECTION
A white powder.

REGISTRATION NUMBER
43/21.5/1143

NAME AND ADDRESS OF REGISTRATION HOLDER
Macleods Pharmaceuticals SA (Pty) Ltd
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock,
Ext. 12, Alberton.

DATE OF PUBLICATION
9 June 2016

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.

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255 mm

230 mm

INLIGTINGSBROSJURE VIR PASIËNTE

SKEDULERINGSTATUS: S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:
MACLEODS HYDROCORTISONE INJECTION 100 mg inspuiting.
Vir IM of IV gebruik.

LEES DIE HELE BROSJURE SORGVULDIG VOORDAT U MACLEODS HYDROCORTISONE INJECTION ONTVANG.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- Hierdie medisyne is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit kan hulle skade aandoen, ookal het hulle dieselfde simptome as u.

WAT MACLEODS HYDROCORTISONE INJECTION BEVAT:
Elke flessie bevat hidrokortisoonnatriumsuksinaat ekwivalent aan 100 mg hidrokortisoon.
Dit bevat ook fosfaatbuffer as eksipiënt.

WAARVOOR MACLEODS HYDROCORTISONE INJECTION GEBRUIK WORD:
MACLEODS HYDROCORTISONE INJECTION is 'n kortikosteroïedmiddel wat vir baie verskillende kondisies voorgeskryf word, insluitende ernstige siektes soos:
- Skok, die gevolg van u byniere wat nie genoeg van hul eie kortikosteroïede produseer nie.
- Sistemiese lupus erythematosus (uitslag met koors, artritis, inflammasie van die bloedvate, nierprobleme en probleme wat die brein aantas).
- As die byniere om een of ander rede nie behoorlik funksioneer nie, sodat die liggaam nie genoeg van sy eie steroïede natuurlik kan produseer nie.
- Allergiese afwykings en afwykings van die immuunstelsel waar teenliggaampies teen verskeie verskillende dele van die liggaam gevorm word.

VOORDAT U MACLEODS HYDROCORTISONE INJECTION ONTVANG:
ALLERGIEË:
- Stel u dokter of professionele gesondheidswerker in kennis as u 'n allergiese reaksie soos veluitslag, swelling, hyging of asemhalingsprobleme ondervind het nadat **MACLEODS HYDROCORTISONE INJECTION**, of 'n ander kortikosteroïed aan u toegedien is.

SWANGERSKAP:
- Dit is belangrik om u dokter in kennis te stel as u swanger is en hy sal die toepaslike medisyne vir u gee.

BORSVOEDING:
- Dit is belangrik om u dokter in kennis te stel as u borsvoed en hy sal die toepaslike medisyne vir u gee. Hoë dosisse kan veroorsaak dat u baba se byniere nie behoorlik werk nie.

KINDERS:
MACLEODS HYDROCORTISONE INJECTION onderdruk die groei in babas, kinders en adolessente en daarom sal behandeling teen die laagste moontlike dosis vir kortste moontlike periode van tyd beperk word.

MACLEODS HYDROCORTISONE INJECTION maag nie aan u toegedien word nie:
Dit is belangrik dat u u dokter of professionele gesondheidswerker in kennis stel as u aan enige van die kondisies wat hieronder genoem word, ly as u MACLEODS HYDROCORTISONE INJECTION ontvang of as MACLEODS HYDROCORTISONE INJECTION aan u voorgeskryf word:

- As u 'n allergiese reaksie soos veluitslag, swelling, hyging of asemhalingsprobleme gehad het nadat **MACLEODS HYDROCORTISONE INJECTION** of 'n ander kortikosteroïed aan u gegee is, moet u u dokter of professionele gesondheidswerker in kennis stel.
- Enige infeksie wat nie met antibiotika of teenvirusmiddels behandel word nie, of as u 'n verspreide (sistemiese) swaminfeksie gehad het.
- Herpes simplex infeksie van die oog.
- Enige erge psigiatriese probleme, insluitende erge emosionele onstabiliteit, depressie, delusies.
- Latente, geneesde of aktiewe tuberkulose.
- Dermprobleme soos maagswere, divertikulitis (ontsteekte sakkies in die dikdermwand wat buikpyn aan die linkerkant, hardlywigheid en diaree veroorsaak.
- Nierprobleme.
- Hoë bloeddruk.
- Diabetes mellitus
- Osteoporose.

Neem spesiale sorg met MACLEODS HYDROCORTISONE INJECTION:
- As u aan waterpokkies ly.
- As u aan masels ly.

Ontvange van MACLEODS HYDROCORTISONE INJECTION saam met kos en drank:
Terwyl u **MACLEODS HYDROCORTISONE INJECTION** ontvang, kan u dokter u aanraai om die hoeveelheid sout te beperk en om ekstra kalium aanvullings te neem in u dieet.

Swangerskap en borsvoeding:
MACLEODS HYDROCORTISONE INJECTION sal nie aan u toegedien word nie as u swanger is of u baba borsvoed.
As u swanger is of u baba borsvoed, moet u asseblief u dokter apteker of ander gesondheidsbeampte vir advies raadpleeg voordat u **MACLEODS HYDROCORTISONE INJECTION** neem.

Bestuur en die gebruik van masjinerie
MACLEODS HYDROCORTISONE INJECTION kan veroorsaak duiseligheid, verwarring, disoriëntasie en rukke en indien geraak het, moet u nie bestuur of met masjinerie werk.

Die neem van MACLEODS HYDROCORTISONE INJECTION saam met ander medisyne
Stel altyd u gesondheidsbeampte in kennis as u enige ander medisyne neem. (Dit sluit komplementêre en tradisionele medisyne in.)

Wanneer u **MACLEODS HYDROCORTISONE INJECTION** ontvang, is dit veral belangrik om u dokter of professionele gesondheidswerker in kennis te stel as u enige van die volgende neem:

- Siklosporien, aangesien die gebruik van siklosporien saam met **MACLEODS HYDROCORTISONE INJECTION** tot stuipaanvalle kan lei.
- Rifampisien, karbamasepien en fenitoïen, aangesien die gebruik van hierdie medisyne die effektiwiteit van **MACLEODS HYDROCORTISONE INJECTION** kan verminder.
- Eritromisien en ketokonasool aangesien die gebruik daarvan saam met **MACLEODS HYDROCORTISONE INJECTION** tot 'n toename in newe-effekte kan lei.
- Lewende entstowwe en as u in noue kontak met persone of familielede is wat met orale polio entstof ingeënt gaan word.
- Salisilate (aspirienbevattende middels).
- Pankuronium.
- Ander immuunonderdrukkende middels.
- Diuretika.
- Digoksien.
- Antidiabetiese medisyne, oraal en insulien aangesien die gelyktydige gebruik bloedglukosevlakke kan laat toeneem.
- Warfarien.
- Neostigmien en piridostigmien.
- Amfoterisien B.
- Antihipertensiewe middels (middels vir hoë bloeddruk).

HOE MACLEODS HYDROCORTISONE INJECTION TOEGEDIEN WORD:
MACLEODS HYDROCORTISONE INJECTION deur 'n naald in 'n aar of spier te druk.
U dokter, verpleegster of ander gesondheidswerker sal hierdie inspuiting toedien.
Die dosis word eerder deur die graad van erns van die kondisie en respons van die pasiënt as deur ouderdom en liggaamsmassa bepaal, maar nooit minder as 25 mg per dag nie.

As te veel MACLEODS HYDROCORTISONE INJECTION toegedien is:
Te veel **MACLEODS HYDROCORTISONE INJECTION** kan veroorsaak dat newe-effekte voorkom.
In die geval van oordosering moet u u dokter of apteker raadpleeg. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of Giftebeheersentrum.

MOONTLIKE NEWE-EFFEKTE:
MACLEODS HYDROCORTISONE INJECTION mag newe-effekte hê.
Nie al die newe-effekte wat vir **MACLEODS HYDROCORTISONE INJECTION** aangemeld is, word in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of u ondervind enige ongewone effekte terwyl u **MACLEODS HYDROOCORTISONE INJECTION** neem, moet u asseblief u dokter, apteker of gesondheidsbeampte vir advies raadpleeg.

Stel u dokter so gou as moontlik in kennis as enige van die volgende newe-effekte voorkom:
- 'n Anafilaktiese reaksie met netelroos, kortademheid, swelling van die gesig, neusmembrane en ooglede, beklemde bors, moeite met asemhaling en hyging.
- Diabetes mellitus (afname in gesig of onduidelike gesig), dikwelse urinering, toename in dors.
- Branderigheid, ongevoeligheid, pyn of prikkeling by of naby die plek van inspuiting.
- Veluitslag of netelroos.
- Lokale allergiese reaksie of infeksie by die plek van inspuiting, met rooiheid, swelling en pyn.
- Verwardheid, opgewondenheid, rusteloosheid, disoriëntasie, vals gevoel van euforie, sien, voel of hoor dinge wat nie daar is nie, skielike wye buiveranderinge, verkeerde gevoel van selfbelang, vervolgingswaan.
- Skielike blindheid.
- Naarheid, braking, toename in eetlus, massatoename, moeite met slaap.
- Verdonkering of verligting van die velkleur, duiseligheid, lighoofdigheid, draaigevoel, hittegloede van die gesig of wange, hoofpyn, hik, toename in gewrigspyn, toename in sweet, neusbloeding.

As u enige newe-effekte waarneem wat nie in hierdie blaadjie genoem word nie, moet u asseblief u dokter of apteker daarvan in kennis stel.

BERGING EN WEGDOEN VAN MACLEODS HYDROCORTISONE INJECTION:
Berg by of onder 25 °C. Beskerm teen lig.
Die oplossing is stabiel vir 2 uur na die hersamestelling en moet dus onmiddellik gebruik word. Ongebruikte oplossing moet vernietig word.
HOU BUITE BEREIK VAN KINDERS.

AANBIEDING VAN MACLEODS HYDROCORTISONE INJECTION*:
'n 7,5 ml helder, kleurlose glasflessie geseël met 'n grys bromo butielprop en 'n donker blou aluminium knipseël. Elke flessie word in 'n buitenste karton verpak pakke van 1's, 5's & 50's.

* Nie alle pakgroottes word dalk bemark nie.

IDENTIFIKASIE VAN MACLEODS HYDROOCRTISONE INJECTION:
'n Wit poeier.

REGISTRASIENOMMER:
43/21.5/1143

NAAM EN BESIGHEIDSADRES ADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
Macleods Pharmaceuticals SA (Edms.) Bpk
Kantoorblok 1, Bassonia Estate Office Park (Oos),
Cussoniarylaan 1, Bassonia Rock,
Uitbr. 12, Alberton.

DATUM VAN PUBLIKASIE
9 Junie 2016

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: MACLEODS HYDROCORTISONE INJECTION 100 mg					
2. Country: South Africa - Tender		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: 255 (L) x 230 (W)mm			
9. Design / Style: Booklet type		10. Item code No.: PM04335715			
11. Artwork has been made: Actual Size		12. Pharma code No.: 34026 mini			
13. Barcode/NDC no: NA		14. Supersedes Item code No: NA			
15. Revision no: 00		16. File Name : Z:\HYDROCORTISONE\Tender\Hydrocortisone PIL - PM04335715.cdr			
Approved By:		17. Location: Daman			
PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
22/07/24	Vanita Rajoo	22/07/24	22/07/24	22/07/24	23/07/24

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 - Tender	PM04335715		