SCHEDULING STATUS S3

1. NAME OF THE MEDICINE
SPIRONOLACTONE 25 KIARA (tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each SPIRONOLACTONE 25 KIARA tablet contains 25 mg spironolactone. Contains sugar (lactose monohydrate 90 mg).

3. PHARMACEUTICAL FORM
Round, mottled pinky-orange, flat, bevelled edged tablet, scored on one side.

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
SPIRONOLACTONE 25 KIARA may be used initially in the treatment of patients with oedema and ascites associated with hepatic cirrhosis to avoid depletion of potassium or precipitation of hepatic coma that may follow use of a thiazide diuretic. Spironolactone may be used concomitantly with a thiazide or other diuretics if more profound diuresis is necessary, or in patients with congestive heart failure and the nephrotic syndrome.

SPIRONOLACTONE 25 KIARA may be effective in treating patients who do not respond satisfactorily to other diuretic agents, but it is most useful when given with another diuretic.

4.2. Posology and method of administration
Adults:
The initial dose is 100 mg daily in 4 divided doses. After 5 days the effect is evaluated, and if the response is satisfactory the drug is continued, if possible at a lower dose. If the response is not satisfactory, a conventional diuretic may be given concomitantly at usual doses. In certain circumstances the dose of spironolactone may have to be increased to 400 mg daily. On discontinuing the drug, the dose should be gradually decreased.

Children:
The recommended dosage is 1,5 to 3 mg/kg body mass daily.

Spironolactone is insoluble in water but the tablets may be crushed and given in suspension if necessary.

4.3. Contraindications
SPIRONOLACTONE 25 KIARA should not be given in acute renal insufficiency, rapidly progressing impairment of renal function, anuria or hyperkalaemia.

4.4. Special warnings and precautions for use
Because of the risk of producing hyperkalaemia, SPIRONOLACTONE 25 KIARA should not be given with other potassium sparing diuretics or to patients receiving potassium supplementation, and should only be given with great caution to patients with impaired renal function.

It should only be given under careful supervision in patients with severe hepatic disease as stupor and transient hepatic coma may develop in these patients.

SPIRONOLACTONE 25 KIARA may enhance the effect of other antihypertensive agents, of which the dose may need to be reduced. It should be given with caution with other potassium sparing medicines. Serum electrolytes should be estimated periodically.

Lactose intolerance
SPIRONOLACTONE 25 KIARA contains lactose monohydrate. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take SPIRONOLACTONE 25 KIARA.

SPIRONOLACTONE 25 KIARA contains lactose monohydrate, which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5. Interaction with other medicines and other forms of interaction
Because of the risk of producing hyperkalaemia, SPIRONOLACTONE 25 KIARA should not be given with other potassium sparing diuretics or to patients receiving potassium supplementation.

SPIRONOLACTONE 25 KIARA may enhance the effect of other antihypertensive agents, of which the dose may need to be reduced. It should be given with caution with other potassium-sparing medicines.
(Refer section 4.4).

4.6. Fertility, pregnancy and lactation
Safety and/or efficacy has not been established.

4.7. Effects on ability to drive and use machines
SPIRONOLACTONE 25 KIARA may cause drowsiness (refer section 4.8) which may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8. Undesirable effects
Hyperkalaemia and hyponatraemia have been observed in patients treated with spironolactone. Drowsiness, headache, ataxia, coma, maculopapular or erythematous cutaneous eruptions, impotence, gynaecomastia, mild androgenic effects including hirsutism, irregular menses and deepening voice may occur occasionally.

4.9. Overdose
Hyperkalaemia which may be manifested clinically by paraesthesia, weakness, flaccid paralysis or muscle spasms. Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties
Pharmacological classification:
A 18.1 Diuretics
ATC Code: C03DA01 - Aldosterone antagonists

Spironolactone blocks the sodium retaining action of aldosterone on the distal convoluted renal tubule and thereby increases urinary excretion of sodium and chloride, however, it reduces excretion of potassium and ammonium and decreases the titratable acidity of urine.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
Lactose monohydrate, maize starch, magnesium stearate, peppermint oil, povidone K30, sunset yellow.

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
48 months if stored in a dry place at or below 25 °C and protected from light.

6.4. Special precautions for storage
This medicine does not require any special storage conditions.

6.5. Nature and contents of container
28, 56, 84, 100 tablets packed in securitainers, sealed aluminium bags or blisters.
30, 56, 60 or 84 tablets packed in securitainers, amber glass bottles, sealed aluminium bags or blisters.
200 tablets in securitainers, amber glass bottles or blisters.

6.6. Special precautions for disposal
No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Kiara Health (Pty) Ltd
72 Steel Road
Spartan
Kempton Park
1619
South Africa

8. REGISTRATION NUMBER
Q/18.1/70

9. DATE OF RENEWAL OF AUTHORISATION
26 November 2009

10. DATE OF REVISION OF THE TEXT
24 May 2021

Additional countries registration details:

Country	Product name	Scheduling status (or Category of distribution)	Registration number
Botswana	SPIRONOLACTONE 25 KIARA	S2	B9309355
Namibia	SPIRONOLACTONE 25 KIARA	NS2	90/18.1/001504
Mauritius	SPIRONOLACTONE 25 KIARA		R3005/02/14

ATC Code: C03DA01 - Aldosterone antagonists

Name and address of manufacturer:
Kiara Health (Pty) Ltd
72 Steel Road, Spartan
Kempton Park, 1619, South Africa

KIARA

FF-51009979
UF-51009980
V1 (27/11/2020)
Pro-Print
002-SPIRO-UF-27/20

SKEDULERINGSTATUS S3

1. NAAM VAN DIE MEDISYNE
SPIRONOLACTONE 25 KIARA (tablette)

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING
Elke SPIRONOLACTONE 25 KIARA tablet bevat 25 mg spironolaktoon. Bevat suiker (laktosemonohidraat 90 mg).

3. FARMASEUTIESE VORM
Ronde, gevlekte pienkerige oranje, plat tablet met afgeskuinsde rande, gekeep aan die een kant.

4. KLINIESE BESONDERHEDE
4.1. Terapeutiese indikasies
SPIRONOLACTONE 25 KIARA mag aanvanklik gebruik word vir die behandeling van pasiënte met edeem en askites geassosieer met hepatiese sirrose om uitputting van kalium of presipitasie van hepatiese koma, wat op die gebruik van 'n tiasieddiuretikum mag volg, te voorkom. Spironolaktoon kan gesamentlik met tiasied- of ander diuretika gebruik word indien meer uitgesproke diurese nodig is of in pasiënte met kongestiewe hartversaking en die nefrotiese sindroom.

SPIRONOLACTONE 25 KIARA mag effektief wees in die behandeling van pasiënte wat nie bevredigend op ander diuretiese middels reageer nie, maar dit is die nuttigste wanneer dit saam met 'n ander diuretikum gegee word.

4.2. Posologie en metode van toediening
Volwassenes:
Die aanvanklike dosis is 100 mg daagliks in 4 verdeelde dosisse. Na 5 dae word die uitkoms evalueer, en as die respons bevredigend is, word die middel voortgesit teen 'n laer dosis, indien moontlik. As die respons nie bevredigend is nie, kan 'n konvensionele diuretikum teen die normale dosisse gesamentlik gegee word. In sommige omstandighede mag die dosis van spironolaktoon tot 400 mg daagliks verhoog moet word. Wanneer die middel gestaak word, moet die dosis geleidelik verminder word.

Kinders:
Die aanbevole dosering is 1,5 tot 3 mg/kg liggaamsmassa daagliks.

Spironolaktoon is onoplosbaar in water, maar die tablette kan fyngemaak en in suspensie gegee word, indien nodig.

4.3. Kontra-indikasies
SPIRONOLACTONE 25 KIARA moenie in akute renale ontoereikendheid, vinnige agteruitgang in renale funksie, anurie of hiperkalemie gegee word nie.

4.4. Spesiale waarskuwings en voorsorgmaatreëls vir gebruik
Vanweë die risiko om hiperkalemie teweeg te bring, moet SPIRONOLACTONE 25 KIARA nie saam met ander kaliumbesparende diuretika gegee word of vir pasiënte wat kaliumaanvullings ontvang nie en slegs met groot omsigtigheid vir pasiënte met ingekorte renale funksie.

Dit moet onder sorgvuldige toesig gegee word vir pasiënte met erge hepatiese siekte aangesien stupor en kortstondige hepatiese koma in hierdie pasiënte mag ontwikkel.

SPIRONOLACTONE 25 KIARA mag die effek van ander antihipertensiewe middels versterk en dit mag nodig wees om die dosis van hierdie middels te verlaag. Dit moet met groot omsigtigheid saam met ander kaliumbesparende geneesmiddels gegee word. Serumelektroliete moet periodiek bepaal word.

Laktose-intoleransie
SPIRONOLACTONE 25 KIARA bevat laktosemonohidraat. Pasiënte met die raar oorerflikheidstoestande van galaktose-intoleransie, bv. galaktosemie, Lapp-laktasetekort, glukose-galaktose-wanabsorpsie of fruktose-intoleransie, moenie SPIRONOLACTONE 25 KIARA neem nie.

SPIRONOLACTONE 25 KIARA bevat laktosemonohidraat wat 'n effek op die glisemiese kontrole van pasiënte met diabetes mellitus mag hê.

4.5. Interaksie met ander medisyne en ander vorms van interaksie
Vanweë die risiko om hiperkalemie teweeg te bring, moet SPIRONOLACTONE 25 KIARA nie saam met ander kaliumbesparende diuretika gegee word of vir pasiënte wat kaliumaanvullings ontvang nie.

SPIRONOLACTONE 25 KIARA mag die effek van ander antihipertensiewe middels versterk en dit mag nodig wees om die dosis van hierdie middels te verlaag. Dit moet met omsigtigheid saam met ander kaliumbesparende geneesmiddels gegee word.
(Verwys na afdeling 4.4).

4.6. Fertiliteit, swangerskap en laktasie
Veiligheid en/of effektiwiteit is nie vasgestel nie.

4.7. Effekte op die vermoë om te bestuur en masjiene te gebruik
SPIRONOLACTONE 25 KIARA mag lomerigheid (verwys na afdeling 4.8) veroorsaak en dit kan 'n effek hê op die verstandelike en/of fisiese vermoë om take of aktiwiteite wat verstandelike helderheid, oordeel en/of gesonde koördinasie en visie benodig, te verrig of uit te voer.

4.8. Ongewenste effekte
Hiperkalemie en hiponatremie is in pasiënte wat met spironolaktoon behandel is, waargeneem. Lomerigheid, hoofpyn, ataksie, koma, makulopapulêre of eritemateuse kutane uitbarstings, impotensie, ginekomastie, milde androgene effekte insluitende hirsutisme, ongereelde menses en verdiepende stem mag soms voorkom.

4.9. Oordosis
Hiperkalemie wat klinies as parestesie, swakheid, slap verlamming of spierspasmas mag manifesteer. Behandeling is simptomaties.

5. FARMAKOLOGIESE EIENSKAPPE
5.1. Farmakodinamiese eienskappe
Farmakologiese klassifikasie:
A 18.1 Diuretika
ATC-Kode: C03DA01 - Aldosteroonantagoniste

Spironolaktoon blok die natriumbehoudende werking van aldosteroon op die distale renale kronkelbuis en verhoog daardeur urinêre uitskeiding van natrium en chloried; dit verminder egter uitskeiding van kalium en ammonium en verlaag die titreerbare asiditeit van urine.

6. FARMAKOLOGIESE BESONDERHEDE
6.1. Lys van eksipiënte
Laktosemonohidraat, mieliestysel, magnesiumstearaat, pepermentolie, povidoon-K30, sonsonderganggeel.

6.2. Onverenigbaarhede
Nie van toepassing nie.

6.3. Raklewe
48 maande as geberg word teen of benede 25 ºC en beskerm teen lig.

6.4. Spesiale voorsorgmaatreëls vir berging
Hierdie medisyne benodig nie enige spesiale bergingstoestande nie.

6.5. Aard en inhoud van die houer
28, 56, 84, 100 tablette verpak in sekuriteitsbewaarders, geseëlde aluminiumsakke of stulpstroke.
30, 56, 60 of 84 tablette verpak in sekuriteitsbewaarders, amberkleurige glasbottels, geseëlde aluminiumsakke of stulpstroke.
200 tablette in sekuriteitsbewaarders, amber amberkleurige glasbottels, of stulpstroke.

6.6. Spesiale voorsorgmaatreëls vir wegdoening
Geen spesiale vereistes nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
Kiara Health (Pty) Ltd
72 Steel Road
Spartan
Kempton Park
1619
South Africa

8. REGISTRASIENOMMER
Q/18.1/70

9. DATUM VAN HERNUWING VAN MAGTIGING
26 November 2009

10. DATUM VAN HERSIENING VAN TEKS
24 Mei 2021

Bykomende lande se registrasiebesonderhede:

Land	Produknaam	Skeduleringstatus (of Kategorie van verspreiding)	Registrasie-nommer
Botswana	SPIRONOLACTONE 25 KIARA	S2	B9309355
Namibië	SPIRONOLACTONE 25 KIARA	NS2	90/18.1/001504
Mauritius	SPIRONOLACTONE 25 KIARA		R3005/02/14

ATC-Kode: C03DA01 - Aldosteroonantagoniste

Naam en adres van vervaardiger:
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