PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

CETICIT 10 mg (film-coated tablet)

Cetirizine dihydrochloride

Contains sugar: Lactose monohydrate

Read all of this leaflet carefully because it contains important information for you

CETICIT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **CETICIT** carefully to get the best results from it.

- Keep this leaflet. You may need it to read it again.
- Do not share **CETICIT** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What CETICIT is and what it is used for

CETICIT (cetirizine dihydrochloride 10mg).

The active substance cetirizine dihydrochloride, is part of a group of molecules with antihistaminic activity.

CETICIT is used for symptomatic relief of allergic conditions such as allergic rhinitis (hay fever), and allergic skin conditions, associated with pruritus (severe itching), such as urticaria (hives or itchy areas of the skin).

2. What you need to know before you take CETICIT

Do not take CETICIT

- If you are hypersensitive (allergic) to cetirizine dihydrochloride or hydroxyzine, any piperazine derivatives, or any of the other ingredients of **CETICIT.**
- If you are pregnant, as the safety of this medicine in pregnant women has not been determined.
- If you are breastfeeding, since cetirizine dihydrochloride passes into the breast milk.
- If the child you are caring for is under the age of 2 years, as it is not yet known whether this medicine is safe or effective in this age group.
- If you suffer from severe renal impairment (kidney disease).
- If you suffer from asthma, as it may cause obstruction of the airways (tight chest) if you have previously experienced adverse reactions to this type of medicine.

Warnings and precautions

Take special care with CETICIT

- If you are going to perform hazardous activities or if you are driving or operating machinery; as your mental alertness and physical coordination may be impaired.
- If you are taking alcohol, as this may lead to drowsiness when taken with **CETICIT**.
- If you suffer from conditions that may increase the risk of urinary retention (unable to empty your bladder), e.g., spinal cord lesion, prostatic hyperplasia (prostate gland enlargement).
- If you suffer from epilepsy and or convulsions (spasms / seizures).
- if you are advised by your doctor to have an allergy skin test done, as **CETICIT** interferes with the outcome of the test results. You should stop taking **CETICIT** 3 days prior to a scheduled allergy skin test.
- When you stop taking **CETICIT,** pruritus (severe itching) and/or urticaria (itchy, raised red areas on the skin) may occur when **CETICIT** is stopped, even if those symptoms were not present before you started taking **CETICIT**. The symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.
- If you suffer from the rare hereditary (inherited) condition of galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance as **CETICIT** contains lactose.
- If you suffer from diabetes mellitus, as lactose may have an effect on your sugar control.
- If you suffer from porphyria (a metabolic disease of blood components, affecting the skin and nervous system).

Children and adolescents

Do not give CETICIT to children under the age of two years, as safety and efficacy have not been demonstrated.

Do not give CETICIT to children under the age of six years, as the tablet do not allow for an appropriate dose for this age group.

Other medicines and CETICIT

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

- There are no known interactions with other medicines, including pseudoephedrine (a medicine used to treat a blocked nose) or theophylline (used to treat a tight chest).
- Diazepam (a calming medicine), glipizide (to treat diabetes), pseudoephedrine (a medicine used to treat a blocked nose), ketoconazole (to treat fungal and yeast infections), azithromycin and erythromycin (to treat bacterial infections) and cimetidine (to treat acid reflux) have not shown evidence of interactions with **CETICIT**.
- As with other antihistamines it is advisable to avoid excessive alcohol consumption and other sedating medicines .

CETICIT with food and alcohol

The amount of cetirizine taken up by your body is not affected by food, but it may happen at a slower rate.

Since alcohol may compound the drowsiness and impaired concentration that may be caused by **CETICIT,** alcohol should not be taken simultaneously with **CETICIT**.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

CETICIT is contraindicated in pregnancy as the safety has not been established.

CETICIT is contraindicated in lactating women since the active ingredient is excreted in breast milk.

Driving and using machines

- **CETICIT** may make you feel drowsy.
- **CETICIT** could interfere with your ability to drive safely.
- Do no operate any tools or machines when using **CETICIT.**

It is not always possible to predict to what extent **CETICIT** 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 **CETICIT** affects them.

CETICIT contains lactose. Patients with the rare hereditary (inherited) conditions of galactose intolerance e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **CETICIT**.

Lactose may have an effect on the glycaemic control of patients with diabetes mellitus**.**

3. How to take CETICIT

The usual dose is as follows:

Adults or children 12 years of age or older:

One 10 mg tablet daily once daily.

Children 6 to 12 years old:

10 mg (one tablet) once daily or 5 mg (half a tablet) twice daily.

Dosage in patients with kidney impairment (deficiency / disease)

In patients with kidney disease, half the recommended daily dose of cetirizine should be taken.

Dosage in liver impairment (deficiency / disease)

In patients with liver disease, half the recommended daily dose should be taken.

Dosage in the elderly

No dose adjustment is necessary.

If you use more CETICIT than you should

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

Drowsiness (sleepiness) may be expected with an overdosage of **CETICIT.** Overdosage may produce agitation, confusion, diarrhoea, dizziness, headache, mydriasis (dilation of the pupil), restlessness, somnolence (a state of drowsiness), stupor (a state of near-unconsciousness), pruritus (severe itching) sleepiness, itching, skin rash, difficulty in urinating, exhaustion, tremor and an increased heart rate.

If you forget to take CETICIT

Do not take a double dose to make up for forgotten individual doses. Take **CETICIT** as soon as possible after the forgotten dose and then continue with the normal dose.

If you stop taking CETICIT

When you stop taking **CETICIT**, pruritus (severe itching) and/or urticaria (itchy, raised red areas on the skin) may occur even if these symptoms were not present before starting treatment with **CETICIT**. The symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

4. Possible side effects

CETICIT can have side effects.

Not all side effects reported for **CETICIT** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other health care professional for advice.

If any of the following happens, stop taking **CETICIT** and tell your doctor immediately or go to the casualty department of your nearest hospital:

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

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

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

- you pass less urine than normal;

- a tight chest or difficulty in breathing;
- increase in epileptic seizures (if you are an epileptic patient);
- abdominal pain, muscle weakness, -cramping or -pain, darkening of the skin, skin rashes, skin blisters, increased heart rate, confusion which may be symptoms of porphyria problems (if you are a porphyria patient).

These all are serious side effects. You may need urgent medical attention. **CETICIT.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pharyngitis (sore throat), rhinitis (a congested, itchy, and runny nose).

Less frequent side effects:

- Urticaria (itchy, raised red areas on the skin), skin rash, pruritus (severe itching), angioedema (an allergic skin disease characterised by swelling of the surrounding skin and the mucous membranes).
- Somnolence (a state of drowsiness), depression, confusion, agitation, aggression, hallucinations (visions and imaginations), insomnia (suffering to fall asleep).
- Drowsiness, fatigue, malaise (general feeling of discomfort, illness, or lack of well-being), asthenia (weakness; lack of energy and strength), tics.
- Blurred vision, oculogyration (uncontrolled and repetitive movement of the eye).
- Tinnitus (ringing sound in ear), vertigo (feeling off-balance)
- Palpitations (a rapid and irregular heartbeat), dysrhythmias (abnormal heartbeat), tachycardia (increased heart rate).
- Hypotension (low blood pressure).
- Thickening of mucous, bronchospasm (tight chest / shortness of breath)

- Nausea, gastrointestinal (stomach) discomfort, diarrhoea (runny stomach), constipation, dry mouth.
- Jaundice (a condition in which the skin and whites of the eyes become yellow).
- Fixed drug-eruption (hyperpigmentation of the skin), photosensitivity (increased sensitivity of the skin to light), hair loss, sweating.
- Myalgia (muscle aches and pains).
- Dysuria (discomfort or burning with urination), enuresis (bed-wetting), urinary retention (unable to emptying your bladder).
- Oedema (build-up of fluid in the body which causes the affected tissue to become swollen).
- Weight increase.

Frequency unknown side effects:

- Increased appetite.
- Suicidal ideation (thinking about suicide), nightmares.
- Headaches, dizziness, anxiety, nervousness, paraesthesia (tingling or pins-and-needles), convulsions (spasms / seizures), movement disorders, dysgeusia (a distortion of the sense of taste), syncope (temporary loss of consciousness), tremor, dystonia (a state abnormal of muscle tone), dyskinesia (writhing movements of the face), amnesia (forgetfulness), memory loss.
- Hepatitis (inflammation in the liver).
- Acute generalised exanthematous pustulosis (a skin reaction related to medication).
- Arthralgia (pain in a joint).

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, pharmacist or nurse or other health care provider. 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 **CETICIT.**

Adverse Drug Reactions may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com.

5. How to store CETICIT

Store at or below 25 °C.

Keep tablets in dry place. Protect from light.

Do not remove the blisters from the carton until required for use.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What CETICIT contains

The active substance is cetirizine dihydrochloride. Each tablet contains 10 mg.

The other ingredients are:

calcium hydrogen phosphate anhydrous,

colloidal anhydrous silica,

hypromellose (E-5),

maize starch,

magnesium stearate,

povidone (K-30),

propylene glycol,

purified talc,

sodium starch glycolate (type-A),

titanium dioxide and lactose monohydrate,

lactose monohydrate (sugar).

What CETICIT looks like and contents of the pack

Film coated tablets

White, capsule shaped, film-coated tablets with break line on one side and "M+" embossed on the other side.

Packaged in blisters strips of 10's. Available in cartons of 10’s, 20’s or 30’s.

Not all pack sizes may be marketed at the same time.

Holder of certificate of registration

Adcock Ingram Limited

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PASIËNT INLIGTINGSVOUBILJET

SKEDULERINGSTATUS: S1

CETICIT 10 mg (filmbedekte tablet)

Setirisiendihidrochloried

Bevat suiker: Laktosemonohidraat

Lees hierdie hele voubiljet noukeurig, want dit bevat belangrike inligting vir u

CETICIT is sonder 'n doktersvoorskrif beskikbaar, vir u om 'n minder ernstige siekte te behandel.

Nietemin moet u steeds **CETICIT** versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie voubiljet. U het dalk nodig om dit weer te lees.
- Moenie CETICIT **met enige ander persoon** deel nie.
- Raadpleeg u apteker indien u meer inligting of advies benodig.
- U moet 'n dokter besoek indien u simptome vererger, of nie na 10 dae verbeter nie.

Wat in hierdie voubiljet is

1. Wat CETICIT is en waarvoor dit gebruik word

CETICIT (setirisiendihidrochloried 10mg).

Die aktiewe bestanddeel setirisiendihidrochloried, is deel van 'n groep molekules met antihistamien-aktiwiteit.

CETICIT word gebruik vir simptomatiese verligting van allergiese toestande soos allergiese rinitis (hooikoors) en allergiese veltoestande, wat gepaard gaan met pruritus (erge jeukerigheid), soos urtikaria (galbulte of jeukerige dele van die vel).

2. Wat u moet weet voordat u CETICIT neem

Moenie CETICIT neem nie

- Indien u hipersensitief (allergies) is vir setirisiendihidrochloried of hidroksisien, enige piperasien-derivate, of enige van die ander bestanddele van **CETICIT.**
- Indien u swanger is, aangesien die veiligheid van hierdie medisyne by swanger vroue nie bepaal is nie.
- Indien u borsvoed, aangesien setirisiendihidrochloried in die borsmelk uitgeskei word.
- Indien die kind wat u versorg onder die ouderdom van 2 jaar is, aangesien dit nog nie bekend is of hierdie medisyne veilig of effektief is in hierdie ouderdomsgroep nie.
- Indien u aan ernstige nierinkorting (niersiekte) ly.
- Indien u aan asma ly, aangesien dit obstruksie van die lugweë (benoude bors) kan veroorsaak as u voorheen nadelige reaksies op hierdie tipe medisyne ervaar het.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met CETICIT

- Indien u gevaarlike aktiwiteite gaan verrig of indien u bestuur of masjinerie gebruik; aangesien u verstandelike waaksaamheid en fisiese koördinasie benadeel kan wees.
- Indien u alkohol neem, aangesien dit tot slaperigheid kan lei wanneer dit saam met **CETICIT** geneem word.
- Indien u ly aan toestande wat die risiko van urienretensie kan verhoog (nie in staat om u blaas leeg te maak nie), bv. rugwerwel-beskadiging, prostaat-hiperplasie (vergrote prostaat).
- Indien u aan epilepsie en of stuiptrekkings (spasmas / stuipaanvalle) ly.
- indien u deur u dokter aangeraai word om 'n allergie-veltoets te ondergaan, aangesien **CETICIT** inmeng met die uitslag van dié toetsuitslae. U moet **CETICIT** 3 dae voor 'n geskeduleerde allergie-veltoets staak.
- Wanneer u ophou om **CETICIT** te neem, kan pruritus (erge jeukerigheid) en/of urtikaria (jeukerige, opgeswelde rooi areas op die vel) voorkom wanneer **CETICIT** gestaak word, selfs al was daardie simptome nie teenwoordig voordat u **CETICIT** begin neem het nie. Die simptome kan intens wees en die behandeling mag weer vereis word. Die simptome behoort op te klaar sodra die behandeling weer begin word.
- Indien u ly aan die seldsame oorerflike (oorgeërfde) toestand van galaktose-intoleransie, Lapp-laktase-tekort, glukose-galaktose-wanabsorpsie of fruktose-intoleransie, aangesien **CETICIT** laktose bevat.
- Indien u aan diabetes mellitus ly, aangesien laktose 'n uitwerking op u suikerbeheer kan hê.
- Indien u aan porfirie ly ('n metaboliese siekte van bloedkomponente wat die vel en senuweestelsel beïnvloed).

Kinders en adolessente

Moenie CETICIT aan kinders onder die ouderdom van twee jaar gee nie, aangesien veiligheid en doeltreffendheid nie bewys is nie.

Moenie CETICIT aan kinders onder die ouderdom van ses jaar gee nie, aangesien die tablet nie 'n toepaslike dosis vir hierdie ouderdomsgroep toelaat nie.

Ander medisyne en CETICIT

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre medisyne in).

- Daar is geen bekende interaksies met ander medisyne nie, insluitend pseudoefedrien ('n medisyne wat gebruik word om 'n geblokte neus te behandel) of teofillien (wat gebruik word om 'n benoude bors te behandel).
- Diasepaam ('n kalmerende medisyne), glipisied (om diabetes te behandel), pseudoefedrien ('n medisyne wat gebruik word om 'n geblokte neus te behandel), ketokonasool (om swam- en gisinfeksies te behandel), azitromisien en eritromisien (om bakteriële infeksies te behandel) en simetidien (om suur-refluks te behandel) het nie bewyse getoon van interaksies met **CETICIT nie**.
- Soos met ander antihistamiene, is dit raadsaam om oormatige alkoholverbruik en ander kalmerende medisyne te vermy.

CETICIT saam met kos en alkohol

Die hoeveelheid setirisien wat deur u liggaam opgeneem word, word nie deur voedsel beïnvloed nie, maar dit kan teen 'n stadiger tempo gebeur.

Aangesien alkohol die slaperigheid en verswakte konsentrasie wat deur **CETICIT** veroorsaak kan word, kan vererger**,** moet alkohol nie gelyktydig met **CETICIT geneem word nie**.

Swangerskap en borsvoeding

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

CETICIT is teenaangedui tydens swangerskap aangesien die veiligheid daarvan nie vasgestel is nie.

CETICIT is teenaangedui by lakterende vroue, aangesien die aktiewe bestanddeel in borsmelk uitgeskei word.

Bestuur en gebruik van masjinerie

- **CETICIT** kan u lomerig laat voel.
- **CETICIT** kan inmeng met u vermoë om veilig te bestuur.
- Moenie enige gereedskap of masjiene gebruik wanneer **CETICIT** gebruik word nie.

Dit is nie altyd moontlik om te voorspel in watter mate **CETICIT** die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle bewus is van die mate waartoe **CETICIT** hulle raak nie.

CETICIT bevat laktose. Pasiënte met die seldsame oorerflike (oorgeërfde) toestande van galaktose-intoleransie, bv. galaktosemie, Lapp-laktase-tekort, glukose-galaktose-wanabsorpsie of fruktose-intoleransie moet nie **CETICIT** neem nie.

Laktose kan 'n effek hê op die glukemiese beheer van pasiënte met diabetes mellitus**.**

3. Hoe om CETICIT te neem

Die algemene dosis is soos volg:

Volwassenes of kinders van 12 jaar of ouer:

Een 10 mg tablet daagliks eenmaal per dag.

Kinders 6 tot 12 jaar oud:

10 mg (een tablet) eenmaal per dag of 5 mg ('n halwe tablet) tweemaal per dag.

Dosis by pasiënte met nierinkorting (tekort / siekte)

By pasiënte met niersiekte moet die helfte van die aanbevole daaglikse dosis setirisien geneem word.

Dosis in lewerinkorting (tekort / siekte)

By pasiënte met lewersiekte moet die helfte van die aanbevole daaglikse dosis geneem word.

Dosis by bejaardes

Geen dosisaanpassing is nodig nie.

Indien u meer CETICIT gebruik as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van die twee beskikbaar is nie, soek hulp by die naaste hospitaal of gifhulpsentrum.

Lomerigheid (slaperigheid) kan verwag word met 'n oordosis **CETICIT.** Oordosering kan opgewerktheid, verwarring, diarree, duiseligheid, hoofpyn, midriase (verwyding van die pupil), rusteloosheid, slaperigheid ('n toestand van lomerigheid), stupor ('n toestand van byna-bewusteloosheid), pruritus (erge jeukerigheid) slaperigheid, jeukerigheid, veluitslag, probleme met urinering, uitputting, bewerasies en 'n verhoogde hartklop veroorsaak.

Indien u vergeet om CETICIT te neem

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie. Neem **CETICIT** so gou as moontlik na die vergete dosis en gaan dan voort met die normale dosis.

Indien u ophou om CETICIT te neem

Wanneer u die gebruik van **CETICIT** staak, kan pruritus (erge jeukerigheid) en/of urtikaria (jeukerige, opgeswelde rooi areas op die vel) voorkom, selfs al was hierdie simptome nie teenwoordig voordat behandeling met **CETICIT** begin is nie. Die simptome kan intens wees en behandeling kan weer vereis word. Die simptome behoort op te klaar wanneer die behandeling weer begin word.

4. Moontlike newe-effekte

CETICIT kan newe-effekte hê.

Nie alle newe-effekte wat vir **CETICIT** aangemeld word, is in hierdie voubiljet ingesluit nie.

Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u hierdie medisyne neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

PASIËNT INLIGTINGSVOUBILJET

Indien enige van die volgende gebeur, staak die gebruik van **CETICIT** en raadpleeg u dokter dadelik of gaan na die ongevalle-afdeling van u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik maak om asem te haal;
- veluitslag of jeukerigheid;
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op **CETICIT** gehad**.** U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in of gaan na die ongevalle-afdeling van u naaste hospitaal indien u enige van die volgende opmerk:

- u skei minder urien uit as normaal;
- 'n benoude bors of moeite of asem te haal;
- toename in epileptiese aanvalle (indien u 'n epileptiese pasiënt is);
- buikpyn, spierswakheid, -krampe of -pyn, verdonkering van die vel, veluitslag, velblase, verhoogde hartspoed, verwarring, wat simptome van porfirie-probleme kan wees (indien u 'n porfirie-pasiënt is).

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê. **CETICIT.**
U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Algemene newe-effekte:

- Faringitis (seer keel), rinitis ('n geblokte, jeukerige en waterige neus).

Minder algemene newe-effekte:

- Urtikaria (jeukerige, opgeswelde rooi areas op die vel), veluitslag, pruritus (erge

jeuk), angio-edeem ('n allergiese velsiekte wat gekenmerk word deur swelling van die omliggende vel en die slymvliese).

- Slaperigheid ('n toestand van lomerigheid), depressie, verwarring, opgewerktheid, aggressie, hallusinasies (visioene en verbeelding), slapeloosheid (sukkel om aan die slaap te raak).
- Slaperigheid, moegheid, malaise (algemene gevoel van ongemak, siekte of gebrek aan welstand), astenie (swakheid; gebrek aan energie en krag), ligte spierbewegings.
- Versteurde visie, okulogirasie (onbeheerde en herhalende beweging van die oog).
- Tinnitus (gelui in die oor), vertigo (voel van balans af)
- Hartkloppings ('n vinnige en onreëlmatige hartklop), disritmie (abnormale hartslag), tagikardie (verhoogde hartspoed).
- Hipotensie (lae bloeddruk).
- Verdikking van slym, bronchospasma (benoude bors / kortasem)
- Naarheid, gastroïntestinale (maag) ongemak, diarree (omgekrapte maag), hardlywigheid, droë mond.
- Geelsug ('n toestand waarin die vel en wit van die oë geel word).
- Area-spesifieke geneesmiddel-uitslag (hiperpigmentasie van die vel), fotosensitiwiteit (verhoogde sensitiwiteit van die vel vir lig), haarverlies, sweet.
- Mialgie (spierpyne en -pyne).
- Disurie (ongemak of brand met urinering), enurese (bed-natmaak), urienretensie (nie in staat om u blaas te ledig nie).
- Edeem (opbou van vloeistof in die liggaam wat veroorsaak dat die aangetaste weefsel opswel).
- Gewigstoename.

Newe-effekte met onbekende frekwensie:

- Verhoogde eetlus.
- Selfdoodgedagtes (dink aan selfdood), nagmerries.
- Hoofpyn, duiseligheid, angs, senuweeagtigheid, parestesie (tinteling of naalde-en-spelde gevoel), stuiptrekkings (spasmas / stuipaanvalle), bewegingsversteurings, disgeusie ('n vervorming van die smaaksintuig), sinkopee (tydelike verlies van bewussyn), bewerasies, distonie ('n toestand van abnormale spiertonus), diskinesie (verwronge bewegings van die gesig), amnesie (vergeetagtigheid), geheueverlies.
- Hepatitis (ontsteking in die lewer).
- Akute algemene eksantematiese pustulose ('n velreaksie wat verband hou met medikasie).
- Artralgie (pyn in 'n gewrig).

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige of ander gesondheidsorgverskaffer. U kan ook newe-effekte by SAHPRA aanmeld via die vorm "**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 u help om meer inligting oor die veiligheid van **CETICIT** te verskaf.

Nadelige geneesmiddel-reaksies kan ook by Adcock Ingram Limited aangemeld word deur die volgende e-pos te gebruik: Adcock.AEReports@adcock.com.

5. Hoe om CETICIT te bêre

Bêre teen of benede 25 °C.

Hou tablette op droë plek. Beskerm teen lig.

Moenie die stulpstroke uit die kartonboksie haal voordat dit benodig word vir gebruik nie.

HOU BUITE BEREIK EN SIG VAN KINDERS.

6. Inhoud van die verpakking en ander inligting

Wat CETICIT bevat

Die aktiewe bestanddeel is setirisiendihidrochloried. Elke tablet bevat 10 mg.

Die ander bestanddele is:

watervrye kalsiumwaterstoffosfaat,

kolloïdale watervrye silika,

hipromellose (E-5),

mieliestysel,

magnesiumstearaat,

povidoon (K-30),

propileenglikol,

gesuiwerde talk,

natriumstyselglikolaat (tipe-A),

titaandioksied en laktosemonohidraat,

laktosemonohidraat (suiker).

Hoe CETICIT lyk en inhoud van die verpakking

Filmbedekte tablette

Wit, kapsuul-vormige, filmbedekte tablette met ‘n breeklyn aan die een kant en "M+" gedruk aan die ander kant.

Verpak in stulpstroke van 10'e. Beskikbaar in kartonboksies van 10'e, 20's of 30's.

Nie alle verpakkingsgroottes mag gelyktydig bemark word nie.

PASIËNT INLIGTINGSVOUBILJET

Houer van registrasiesertifikaat

Adcock Ingram Limited

New Road 1

Erand Gardens,

Midrand, 1685, RSA

Kliëntediens: 0860 ADCOCK / 232625

Hierdie voubiljet is mees onlangs hersien op

7 Desember 2023

Registrasie nommer

42/5.7.1/0821