**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S1

**CETICIT SYRUP 1 mg/1 mL (syrup)**

Cetirizine dihydrochloride

Contains: Sorbitol

Contains: Sweetener (saccharin sodium)

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

**CETICIT SYRUP** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **CETICIT SYRUP** carefully to get the best results from it.

- Keep this leaflet. You may need it to read it again.
- Do not share **CETICIT SYRUP** 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 SYRUP is and what it is used for

**CETICIT SYRUP (cetirizine dihydrochloride 1 mg/ 1 ml syrup).**

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

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

## 2. What you need to know before you take CETICIT SYRUP

### Do not take CETICIT SYRUP

- If you are hypersensitive (allergic) to cetirizine dihydrochloride or hydroxyzine, any piperazine derivatives, or any of the other ingredients of **CETICIT SYRUP**.
- 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 SYRUP

- 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 suffer from porphyria (a metabolic disease of blood components, affecting the skin and nervous system).

- 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 SYRUP** interferes with the outcome of the test results. You should stop taking **CETICIT SYRUP** 3 days prior to a scheduled allergy skin test.
- If you are allergic to the preservatives methylparahydroxybenzoate and propylparahydroxybenzoate, they may cause an allergic reaction (possibly delayed).
- If you suffer from the rare hereditary (inherited) condition of sorbitol / malitol / lactitol intolerance.
- When you stop taking **CETICIT SYRUP,** pruritus (severe itching) and/or urticaria (itchy, raised red areas on the skin) may occur when **CETICIT SYRUP** is stopped, even if those symptoms were not present before you started taking **CETICIT SYRUP**. The symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.
- If you are an elderly person, as the elderly are more susceptible to many of these effects of **CETICIT SYRUP**.

**Children and adolescents**

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

**Other medicines and CETICIT SYRUP**

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

- There is no evidence of an interaction between cetirizine and cimetidine (a medicine for the treatment of stomach ulcers), ketoconazole (a medicine for the treatment of fungal infections), erythromycin & azithromycin (antibiotics), diazepam (a calming medicine) and pseudoephedrine (medicine used to treat a blocked nose).

**CETICIT SYRUP with alcohol**

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

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

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

**Driving and using machines**

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

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

**CETICIT SYRUP** contains sorbitol. Sorbitol may have a laxative effect**.** Patients with the rare hereditary (inherited) condition of sorbitol/maltitol/lactitol intolerance should not take **CETICIT SYRUP.**

**CETICIT SYRUP** contains he preservatives, methylparahydroxybenzoate and propylparahydroxybenzoate which may cause allergic reactions (possibly delayed).

## 3. How to take CETICIT SYRUP

The usual dose is as follows:

*Adults or children 12 years of age or older:*

Take 10 ml (two medicine measures) once daily.

*Children 6 to 12 years old:*

Take 10 ml (two medicine measures) daily, either as a single dose or as divided doses of 5 ml (one medicine measure) in the morning and 5 ml (one medicine measure) in the evening.

*Children 2 to 6 years old:*

Take 5 ml (one medicine measure) daily. Either as a single dose or as divided dose of 2,5 ml (half a medicine measure) in the morning and 2,5 ml (half a medicine measure) in the evening. No dose adjustment is necessary in healthy elderly patients with normal kidney function.

**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.

**If you use more CETICIT SYRUP 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 SYRUP.** Overdosage may also produce agitation (anxiety), confusion, diarrhoea, dizziness, headache, malaise (general feeling of discomfort, illness, or lack of well-being), mydriasis (dilation of the pupil), restlessness, sedation (drowsiness), somnolence (sleepiness), stupor (weariness), pruritus (severe itching), skin rash, urinary retention (unable to emptying your bladder), exhaustion, tremor and an increased heart rate.

There is no specific remedy for an overdose with **CETICIT SYRUP**. Treatment is symptomatic and supportive.

**If you forget to take CETICIT SYRUP**

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

If you stop taking **CETICIT SYRUP**

When you stop taking **CETICIT SYRUP**, 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 SYRUP**. 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 Syrup** can have side effects.

Not all side effects reported for **CETICIT SYRUP** 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 SYRUP** 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 SYRUP.** 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);
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;
- 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 SYRUP.** 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 SYRUP.**

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

## 5. How to store CETICIT SYRUP

Store in a well-closed container at or below 25 °C. Protect from light.

Do not use after the expiry date on the bottle. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems e.g., toilets.

KEEP OUT OF REACH OF CHILDREN

## 6. Contents of the pack and other information

**What CETICIT SYRUP contains:**

The active substance in **CETICIT SYRUP** is cetirizine dihydrochloride. Each 1 ml of syrup contains 1 mg cetirizine dihydrochloride.

The other ingredients are:

- acetic acid,
- flavour banana LR 4186,
- Glycerol,
- methylparahydroxybenzoate 0,135 % m/v) (preservative),
- propylparahydroxybenzoate 0,015 % m/v (preservative),
- propylene glycol,
- saccharin sodium 5,0 mg (sweetener),
- sodium acetate,
- sorbitol 70% 2,25 g (sweetener).

**What CETICIT SYRUP looks like and contents of the pack:**

**CETICIT SYRUP is a c**lear, or almost clear colourless solution with the taste and odour of banana. The product is pack in amber glass bottles of 60 ml, 100 ml and 200 ml syrup supplied with a 20 ml measuring cup, or in amber glass bottles of 50 ml and 150 ml syrup (without a measuring cup).

**Holder of the certificate of registration**

Adcock Ingram Limited

1 New Road

Erand Gardens,

Midrand, 1685, RSA

Customer Care: 0860 ADCOCK/232625

**This leaflet was last revised**

07/12/2024

**PASIËNT INLIGTINGSVOUBILJET**

**SKEDULERINGSTATUS:** S1

**CETICIT SYRUP 1 mg / 1 ml (stroop)**

Setirisiendihidrochloried

Bevat: Sorbitol

Bevat: Versoeter (natriumsakkarien)

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

**CETICIT SYRUP** is sonder 'n doktersvoorskrif beskikbaar, vir u om 'n minder ernstige siekte te behandel. Nietemin moet u steeds **CETICIT SYRUP** versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie voubiljet. U het dalk nodig om dit weer te lees.
- Moenie **CETICIT SYRUP** 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 SYRUP is en waarvoor dit gebruik word

**CETICIT SYRUP (setirisiendihidrochloried 1 mg / 1 ml stroop).**

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

**CETICIT SYRUP** word gebruik vir die 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 SYRUP neem

### Moenie CETICIT SYRUP neem nie

- Indien u hipersensitief (allergies) is vir setirisiendihidrochloried of hidroksisien, enige piperasien-derivate, of enige van die ander bestanddele van **CETICIT SYRUP.**
- 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 SYRUP

- Indien u gevaarlike aktiwiteite gaan verrig of indien u bestuur of masjinerie gebruik; aangesien u verstandelike waaksaamheid en fisiese koördinasie ingeperk kan wees.
- Indien u aan porfirie ly ('n metaboliese siekte van bloedkomponente wat die vel en senuweestelsel beïnvloed).

- Indien u ly aan toestande wat die risiko van urienretensie kan verhoog (nie in staat om u blaas te ledig nie), bv. rugwerwel-beskadiging, prostaat-hiperplasie (vergrote prostaat).
- Indien u aan epilepsie en of stuiptrekkings (spasmas / aanvalle) ly
- indien u deur u dokter aangeraai word om 'n allergie-veltoets te laat doen, aangesien **CETICIT SYRUP** inmeng met die uitslag van die toetsuitslae. U moet die gebruik van **CETICIT SYRUP** 3 dae voor 'n geskeduleerde allergie-veltoets staak.
- Indien u allergies is vir die preserveermiddels metielparahidroksibensoaat en propielparahidroksibensoaat, kan dit 'n allergiese reaksie veroorsaak (moontlik vertraag).
- Indien u ly aan die seldsame oorerflike (oorgeërfde) toestand van sorbitol- / maltitol- / laktitol-onverdraagsaamheid.
- Wanneer u die gebruik van **CETICIT SYRUP** staak, kan pruritus (erge jeukerigheid) en/of urtikaria (jeukerige, opgeswelde rooi areas op die vel) voorkom wanneer **CETICIT SYRUP** gestaak word, selfs al was daardie simptome nie teenwoordig voordat u **CETICIT SYRUP begin neem het nie**. Die simptome kan intens wees en die behandeling mag dalk weer vereis word. Die simptome behoort op te klaar wanneer die behandeling weer begin word.
- Indien u 'n bejaarde persoon is, aangesien bejaardes meer vatbaar is vir baie van hierdie effekte van **CETICIT SYRUP.**

**Kinders en adolessente**

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

**Ander medisyne en CETICIT SYRUP**

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

- Daar is geen bewyse van 'n interaksie tussen setirisien en simetidien ('n medisyne vir die behandeling van maagsere), ketokonasool ('n medisyne vir die behandeling van swaminfeksies), eritromisien en azitromisien (antibiotika), diasepaam ('n kalmerende medisyne) en pseudoefedrien (medisyne wat gebruik word om 'n geblokte neus te behandel nie).

**CETICIT SYRUP met alkohol**

Aangesien alkohol die slaperigheid en verswakte konsentrasie wat deur **CETICIT SYRUP** veroorsaak kan word, mag vererger, moet alkohol nie gelyktydig met **CETICIT SYRUP** 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 SYRUP** is teenaangedui tydens swangerskap aangesien die veiligheid nie vasgestel is nie.

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

**Bestuur en gebruik van masjinerie**

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

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

**CETICIT SYRUP** bevat sorbitol. Sorbitol kan 'n lakserende effek hê**.** Pasiënte met die seldsame oorerflike (oorgeërfde) toestand van sorbitol-/maltitol-/laktitol-onverdraagsaamheid moet nie **CETICIT SYRUP** neem nie.

**CETICIT SYRUP** bevat preserveermiddels, metielparahidroksibensoaat en propielparahidroksibensoaat wat allergiese reaksies (moontlik vertraag) kan veroorsaak.

## 3. Hoe om CETICIT SYRUP te neem

Die algemene dosis is soos volg:

*Volwassenes of kinders van 12 jaar of ouer:*

Neem 10 ml (twee medisynemate) eenmaal per dag.

*Kinders van 6 tot 12 jaar oud:*

Neem 10 ml (twee medisynemate) eenmaal per dag, hetsy as 'n enkele dosis, óf as verdeelde dosisse van 5 ml (een medisynemaat) in die oggend en 5 ml (een medisynemaat) in die aand.

*Kinders van 2 tot 6 jaar oud:*

Neem 5 ml (een medisynemaat) eenmaal per dag. Hetsy as 'n enkele dosis óf as verdeelde dosisse van 2,5 ml ('n halwe medisynemaat) in die oggend en 2,5 ml ('n halwe medisynemaat) in die aand. Geen dosisaanpassing is nodig by gesonde bejaarde pasiënte met normale nierfunksie nie.

**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.

**Indien u meer CETICIT SYRUP gebruik indien 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 SYRUP.** Oordosering kan ook opgewerktheid (angs), verwarring, diarree, duiseligheid, hoofpyn, malaise (algemene gevoel van ongemak, siekte of gebrek aan welstand), midriase (verwyding van die pupil), rusteloosheid, sedasie (slaperigheid), lomerigheid (slaperigheid), stupor (moegheid), pruritus (erge jeukerigheid), veluitslag, urienretensie (nie in staat om u blaas te ledig nie), uitputting, bewerasies en 'n verhoogde hartspoed veroorsaak.

Daar is geen spesifieke behandeling vir 'n oordosis met **CETICIT SYRUP** nie. Behandeling is simptomaties en ondersteunend.

**Indien u vergeet om CETICIT SYRUP te neem**

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

Indien u ophou om **CETICIT SYRUP** te neem

Wanneer u die gebruik van **CETICIT SYRUP** 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 SYRUP** 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 SYRUP** kan newe-effekte hê.

Nie alle newe-effekte wat vir **CETICIT SYRUP** aangemeld word, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid veswak of indien u enige ongewenste gevolge ervaar terwyl u hierdie medisyne neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

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

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat moeilike asemhaling kan veroorsaak;
- veluitslag of jeukerigheid;
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op **CETICIT SYRUP** 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 om asem te haal;
- toename in epileptiese aanvalle (indien u 'n epileptiese pasiënt is);
- vergeling van die vel en oë, donker urien en moegheid wat simptome van lewerprobleme kan wees;

- 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 SYRUP.** 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 jeukerigheid), 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 hartklop), 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 SYRUP** te verskaf.

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

## 5. Hoe om CETICIT SYRUP te bêre

Bêre in 'n diggeslote houer teen of benede 25 °C. Beskerm teen lig.

Moenie ná die vervaldatum gebruik wat op die bottel aangedui is nie. Neem alle ongebruikte medisyne terug na u apteker. Moenie ongebruikte medisyne in afvoerpype of rioolstelsels weggooi nie, bv. toilette.

HOU BUITE BEREIK VAN KINDERS

## 6. Inhoud van die verpakking en ander inligting

**Wat CETICIT SYRUP bevat:**

Die aktiewe bestanddeel in **CETICIT SYRUP** is setirisiendihidrochloried. Elke 1 ml stroop bevat 1 mg setirisiendihidrochloried.

Die ander bestanddele is:

- asynsuur,
- piesang geursel LR 4186,
- Gliserol,

- metielparahidroksibensoaat 0,135% m/v) (preserveermiddel),
- propielparahidroksibensoaat 0,015% m/v (preserveermiddel),
- propileenglikol,
- natriumsakkarien 5,0 mg (versoeter),
- natriumasetaat,
- sorbitol 70% 2,25 g (versoeter).

**Hoe CETICIT SYRUP lyk en inhoud van die verpakking:**

**CETICIT SYRUP** is 'n deurskynende, of byna deurskynende, kleurlose oplossing met die smaak en geur van piesang**.** Die produk word verpak in amberkleurige glasbottels van 60 ml, 100 ml en 200 ml stroop wat saam met 'n maatbekertjie van 20 ml voorsien word, of in amberkleurige glasbottels van 50 ml en 150 ml stroop (sonder 'n maatbekertjie).

**Houer van die registrasiesertifikaat**

Adcock Ingram Limited

New Road 1

Erand Gardens,

Midrand, 1685, RSA

Kliëntediens: 0860 ADCOCK / 232625

**Hierdie voubiljet is mees onlangs hersien op**

07/12/2024