PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

COGESIC, tablets

500 mg Paracetamol and 8 mg Codeine Phosphate

Contains sugar (sucrose 20 mg per tablet)

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share COGESIC with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days**.**

What is in this leaflet

1. What COGESIC is and what it is used for

2. What you need to know before you take COGESIC

3. How to take COGESIC

4. Possible side effects

5. How to store COGESIC

6. Contents of the pack and other information

1. What COGESIC is and what it is used for

COGESIC contains paracetamol and codeine phosphate.

Codeine phosphate is a painkiller belonging to the class of the opioids that acts on the central nervous system. Paracetamol, the other active substance, has centrally acting analgesic effects.

COGESIC is used for the relief of mild to moderate pain and fever.

2. What you need to know before you take COGESIC

Do not take COGESIC:

- If you are allergic to paracetamol or codeine phosphate, any of the other ingredients mentioned in section 6.
- If you suffer from severe breathing problems, for example chronic bronchitis or emphysema or having an asthma attack and especially if you have bluish coloured skin (due to poor circulation) or you have excess secretions from the lungs.
- If you have recently had an operation to your gall bladder.
- If you drink a lot of alcohol.
- If you have a head injury or suffer from increased pressure on the brain.
- If you are taking medicines called monoamine oxidase inhibitors (MAOIs) used to treat depression such as tranylcypromine and moclobemide or have taken them in the last 14 days before treatment with COGESIC.

Warnings and precautions

Take special care with COGESIC:

- **This product contains paracetamol and you should not take more than the recommended dose. If you have overdosed or suspect you have overdosed, contact a doctor, hospital or poison centre immediately.**
- **COGESIC contains codeine and exceeding the prescribed dose, together with prolonged and continuous use of this medicine, may lead to dependency and addiction.**
- Dosages in excess of those recommended may cause severe liver damage.
- Consult your doctor if no relief is obtained with the recommended dosage.
- Do not use continuously for longer than 5 days without consulting your doctor.
- If you are suffering from liver or kidney disease you should take COGESIC under medical supervision.
- COGESIC contains paracetamol. If you are allergic to paracetamol, you may break out in a severe skin rash after you take COGESIC. You should stop using COGESIC at the first appearance of a skin rash or any other sign of allergy.
  - Tell your doctor if you experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4).
- Tell your doctor if you are suffering from hypothyroidism, Addison's disease, myasthenia gravis (muscle weakness), impaired liver function, prostate gland enlargement, shock, inflammatory or obstructive bowel disorders.
- Reduce the dose if you are very weak or an elderly patient.
- The administration of COGESIC during labour may cause breathing difficulties in the newborn child.

- Children
    - Not recommended for children under 6 years.

Other medicines and COGESIC

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

COGESIC should not be administered with the following:

- A group of antidepressant medicines called Monoamine Oxidase (MAO) Inhibitors (such as moclobemide and tranylcypromine). When taken together with COGESIC it can cause diarrhoea, tachycardia (irregular heartbeat), hyperhidrosis (excessive sweating), trembling, confusional state, even coma.

Caution is advised when the following medicines are given with COGESIC:

- If you are taking alcohol, anaesthetics, other pain relievers such as morphine as well as sedative medicines such as benzodiazepines (alprazolam, diazepam, lorazepam) or medicines used for mental illness and depression (phenothiazines and tricyclic antidepressants) with COGESIC as there is an increased risk of drowsiness, difficulties in breathing (respiratory depression), coma which may be life-threatening.
- Tell your doctor or pharmacist if you are taking any of the following medicines:
    - Rifampicin and isoniazid (medicines for TB)
    - Carbamazepine (for epilepsy or fits)
    - Metoclopramide and domperidone (for nausea and vomiting)

- Cholestyramine (for lowering cholesterol levels). Take COGESIC one hour after taking cholestyramine.
- Aspirin (for fever and pain)

COGESIC with food and drink

Do not drink alcohol during treatment with COGESIC as the effects of COGESIC and alcohol may intensify each other.

Pregnancy and breastfeeding and fertility

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 healthcare professional for advice before taking this medicine.

COGESIC must not be taken during pregnancy and breastfeeding. Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the newborn child. The administration of COGESIC during labour may cause breathing difficulties in the newborn child or may lead to delayed emptying of the stomach of the mother during labour, increasing the risk of lung infection in the mother.

The administration of COGESIC during breastfeeding may cause breathing difficulties in the child.

Driving and using machines

Do not drive while taking this medicine until you know how it affects you. COGESIC can affect your ability to drive as it may make you sleepy or dizzy. If you feel drowsy while taking COGESIC, do not drive, use tools or use machinery.

COGESIC contains sugar

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking COGESIC.

3. How to take COGESIC

Do not share medicines prescribed for you with any other person.

Always take COGESIC exactly as described in this leaflet or your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults:

Take 1 or 2 tablets every 4 to 6 hours.

Do not take more than 8 tablets per day.

Children over 12 years: One tablet every four to six hours.

Children 6 to 12 years: Half to one tablet every six hours.

Do not exceed the recommended dose.

Do not use continuously for longer than five (5) days without consulting your doctor.

Talk to your doctor or pharmacist or nurse if you are elderly or physically very weak, as the dose of COGESIC needs to be reduced.

Not recommended for children under 6 years.

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

Do not chew the tablets.

If you take more COGESIC than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed, serious liver damage from too much paracetamol. Your kidneys can also become damaged in the absence of liver damage.

If you forget to take COGESIC

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

COGESIC can have side effects.

Not all side effects reported for COGESIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COGESIC, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking COGESIC 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 all over the body

These are all very serious side effects. If you have them, you may have had a serious reaction to COGESIC. 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: The following side effects occur frequently:

- A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- Onset of rash at a fixed location on the body each time you take the same medicines (fixed drug eruption).
- Increased pressure on the brain.
- Loss in body temperature.
- A state of deep unconsciousness (coma).
- Inflammation of the liver, resulting in abdominal pain, dark urine, pale stools, weakness, fatigue.
- Less urine than is normal for you.
- Upper abdominal pain; abdominal pain that radiates to your back; tenderness when touching the abdomen; fever; rapid pulse; nausea; vomiting are symptoms of inflammation of the pancreas.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

<u>Frequent side effects</u>

- Confusion, restlessness

- Drowsiness, dizziness
- Nausea, vomiting, constipation
- Facial flushing

Less frequent side effects

- Agranulocytosis (less white blood cells in the body)
- Thrombocytopenia (abnormally low blood platelets)
- Leukopenia (lower-than-normal white blood cells in the blood)
- Pancytopenia (lower-than-normal red and white bloods cells in the blood)
- Neutropenia (deficiency of white blood cells);
- Anaemia (lower-than-normal red bloods cells in the blood)
- Drop in blood pressure when standing from a lying position, low blood pressure
- Skin rash, skin inflammation
- Muscle stiffness
- Painful urination
- Sterile pyuria (excess of white blood cells in the urine)
- Tightening of the muscles that line the airways in your lungs (bronchospasms)
- Restlessness, mood changes
- Feeling you are going to become unconscious (faintness), feeling like your environment is spinning in circles (vertigo)
- Constriction of the pupil (miosis)
- A slower than normal heart rate or your heartbeat feels uncomfortable or unusual
- Dry mouth
- Sweating
- Drug withdrawal syndrome

Frequency unknown

- Buildup of acid in the body
- Hyperglycaemia (abnormally high levels of sugar in the blood)
- Anorexia (an eating disorder)
- Mood changes (anxiety, nervousness, feeling of high spirits, depression, sadness, feeling very unhappy, uneasy, or dissatisfied (dysphoria))
- Hallucinations and nightmares
- Headache, convulsions (fits)
- Vertigo (spinning sensation)
- Blurred or double vision or other changes in vision
- Rapid, strong heartbeat, very slow heartbeat
- Low blood pressure (on standing) (postural hypotension)
- Shortness of breath (dyspnoea)
- Nausea, vomiting, constipation, dry mouth, stomach cramps
- Spasm of the ureter or biliary tract
- Urticaria, pruritis, sweating, facial flushing, skin rashes
- Uncontrolled muscle movements and restlessness, muscle rigidity, twitching and weakness
- Kidney damage, difficulty in passing urine, passing less urine than usual, stinging or burning when emptying the bladder (dysuria)
- Reduced sexual drive or impotence (inability for a male to get an erection)
- Low body temperature, lack of energy or feeling unwell and weak (malaise), facial swelling

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via http:///www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store COGESIC

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C and protect from strong light in a well-closed container. Protect from moisture. Exposure to air should be minimal.

Store in the original package/container.

Do not store in a bathroom.

Do not use COGESIC after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COGESIC contains

The active substances in each tablet are 500 mg paracetamol and 8 mg codeine phosphate.

The other ingredients are: Gelatin, Indigo Carmine Lake E 132 IH (CI 73015:1), povidone, magnesium stearate, maize starch, modified starch and powdered sucrose.

What COGESIC looks like and contents of the pack

Flat blue tablet, scored on the one side.

COGESIC is packed in:

Cartons containing 2 x 10 tablets in push through blister packs.

White plastic (LDPE) Ziploc bag (Patient Ready Pack) containing 56 tablets.

Amber plastic (PVC) bottles containing 100, 500, and 1 000 tablets.

White plastic (HDPE) bottles containing 1 000 tablets.

Blue / green plastic buckets containing 5 000 tablets.

Name, Business Address and Telephone Number of the Holder of the Certificate of Registration

Oethmaan Biosims (Pty) Ltd

207A Sherwood House

Greenacres Office Park

c/o Victory and Rustenburg Roads

Victory Park

Johannesburg

2195

Telephone number: 011 433 0602

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PASIËNTINLIGTINGSBROSJUUR

SKEDULERINGSSTATUS:

S2

COGESIC, tablette

500 mg Parasetamol en 8 mg Kodeïenfosfaat

Bevat suiker (sukrose 20 mg per tablet)

Lees hierdie hele brosjure noukeurig deur omdat dit belangrike inligting vir jou bevat

COGESIC is beskikbaar sonder 'n doktersvoorskrif, vir jou om 'n ligte siekte te behandel.

Nietemin moet jy nog steeds COGESIC sorgvuldig gebruik om die beste resultate daaruit te kry.

•Hou hierdie brosjure. Jy mag dit weer moet lees.

•Moet COGESIC nie met enige ander persoon deel nie.

•Vra jou gesondheidsorgverskaffer of apteker vir meer inligting of advies as jy dit nodig het.

•Jy moet 'n dokter sien as jou simptome vererger of nie verbeter na 5 dae nie.

Wat is in hierdie brosjure

1. Wat COGESIC is en waarvoor dit gebruik word

2. Wat jy moet weet voordat jy COGESIC inneem

3. Hoe om COGESIC in te neem

4. Moontlike newe-effekte

5. Hoe om COGESIC te stoor

6. Inhoud van die verpakking en ander inligting

1. Wat COGESIC is en waarvoor dit gebruik word

COGESIC bevat parasetamol en kodeïenfosfaat.

Kodeïenfosfaat is 'n pynstillende middel wat behoort tot die groep van die opioïede wat op die sentrale senuweestelsel werk. Parasetamol, die ander aktiewe bestanddeel, het sentraalwerkende pynstillende effekte.

COGESIC word gebruik vir die verligting van ligte tot matige pyn en koors.

2. Wat jy moet weet voordat jy COGESIC inneem

Moenie COGESIC inneem nie:

- As jy allergies is vir parasetamol of kodeïenfosfaat, enige van die ander bestanddele genoem in afdeling 6.
- As jy ernstige asemhalingsprobleme het, byvoorbeeld chroniese bronchitis of emfisema of 'n asma-aanval het en veral as jy bloukleurige vel het (wegens swak sirkulasie) of jy het oormatige afskeidings uit die longe.
- As jy onlangs 'n operasie aan jou galblaas gehad het.
- As jy baie alkohol drink.
- As jy 'n kopbesering het of ly aan verhoogde druk op die brein.
- As jy medisyne neem genaamd monoamienoksidasie-inhibitors (MAOI's) wat gebruik word vir die behandeling van depressie, soos tranylcypromien en moclobemied, of dit die afgelope 14 dae voor behandeling met COGESIC geneem het.

Waarskuwings en voorbehoudsmaatreëls

Neem spesiale sorg met COGESIC:

- **Hierdie produk bevat parasetamol en jy moet nie meer as die aanbevole dosis neem nie. As jy 'n oordosis geneem het of vermoed dat jy 'n oordosis geneem het, kontak 'n dokter, hospitaal of gifsentrum onmiddellik.**

- **COGESIC bevat kodeïen en die oorskryding van die voorgeskrewe dosis, tesame met langdurige en aanhoudende gebruik van hierdie medisyne, kan lei tot afhanklikheid en verslawing.**
- Dose in oormaat van die aanbevole dosis kan ernstige lewerskade veroorsaak.
- Konsulteer jou dokter as geen verligting verkry word met die aanbevole dosis nie.
- Moenie vir langer as 5 dae aanhoudend gebruik sonder om jou dokter te raadpleeg nie.
- As jy ly aan lewer- of nierversaking, moet jy COGESIC onder mediese toesig neem.
- COGESIC bevat parasetamol. As jy allergies is vir parasetamol, kan jy 'n ernstige veluitslag kry nadat jy COGESIC ingeneem het. Jy moet ophou om COGESIC te gebruik by die eerste verskyning van 'n veluitslag of enige ander teken van allergie.
- Sê vir jou dokter as jy of voorheen 'n kombinasie van enige van die volgende simptome ervaar het: uitslag, rooi vel, blaasvorming van die lippe, oë en mond, velafval, hoë koors, griepagtige simptome, verhoogde vlakke van lewerensieme wat in bloedtoetse waargeneem word en 'n toename in 'n tipe wit bloedsel (eosinofilie) en vergrote limfknope (tekens van ernstige velreaksies, sien ook afdeling 4).
- Sê vir jou dokter as jy ly aan hipotiroïedisme, Addison se siekte, miastenie gravis (spierswakheid), geskeurde lewerfunksie, vergroting van die prostaatklier, skok, inflammatoriese of obstruktiewe dermversteurings.
- Verminder die dosis as jy baie swak of 'n bejaarde pasiënt is.
- Die toediening van COGESIC tydens arbeid kan asemhalingsprobleme by die pasgeborene veroorsaak.
- Kinders
  - Nie aanbeveel vir kinders jonger as 6 jaar nie.

Ander medisyne en COGESIC

Sê altyd vir jou gesondheidsorgverskaffer as jy enige ander medisyne neem. (Dit sluit alle aanvullende of tradisionele medisyne in.)

COGESIC moet nie saam met die volgende toegedien word nie:

- 'n Groep antidepressante medisyne genaamd Monoamine Oxidase (MAO) Inhibitors (soos moclobemied en tranylcypromien). Wanneer dit saam met COGESIC geneem word, kan dit diarree, takikardie (onreëlmatige hartklop), hiperhidrose (oormatige sweet), bewing, verwardheid, selfs koma veroorsaak.
- Voorsoorsigtigheid word aanbeveel wanneer die volgende medisyne saam met COGESIC gegee word:
- As jy alkohol, anestetika, ander pynstillers soos morfien, sowel as kalmerende medisyne soos benzodiazepiene (alprazolam, diazepam, lorazepam) of medisyne wat gebruik word vir geestesiektes en depressie (fenotiasiene en trisikliese antidepressante) saam met COGESIC neem, is daar 'n verhoogde risiko van dowwighede, asemhalingsprobleme (respiratoriese depressie), koma wat lewensgevaarlik kan wees.
- Sê vir jou dokter of apteker as jy enige van die volgende medisyne neem:
    - Rifampisien en isoniasied (medisyne vir TB)
    - Karbamasepien (vir epilepsie of aanvalle)
    - Metoklopramied en domperidoon (vir naarheid en braking)
    - Cholestyramien (om cholesterolvlakke te verlaag). Neem COGESIC een uur na die gebruik van cholestyramien.
    - Aspirien (vir koors en pyn)

COGESIC met voedsel en drank

Moenie alkohol drink tydens behandeling met COGESIC nie omdat die effekte van COGESIC en alkohol mekaar kan versterk.

Swangerskap en borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink jy dalk dat jy swanger is of beplan om 'n baba te kry, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorg professionele vir advies voordat jy hierdie medisyne inneem.

COGESIC moet nie gedurende swangerskap en borsvoeding geneem word nie. Gereelde gebruik gedurende swangerskap kan dwelmafhanklikheid in die fetus veroorsaak, wat lei tot onttrekkingsimptome in die pasgeborene. Die toediening van COGESIC tydens arbeid kan asemhalingsprobleme by die pasgeborene veroorsaak of kan lei tot vertraagde lediging van die maag van die moeder tydens arbeid, wat die risiko van longinfeksie in die moeder verhoog.

Die toediening van COGESIC tydens borsvoeding kan asemhalingsprobleme by die kind veroorsaak.

Bestuur en gebruik van masjiene

Moenie bestuur terwyl jy hierdie medisyne neem totdat jy weet hoe dit jou beïnvloed nie.

COGESIC kan jou vermoë om te bestuur beïnvloed omdat dit jou slaperig of duiselig kan maak.

As jy slaperig voel terwyl jy COGESIC neem, moenie bestuur nie, gebruik nie gereedskap of masjienerie nie.

COGESIC bevat suiker

As jou dokter vir jou gesê het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy COGESIC neem.

3. Hoe om COGESIC in te neem

Deel nie voorgeskrewe medisyne met enige ander persoon nie.

Neem altyd COGESIC presies soos beskryf in hierdie brosjure of jou dokter of apteker of verpleegster jou vertel het. Raadpleeg jou dokter of apteker of verpleegster as jy nie seker is nie.

Die gewone dosis is:

Volwassenes:

Neem 1 of 2 tablette elke 4 tot 6 uur.

Moenie meer as 8 tablette per dag neem nie.

Kinders ouer as 12 jaar: Een tablet elke vier tot ses uur.

Kinders van 6 tot 12 jaar: Half tot een tablet elke ses uur.

Moenie die aanbevole dosis oorskry nie.

Moenie vir langer as vyf (5) dae aanhoudend gebruik sonder om jou dokter te raadpleeg nie.

Praat met jou dokter of apteker of verpleegster as jy bejaard of fisies baie swak is, aangesien die dosis van COGESIC verlaag moet word.

Nie aanbeveel vir kinders jonger as 6 jaar nie.

Neem die tablette met 'n voldoende hoeveelheid vloeistof in (byvoorbeeld 'n glas water).

Moenie die tablette kou nie.

As jy meer COGESIC neem as wat jy moet

In die geval van oordosis, raadpleeg jou dokter of apteker. As een van die twee nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Onmiddellike mediese advies moet ingewin word in die geval van 'n oordosis, selfs as jy wel voel, weens die risiko van vertraagde, ernstige lewerskade as gevolg van te veel parasetamol.

Jou niere kan ook beskadig word in die afwesigheid van lewerskade.

As jy vergeet het om COGESIC in te neem

As jy 'n dosis vergeet het, neem dit in sodra jy dit onthou tensy dit amper tyd is vir jou volgende dosis. Moenie 'n dubbele dosis neem om vergeet individuele dosisse op te maak nie.

4. Moontlike newe-effekte:

COGESIC kan newe-effekte hê.

Nie alle newe-effekte wat vir COGESIC gerapporteer is, is ingesluit in hierdie brosjure nie. As jou algemene gesondheid verslegter of as jy enige ongewenste effekte ervaar terwyl jy COGESIC neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, stop die inname van COGESIC en sê vir jou dokter onmiddellik of gaan na die ongevalle-afdeling by die naaste hospitaal:

- Swel van die hande, voete, enkels, gesig, lippe en mond of keel, wat kan lei tot moeilikheid met sliktende of asemhaling;
- Uitslag of jeuk oor die hele liggaam

Dit is almal baie ernstige newe-effekte. As jy dit het, kan jy 'n ernstige reaksie op COGESIC gehad het. Jy mag dringende mediese aandag of hospitaalopname nodig hê.

Sê vir jou dokter onmiddellik of gaan na die ongevalle-afdeling by die naaste hospitaal as jy enige van die volgende opmerk: Die volgende newe-effekte kom dikwels voor:

- 'n Erge uitslag wat vinnig ontwikkel, met blase of velafval en moontlik blase in die mond (Stevens-Johnson-sindroom en toksiese epidermale nekrolose).
- 'n Kombinasie van enige van die volgende simptome: wydverspreide uitslag, hoë liggaamstemperatuur, lewer-ensieme-verhogings, bloed abnormaliteite (eosinofilie), vergrote limfknope en ander liggaamsorgane betrokkenheid (Medikasie-reaksie met

eosinofilie en sistemiese simptome wat ook bekend staan as DRESS of medikasie-hipersensitiwiteit sindroom).

- Aanvang van uitslag op 'n vaste plek op die liggaam elke keer as jy dieselfde medisyne neem (vaste medisyne-uitbarsting).
- Verhoogde druk op die brein.
- Verlies in liggaamstemperatuur.
- 'n Toestand van diep bewussynloosheid (koma).
- Inflammasie van die lewer, wat lei tot buikpyn, donker urine, bleek uitwerpsels, swakheid, uitputting.
- Minder urine as normaal vir jou.
- Buikpyn bo (buikpyn wat na jou rug straal), tederheid wanneer jy die buik raak, koors, vinnige pols, naarheid, braking is simptome van inflammasie van die pankreas.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag nodig hê.

Sê vir jou dokter as jy enige van die volgende opmerk:

<u>Gereelde newe-effekte</u>

- Verwarring, rusteloosheid
- Dowigheid, duiseligheid
- Naarheid, braking, hardlywigheid
- Gesigsrooiheid

<u>Minder gereelde newe-effekte</u>

- Agranulositose (minder witbloedselle in die liggaam)
- Trombositopenie (abnormaal lae bloedplaatjies)
- Leukopenie (laer-as-normale witbloedselle in die bloed)
- Pansitopenie (laer-as-normale rooi en witbloedselle in die bloed)

- Neutropenie (tekort aan witbloedselle);
- Anemie (laer-as-normale rooibloedselle in die bloed)
- Daling in bloeddruk wanneer jy van 'n lê-posisie opstaan, lae bloeddruk
- Veluitslag, velinflammasie
- Spierstyfheid
- Pynlike urinering
- Steriele pirie (oorvloed van witbloedselle in die urine)
- Aanspanning van die spiere wat die lugweë in jou longe bekleed (bronkospasmes)
- Rusteloosheid, humeursveranderinge
- Gevoel dat jy bewusteloos gaan word (duiseligheid), gevoel dat jou omgewing in sirkels draai (duiseligheid)
- Beperking van die pupil (miose)
- 'n Langsamer as normale hartklop of jou hartklop voel ongemaklik of ongewoon aan
- Droë mond
- Sweetaanval
- Dwelmaftreksindroom

Frekwensie onbekend

- Ophoping van suur in die liggaam
- Hiperglykemie (abnormaal hoë vlakke suiker in die bloed)
- Anoreksie ('n eetversteuring)
- Humorsveranderinge (angs, senuweeagtigheid, gevoel van hoë geeste, depressie, hartseer, baie ongelukkig, ongemaklik, of ontevrede (dysforie))
- Hallusinasies en nagmerries
- Kopseer, konvulsies (aanvalle)
- Duiseligheid (draaisensasie)

- Versteurde of dubbele sig of ander veranderinge in sig
- Vinnige, sterk hartklop, baie stadige hartklop
- Lae bloeddruk (by staan) (posturale hipotensie)
- Kortasemheid (dyspnoea)
- Naarheid, braking, hardlywigheid, droë mond, maagkramp
- Spasme van die ureter of galgang
- Netelroos, jeuk, sweet, gesigsrooiheid, veluitslag
- Onbeheerde spierbewegings en rusteloosheid, spierstyfheid, trilling en swakheid
- Nierskade, moeilikheid om urine te laat, minder urine as gewoonlik, steek of brand wanneer die blaas leeggemaak word (dysuria)
- Verlaagde seksuele begeerte of impotensie (onvermoë vir 'n man om 'n ereksie te kry)
- Lae liggaamstemperatuur, gebrek aan energie of gevoel van onwel en swak (malaise), gesigsuier

As jy enige newe-effekte opmerk wat nie in hierdie brosjure genoem word nie, laat weet asseblief jou dokter of apteker.

Verslag doen van newe-effekte

As jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Dit sluit enige moontlike newe-effekte wat nie in hierdie brosjure vermeld word nie, in. Jy kan ook newe-effekte rapporteer via http:///www.sahpra.org.za/Publications/Index/8.

Deur die newe-effekte te meld, kan jy help om meer inligting oor die veiligheid van hierdie medisyne te bekom.

5. Hoe om COGESIC te stoor

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Berg by of onder 25 °C en beskerm teen sterk lig in 'n goed geslote houer. Beskerm teen vog.

Blootstelling aan lug moet minimaal wees.

Berg in die oorspronklike verpakking/houer.

Moenie in 'n badkamer stoor nie.

Moet nie COGESIC gebruik na die vervaldatum wat op die karton aangedui word nie.

Gee alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat COGESIC bevat

Die aktiewe stowwe in elke tablet is 500 mg parasetamol en 8 mg kodeïenfosfaat. Die ander bestanddele is: Gelatien, Indigo Carmine Lake E 132 IH (CI 73015:1), povidoon, magnesiumstearaat, mieliestysel, gemodifiseerde stysel en verpoeierde sukrose.

Hoe COGESIC lyk en wat die verpakking bevat

Plat blou tablet, met kerf aan die eenkant.

Kartonne wat 2 x 10 tablette in deurdruk blisterpakkies bevat.

Wit plastiek (LDPE) Ziploc sak (Pasiënt Gereed Pak) wat 56 tablette bevat.

Amber plastiek (PVC) bottels wat 100, 500 en 1 000 tablette bevat.

Wit plastiek (HDPE) bottels wat 1 000 tablette bevat.

Blou/groen plastiekemmers wat 5 000 tablette bevat.

Naam, besigheidsadres en telefoonnommer van die houer van die registrasiesertifikaat

Oethmaan Biosims (Edms.) Bpk

207A Sherwood Huis

Greenacres Office Park

h/v Victory- en Rustenburgweg

Victory Park

Johannesburg

2195

Telefoonnommer: 011 433 0602

Hierdie pamflet is laas hersien in

27 March 2024

Registrasienommer

X/2.8/109