Front Side

350 mm

335 mm

CARBITHOID
5/10/15/20 mg
PM04318301

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

CARBITHOID 5 mg (Tablet)
Carbimazole 5 mg.
Contains sugar (48,588 mg of lactose monohydrate).

CARBITHOID 10 mg (Tablet)
Carbimazole 10 mg.
Contains sugar (97,175 mg of lactose monohydrate).

CARBITHOID 15 mg (Tablet)
Carbimazole 15 mg.
Contains sugar (145,764 mg of lactose monohydrate).

CARBITHOID 20 mg (Tablet)
Carbimazole 20 mg.
Contains sugar (194,350 mg of lactose monohydrate).

Read all of this leaflet carefully before you start taking CARBITHOID
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **CARBITHOID** have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **CARBITHOID** is and what it is used for
2. What you need to know before you take **CARBITHOID**
3. How to take **CARBITHOID**
4. Possible side effects
5. How to store **CARBITHOID**
6. Contents of the pack and other information

1. What CARBITHOID is and what it is used for

CARBITHOID belongs to a group of medicines called 'anti-thyroid' medicines. It is used for adults and children with an overactive thyroid gland (called 'hyperthyroidism').
- It works by reducing the amount of thyroid hormones made in your thyroid gland.
- It can be used on its own, or with other treatments for an overactive thyroid gland.
- It can also be used before part of the thyroid gland has been removed by surgery. It helps the thyroid gland work properly before the surgery.

2. What you need to know before you take CARBITHOID

Do not take CARBITHOID if:
- If you are hypersensitive (allergic) to carbimazole or any of the other ingredients of **CARBITHOID** tablets (listed in Section 6).
- If you are hypersensitive (allergic) to other anti-thyroid medicines such as thiamazole, methimazole or propylthiouracil.
- If you are breastfeeding
- If you have a severe liver disorder
- If you have a serious blood disorder
- if you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.
- if you suffer from tracheal obstruction, a life-threatening emergency that requires immediate therapy, manifests itself by cough, wheezing, exertional dyspnoea, haemoptysis, and respiratory arrest.

Do not take **CARBITHOID** tablets if any of the above apply to you. If you are not sure talk to your doctor or pharmacist before taking **CARBITHOID.**

Warnings and precautions
Talk to your doctor or pharmacist before taking **CARBITHOID**
Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:
- If you have bone marrow depression. This may be characterised by the presence of mouth ulcers, sore throat, bruising, bleeding, fever, a general sense of feeling unwell and infection.
- If you have mild or moderate liver problems
- If you suffer from low total amount of red blood cells (anaemia) or abnormal levels of platelets (thrombocytopenia).
- If you start having a sore throat, bruising or bleeding, mouth sores, fever and general weakness. You should immediately stop taking **CARBITHOID** and seek medical advice immediately.
- If you are receiving radio-iodine (for thyroid problems)
- If you are of child bearing potential
- If you are allergic to thiamazole, methimazole or propylthiouracil (other thyroid medications)
- If you are lactose intolerant or have any other lactose deficiency.
- If you have a swelling in your neck called an 'intrathoracic goitre'.
- If you are pregnant, think you may become pregnant or are trying to become pregnant
- If you are unable to comply with the instructions for use or cannot be monitored regularly.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking **CARBITHOID.**

Other medicines and CARBITHOID
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Inform your doctor if you are taking any of the following medicines:
- Medicines to thin your blood or to stop clotting
- A medicine to help your breathing called 'theophylline'
- Steroids such as prednisolone
- An antibiotic called erythromycin
- A medicine for heart failure called digitalis
- Medicines for high blood pressure called beta-blockers.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking CARBITHOID.

CARBITHOID with food and drink:
CARBITHOID may be taken with or without food in the morning or evening.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
CARBITHOID can cause harm to an unborn baby.
If you could get pregnant, use reliable contraception from the time you start treatment and during treatment.
Your treatment with **CARBITHOID** may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

Breastfeeding
Do not breastfeed if you are taking **CARBITHOID.** This is because small amounts may pass into the mother's milk.

Driving and using machines
You can drive when taking **CARBITHOID**, but do not drive until you know how it affects you.

Important information about some of the ingredients of CARBITHOID
Tell your doctor if you have galactosaemia (a condition in which the body is unable to use the sugar galactose) or glucose / galactose malabsorption syndrome (a condition in which lactose (milk sugar) and other carbohydrates which contain the sugars glucose and galactose cannot be digested by the body). **CARBITHOID** contains lactose (milk sugar) and is unsuitable for patients with these disorders.
Discuss with your doctor, nurse or pharmacist if you are unsure about anything.
This medicine contains less than 1 mmol sodium per tablet, that is to say essentially 'sodium-free'

3. How to take CARBITHOID

Do not share medicines prescribed for you with any other person.
Always take **CARBITHOID** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
Take **CARBITHOID** by mouth. Swallow the tablets whole with a drink of water. The tablets you take each day may be split into two (morning and evening) or three (morning, afternoon and night). Ask your doctor or pharmacist if you are unsure.

The usual dose is:
Adults
10 mg to 60 mg each day according to the severity of the disease. This dose should be slowly reduced to the smallest amount which will control the disease. Your illness will usually start to improve within one to three weeks. However, it usually takes four to eight weeks to have full benefit from your treatment.
- When your illness is controlled, your doctor will gradually lower your dose according to your needs.
- Do not change your dose without talking to your doctor first.

You may need to keep taking **CARBITHOID** for several months to keep control of your thyroid gland. Your doctor will decide when treatment can be stopped. Your doctor may ask you to have occasional blood tests to see how well your treatment is working. Your doctor may decide to add an additional tablet to help control your condition.

If you take more CARBITHOID than you should
In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.
Overdosage or accidental poisoning may result in hypothyroidism and goitre.

If you forget to take CARBITHOID:
If you forget a dose, take it as soon as you remember. If it is time for your next dose, take both doses together.

If you stop taking CARBITHOID:
Your doctor will tell you how long your treatment with **CARBITHOID** will last. If you stop taking **CARBITHOID** without checking with your doctor first, your illness may worsen.

4. Possible side effects

CARBITHOID can have side effects.
Not all side effects reported for CARBITHOID 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 healthcare professional for advice.
If any of the following happens, stop taking CARBITHOID and tell your doctor immediately or go to the casualty department at your nearest hospital.

swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing,
- lung problems, with symptoms that include shortness of breath or a cough
- kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine,
- sore throat,
- mouth ulcers,
- high temperature or fever,
- significant tiredness,
- increased bruising or bleeding tendency,
- you are feeling generally unwell or think that you may have an infection,
- deadly skin disease (e.g. Stevens-Johnson Syndrome). Symptoms of these will include cough, aching, headaches, fever, red rash across the face and the trunk of the body.

These are all very serious side effects. If you have them, you may have had a serious reaction to **CARBITHOID.** 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:
- muscle pain or weakness,
- yellowing of your skin or the whites of your eyes,
- nerve problems, with symptoms that include pain, pins-and-needles and numbness,
- swollen lymph nodes or swelling of the glands in your mouth,
- feeling faint (low blood sugar)
- These could be signs of muscle problems, jaundice or inflammation of the liver and under medical supervision your doctor may want you to stop taking the medicine and carry out some blood tests on you. **These are all serious side effects.** You may need urgent medical attention.

CARBITHOID can cause bone marrow depression which causes a reduction in the number of blood cells and reduces the ability to fight infection. If it is not treated as soon as it is detected the condition can become life-threatening. Your doctor should carry out tests to check for bone marrow depression before restarting your treatment.
Check with your doctor if any of the following side effects worry you:
Frequent side effects may include:
- **Headaches**
- Nausea, vomiting and stomach discomfort
- Rash, itchy skin, darkening of the skin and hives

Less frequent side effects
- Bone marrow depression. This may be characterised by the presence of mouth ulcers, sore throat, bruising, bleeding, fever, a general sense of feeling unwell and infection.
- Sudden drop in blood sugar levels
- Abnormal sensations such as tingling, pricking, chilling, burning and numbness, swelling of the nerve and damage of the nerves
- Yellowing of the skin, abnormal liver function tests, swelling of the liver
- Stevens-Johnson syndrome which is characterised by flu-like symptoms which appear first and painful rash that spreads, followed by blistering of the skin. Skin redness and itchiness.
- Muscle aches, joint pain
- Fever and general sense of feeling unwell
- Bruising of the skin

Frequency unknown
- Low white and red blood cell counts and low blood platelet count
- Bleeding and swelling of the blood vessels
- Taste disturbances, swelling of the salivary glands
- Abnormal hair loss
- Lupus-like syndrome characterised by muscle aches, joint pain, tiredness, flu-like symptoms, fever, swelling around the lungs and heart and laboratory test abnormalities
- Swelling of the kidneys
- Fever

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem 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 **CARBITHOID.**

5. How to store CARBITHOID

Store at or below 25 °C.
The HDPE containers must be kept tightly closed.
Keep the blister pack in the carton until required for use.
KEEP OUT OF REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What CARBITHOID contains

CARBITHOID 5 mg tablet:
Each tablet contains:
5 mg of Carbimazole.

CARBITHOID 10 mg tablet:
Each tablet contains:
10 mg of Carbimazole.

CARBITHOID 15 mg tablet:
Each tablet contains:
15 mg of Carbimazole.

CARBITHOID 20 mg tablet:
Each tablet contains:
20 mg of Carbimazole.

Other ingredients include:
Lactose monohydrate, ferric oxide red, croscarmellose sodium, magnesium stearate.

What CARBITHOID look like and contents of the pack
CARBITHOID 5 mg
Pink, mottled, round, biconvex uncoated tablets, debossed with "5" on one side and plain on other side.
CARBITHOID 10 mg
Pink, mottled, round, biconvex uncoated tablets, debossed with "10" on one side and plain on other side.
CARBITHOID 15 mg
Pink, mottled, round, biconvex uncoated tablets, debossed with "15" on one side and plain on other side.
CARBITHOID 20 mg
Pink, mottled, round, biconvex uncoated tablets, debossed with "2 and 0" separated by breakline on one side and plain on other side.
HDPE container
Tablets are packed in round white opaque HDPE container closed with child resistant closure with pulp and heat seal liner with polyester coil. Pack sizes include 100 tablets.

Blister pack:
Tablets are packed in blister pack of white opaque PVC as a forming material and Aluminium foil as the lidding material. Pack sizes include 10 tablets.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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Registration number
CARBITHOID 5 mg: 56/21.12/0446.442
CARBITHOID 10 mg: 56/21.12/0447.443
CARBITHOID 15 mg: 56/21.12/0448.444
CARBITHOID 20 mg: 56/21.12/0449.445

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

Back Side

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

CARBITHOID 5 mg (Tablet)
Karbimasool 5 mg.
Bevat suiker (48,588 mg van laktosemonohidraat).

CARBITHOID 10 mg (Tablet)
Karbimasool 10 mg
Bevat suiker (97,175 mg van laktosemonohidraat)

CARBITHOID 15 mg (Tablet)
Karbimasool 15 mg
Bevat suiker (145,764 mg van laktosemonohidraat)

CARBITHOID 20 mg (Tablet)
Karbimasool 20 mg.
Bevat suiker (194,350 mg van laktosemonohidraat).

Lees hierdie hele inligtingstuk sorgvuldig voordat jy CARBITHOID begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **CARBITHOID** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie.

Dit kan skadelik wees vir hulle, selfs al is hulle simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **CARBITHOID** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **CARBITHOID** neem
3. Hoe om **CARBITHOID** te gebruik
4. Moontlike newe-effekte
5. Hoe om **CARBITHOID** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat CARBITHOID is en waarvoor dit gebruik word

CARBITHOID behoort aan 'n groep medisyne wat anti-tiroïedmedisyne genoem word. Dit word gebruik in volwassenes en kinders met 'n oraktiewe tiroïedklier (genoem hipertireose).
- Dit werk deur die hoeveelheid tiroïedhormone wat in jou tiroïedklier gemaak word, te verminder.
- Dit kan op sy eie gebruik word, of saam met ander behandelings vir 'n oraktiewe tiroïedklier.
- Dit kan ook gebruik word voordat 'n deel van die tiroïedklier deur chirurgie verwyder word. Dit help om die tiroïedklier behoorlik te laat werk voor die operasie.

2. Wat jy behoort te weet voordat jy CARBITHOID neem

Moet nie CARBITHOID neem nie:
- Indien jy hipersensitief (allergies) vir karbimasool of enige van die ander bestanddele van **CARBITHOID** tablette is (gelys in Afdeling 6).
- Indien jy hipersensitief (allergies) vir ander anti-tiroïedmedisyne soos tiamasool, metimasool of propiltiourasiel is.
- Indien jy borsvoed
- Indien jy 'n ernstige lewerafwyking het
- Indien jy 'n ernstige bloedafwyking het
- Indien jy in die verlede ontsteking van die pankreas gehad het (akute pankreatitis) na toediening van karbimasool of tiamasool.
- Indien jy aan trageale obstruksie ly, 'n lewensgevaarlike noodgeval wat onmiddellike behandeling vereis, wat manifesteer deur hoes, asemgeflui, inspanningsdispnee, bloedhoes en respiratoriese stilstand.

Moet nie **CARBITHOID** tablette neem nie, indien enige van die bogenoemde op jou van toepassing is. Indien jy nie seker is nie, praat met jou dokter of apteker voordat jy **CARBITHOID** begin gebruik.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat **CARBITHOID** geneem word
Vertel asseblief jou dokter as jy enige ander toestand of siekte het, aangesien jou dokter dit dalk in ag moet neem. Vertel veral jou dokter:
- Indien jy beenmurgonderdrukking het. Dit kan gekenmerk word deur die teenwoordigheid van mondsere, seer keel, knousplekke, bloeding, koors, 'n algemene gevoel van ongesteldheid en infeksie.
- Indien jy ligte of matige lewerprobleme het
- Indien jy aan 'n lae totale aantal rooibloedselle (anemie) of abnormale vlakke van bloedplaatjies (trombositopenie) ly.
- Indien jy 'n seer keel, knousplekke of bloeding, mondsere, koors en algemene swakheid begin kry. Jy moet onmiddellik ophou om **CARBITHOID** te gebruik en dadelik mediese advies inwin.
- Indien jy radio-jodium ontvang (vir skildkliersprobleme)
- Indien jy van kinderbarende potensiaal is
- Indien jy allergies is vir tiamasool, metimasool of propiltiourasiel (ander skildkliermedikasie)
- Indien jy laktose-onverdraagsaam is of enige ander laktosstekort het.
- Indien jy 'n swelling in jou nek het, wat 'n 'intratorakale goiter' genoem word.
- Indien jy swanger is, dink dat jy swanger kan raak, of probeer om swanger te raak
- Indien jy nie die gebruiksaanwysings kan nakom nie of nie gereeld gemonitor kan word nie.

Indien jy nie seker is of die bogenoemde op jou van toepassing is nie, praat dan met jou dokter of apteker voordat jy **CARBITHOID** neem.

Ander medisyne en CARBITHOID
Noem altyd aan jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Lig jou dokter in indien jy enige van die volgende medisyne neem:
- Medisyne om jou bloed te verdun of om stolling te stop
- 'n Medisyne om jou te help met asemhaling, genaamd "teofilliën"
- Steroïede soos prednisoloon
- 'n Antibiotika genaamd eritromisien
- 'n Medisyne vir hartversaking wat digitalis genoem word
- Medisyne vir hoë bloeddruk naamlik beta-blokkers.

Indien enige van die bogenoemde op jou van toepassing is (of indien jy nie seker is nie), praat met jou dokter of apteker voordat jy **CARBITHOID** neem.

CARBITHOID met voedsel en drank:
CARBITHOID kan in die oggend of in die aand met, of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy swanger kan wees, of beplan om 'n baba te hê, vra jou dokter of apteker vir advies voordat jy hierdie medisyne neem.

Swangerskap
CARBITHOID kan skade aan 'n ongebore baba veroorsaak.
Indien jy swanger kan raak, gebruik betroubare voorbehoeding vanaf die tyd wat jy met behandeling begin en tydens behandeling.
Jou behandeling met **CARBITHOID** sal moontlik tydens swangerskap voortgesit moet word indien die potensiële voordeel groter is as die potensiële risiko vir jou en jou ongebore baba.

Borsvoeding
Moet nie borsvoed indien jy **CARBITHOID** gebruik nie. Dit is omdat klein hoeveelhede in die moedersmelk kan oorgaan.

Bestuur en gebruik van masjinerie
Jy kan bestuur wanneer jy **CARBITHOID** neem, maar moet nie bestuur voordat jy weet hoe dit jou affekteer nie.

Belangrike inligting oor sommige van die bestanddele van CARBITHOID
Vertel jou dokter as jy galaktosemie het ('n toestand waarin die liggaam nie in staat is om die suiker galaktose te kan gebruik nie) of glukose / galaktose wanabsorpsie sindroom ('n toestand waarin laktose (melksuiker) en ander koolhidrate wat die suikers glukose en galaktose bevat, nie deur die liggaam kan verteer word nie). **CARBITHOID** bevat laktose (melksuiker) en is nie geskik vir pasiënte met hierdie afwykings nie.
Bespreek met jou dokter, verpleegkundige of apteker indien jy onseker is oor enigiets.
Hierdie medisyne bevat minder as 1 mmol natrium per tablet, dit wil sê in wese 'natriumvry'.

3. Hoe om CARBITHOID te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **CARBITHOID** presies soos wat jou dokter vir jou gesê het. Bevestig met jou dokter of apteker indien jy nie seker is nie.
Neem **CARBITHOID** per mond. Sluk die tablette heel met 'n sluk water. Die tablette wat jy elke dag neem, kan in twee (oggend en aand) of drie (oggend, middag en aand) verdeel word. Vra vir jou dokter of apteker indien jy nie seker is nie.

Die gewone dosis is:
Volwassenes
10 mg tot 60 mg elke dag volgens die erns van die siekte. Hierdie dosis moet geleidelik verminder word tot die kleinste hoeveelheid wat die siekte sal beheer. Jou siekte sal gewoonlik binne een tot drie weke begin verbeter. Dit neem egter gewoonlik vier tot agt weke om volle voordeel uit jou behandeling te kry.
- Indien jou siekte onder beheer is, sal jou dokter jou dosis geleidelik verminder volgens jou behoeftes.
- Moet nie jou dosis verander sonder om eers met jou dokter te praat nie.

Jy sal moontlik **CARBITHOID** vir 'n paar maande moet aanhou gebruik, om die beheer van jou skildklier te behou. Jou dokter sal besluit wanneer die behandeling gestaak kan word. Jou dokter kan jou vra om nou en dan bloedtoetse te ondergaan, om te sien hoe goed jou behandeling werk. Jou dokter kan besluit om 'n addisionele tablet by te voeg om te help om jou toestand te beheer.

Indien jy meer CARBITHOID neem as wat jy behoort te neem
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.
Oordosering of toevallige vergiftiging kan lei tot hipotireose en skildkliergeswel.

Indien jy vergeet om CARBITHOID te neem:
Indien jy 'n dosis vergeet, neem dit sodra jy daarvan onthou. Indien dit tyd is vir jou volgende dosis, neem beide dosisse saam.

Indien jy ophou om CARBITHOID te neem:
Jou dokter sal vir jou sê hoe lank jou behandeling met CARBITHOID sal duur. Indien jy ophou om CARBITHOID te neem, sonder om eers met jou dokter te bevestig, kan jou siekte vererger.

4. Moontlike newe-effekte

CARBITHOID kan newe-effekte hê.
Nie alle newe-effekte wat vir CARBITHOID aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid vererger of indien jy enige ongewenste effekte ervaar terwyl jy hierdie medisyne gebruik, konsulteer asseblief met jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om CARBITHOID te neem en vertel onmiddellik jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, tong en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak,
- longprobleme, met simptome wat kort van asem of 'n hoes insluit
- nierprobleme, met simptome wat 'n vermindering in die hoeveelheid urine wat gepasseer word, vloeistof retensie en bloed in die urine insluit,
- seer keel,
- mondsere,
- hoë temperatuur of koors,
- uitsonderlike moegheid,
- meer knousplekke of neiging tot bloeding,
- jy voel oor die algemeen nie lekker nie of dink dat jy dalk 'n infeksie het,
- dodelike velsiekte (bv. Stevens-Johnson-sindroom). Simptome hiervan sluit in hoes, pyn, hoofpyne, koors, rooi uitslag oor die gesig en die romp van die liggaam.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **CARBITHOID** gehad. Jy mag dalk dringende mediese aandag of hospitalisering benodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- spierpyn of swakheid,
- vergeling van jou vel of die wit van jou oë,
- senuweeprobleme, met simptome wat pyn, naalde-en-speld gevoel en gevoelloosheid insluit,
- geswelde limfknope of swelling van die kliere in jou mond,
- voel ligkoofdig (lae bloedsuiker)

Hierdie kan tekens wees van spierprobleme, geelsug of ontsteking van die lewer, en onder mediese toesig sal jou dokter dalk wil hê dat jy moet ophou om die medisyne te neem en 'n paar bloedtoetse op jou uitvoer. Hierdie is alles ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.
CARBITHOID kan beenmurgonderdrukking veroorsaak, wat 'n vermindering in die aantal bloedselle en die vermoë om infeksie te beveg, veroorsaak. Indien dit nie behandel word sodra dit opgespoor word nie, kan die toestand lewensbedreigend word. Jou dokter moet toetse uitvoer om te kyk vir beenmurgonderdrukking voordat jy weer met jou behandeling begin.
Raadpleeg jou dokter indien enige van die volgende newe-effekte jou bekommerd maak:
Gereelde newe-effekte kan insluit:
- Hoofpyne
- Naarheid, braking en omgekrapte maag
- Uitslag, jeukende vel, verdonkering van die vel en galbulte

Minder gereelde newe-effekte
- Beenmurgonderdrukking. Dit kan gekenmerk word deur die teenwoordigheid van mondsere, seer keel, knousplekke, bloeding, koors, 'n algemene gevoel van ongesteldheid en infeksie.
- Skielike daling in bloedsuikervlakke
- Abnormale sensasies soos tinteling, prikkeling, koue rillings, brandgevoel en gevoelloosheid, swelling van die senuwee en skade aan die senuwees
- Vergeling van die vel, abnormale lewerfunksietoetse, swelling van die lewer
- Stevens-Johnson-sindroom wat gekenmerk word deur griepagtige simptome wat eerste voorkom en pynlike uitslag wat versprei, gevolg deur blase van die vel. Velrooiheid en jeukerigheid.
- Spierpyne, gewrigspyn
- Koors en algemene gevoel van ongesteldheid
- Kneusing van die vel

Frekwensie onbekend
- Lae wit- en rooibloedseltellings en lae bloedplaatjie telling
- Bloeding en swelling van die bloedvate
- Smaakstoornisse, swelling van die speeksekkliere
- Abnormale haarverlies
- Lupusagtige sindroom wat gekenmerk word deur spierpyne, gewrigspyn, moegheid, griepagtige simptome, koors, swelling rondom die longe en hart- en laboratoriumtoetsafwykings
- Swelling van die niere
- Koors

Indien jy enige newe-effek opmerk wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction & Quality Problem Reporting Form"**, wat aanlyn gevind kan word onder SAHPRAse publikasies: https://www.sahpra.org.za/Publications/Index/8
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **CARBITHOID**.

5. Hoe om CARBITHOID te bewaar

Bewaar by of benede 25°C.
Die HDPE-houers moet styf gesluit gehou word.
Hou die stulpstroke in die karton totdat dit benodig word vir gebruik.
HOU BUITE DIE BEREIK VAN KINDERS.
Moet nie in die badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulpstrook/etiket/karton/bottel aangedui is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat CARBITHOID bevat

CARBITHOID 5 mg tablet:
Elke tablet bevat:
5 mg van Karbimasool.

CARBITHOID 10 mg tablet:
Elke tablet bevat:
10 mg van Karbimasool.

CARBITHOID 15 mg tablet:
Elke tablet bevat:
15 mg van Karbimasool.

CARBITHOID 20 mg tablet:
Elke tablet bevat:
20 mg van Karbimasool.

Ander bestanddele sluit in:
Laktosemonohidraat, rooi ferri-oksied, natriumkroskarmellose, magnesiumstearaat.

Hoe CARBITHOID lyk en inhoud van die pak
CARBITHOID 5 mg
Plenk, gevlekte, ronde bikonvekse, onbedekte tablette, gebosseleer met "5" aan die een kant en glad aan die ander kant.
CARBITHOID 10 mg
Plenk, gevlekte, ronde bikonvekse, onbedekte tablette, gebosseleer met "10" aan die een kant en glad aan die ander kant.
CARBITHOID 15 mg
Plenk, gevlekte, ronde bikonvekse onbedekte tablette, gebosseleer met "15" aan die een kant en glad aan die ander kant.
CARBITHOID 20 mg
Plenk, gevlekte, ronde, bikonvekse onbedekte tablette, gebosseleer met "2 en 0" geskei deur 'n breeklyn aan die een kant en glad aan die ander kant.
HDPE-houer
Tablette word verpak in ronde wit ondeursigtige HDPE-houer, gesluit met kinderbestande sluiting met pulp en hitte seëlvoering met poliëstersponsel. Verpakkingsgroottes sluit 100 tablette in.
Stulpstrookverpakking:
Tablette word verpak in stulpstrookpakke van wit ondeursigtige PVC as vormingsmateriaal en aluminiumfoelie as die dekmateriaal. Verpakkingsgroottes sluit 10 tablette in.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid-Afrika

Hierdie inligtingstuk was voorheen hersien in
28 Mei 2024

Registrasienommer
CARBITHOID 5 mg: S6/21.12/0446.442
CARBITHOID **10 mg:** S6/21.12/0447.443
CARBITHOID 15 mg: S6/21.12/0448.444
CARBITHOID 20 mg: S6/21.12/0449.445

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

350 mm

335 mm

MASTER COPY

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: CARBITHOID 5/10/15/20 mg (Carbimazole tablets 5/10/15/20 mg)	
2. Country: South Africa	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 350 (L) x 335 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM04318301
11. Artwork has been made: Actual Size	12. Pharma code No.: 33884 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision No: 00	16. A/W File name:Z:\Carbimazole\SA Private Market\01\Carbimazole Tablets - PIL - PM04318301.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
24/06/2024	Vanita Rajool	24/06/24	28/06/24		02/07/24

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM04318301		

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