

**RE: CARBIMAZOLE 5MG TABLETS**

This notification is sent by LINK to inform your organisation that **CARBIMAZOLE LINK, carbimazole 5 mg tablets, AUST R 254132** is currently unavailable due to manufacturing delays. To cover this shortage, LINK has arranged the supply of an alternative product currently registered in Germany. This is called **Carbimazol ARISTO 5mg tablets**.

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**Comparison table**

Trade name	Carbimazol ARISTO	CARBIMAZOLE LINK
<b>Active ingredient</b>	Carbimazole 5mg/tablet	Carbimazole 5mg/tablet
<b>Excipients</b>	mannitol, microcrystalline cellulose, maize starch, citric acid, sodium starch glycollate type A, magnesium stearate	mannitol, microcrystalline cellulose, maize starch, citric acid, sodium starch glycollate type A, magnesium stearate
<b>Tablet appearance</b>	white, round tablet with a score line on one side	white, round tablet with a score line on one side
<b>Presentation</b>	blister pack of 100 tablet	blister pack of 100 tablet
<b>Labelling</b>	Approved for German market	Approved for Australian market

Despite similarities between **Carbimazol ARISTO** and **CARBIMAZOLE LINK**, **Carbimazol ARISTO** has not been approved for general marketing by the TGA and is being supplied under an approval under section 19A of the *Therapeutic Goods Act (1989)* until **01 December 2016**.

Please disregard the patient leaflet for **Carbimazol ARISTO** contained within the pack and refer to the Australian Consumer Medicine Information for **CARBIMAZOLE LINK** provided with this pack. This is also available from the pharmacist and is on the TGA website at <https://www.ebs.tga.gov.au>

CARBIMAZOLE LINK is contraindicated in: patients with a previous history of adverse reactions to carbimazole or to any of the excipients in the composition; serious pre-existing haematological conditions, severe hepatic insufficiency; and should be given with caution if there is any degree of tracheal obstruction, as high dosage may increase thyroid enlargement and aggravate obstructive symptoms.

Please report any adverse events to the TGA or to Link Healthcare on 02 8401 9771 or [medinfo@linkhealthcare.com.au](mailto:medinfo@linkhealthcare.com.au)

Availability

To order the product, and for supply details, please contact your wholesaler or Link Healthcare Customer Service via phone on 1800 181 060 or via email on [customerservice@linkhealthcare.com.au](mailto:customerservice@linkhealthcare.com.au)

Link Healthcare is committed to patient care and safety and is doing their utmost to ensure normal supply is resumed as soon as possible.



# Carbimazole Link<sup>®</sup>

(car-bim-a-zol)

*carbimazole*

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about Carbimazole Link tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Carbimazole Link against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What Carbimazole Link is used for

Carbimazole Link contains the active ingredient carbimazole.

Carbimazole Link is used to treat hyperthyroidism or overactive thyroid gland (a condition where the thyroid gland produces too much thyroid hormones).

There are different types of medicines used to treat hyperthyroidism.

Carbimazole Link belongs to a group of medicines called anti-hyperthyroidism agents. These medicines work by reducing the production of thyroid hormones.

Your doctor, however, may have prescribed Carbimazole Link for another purpose.

**Ask your doctor if you have any questions about why Carbimazole Link has been prescribed for you.**

Carbimazole Link is not addictive.

This medicine is available only with a doctor's prescription.

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### Before you take Carbimazole Link

*When you must not take it*

**Do not take Carbimazole Link if you have had an allergic reaction to Carbimazole Link or any ingredients listed at the end of this leaflet.**

**Do not take Carbimazole Link if you have a previous history of adverse reactions to carbimazole.**

**Do not take Carbimazole Link if you have an airway obstruction condition.**

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

Carbimazole Link passes into breast milk. Your doctor will discuss the risks and benefits of using Carbimazole Link if you are breastfeeding.

**Do not take Carbimazole Link if you have a serious blood disorder.**

**Do not take Carbimazole Link if you have a severe liver disorder.**

**Do not take Carbimazole Link if:**

- the package is torn or shows signs of tampering
- the expiry date (EXP) printed on the pack has passed

If you take this medicine after the expiry date has passed, it may not work as well.

**Driving and using machines.**

You can drive when taking Carbimazole Link, but do not drive until you know how it affects you.

**If you are not sure if you should be taking Carbimazole Link, talk to your doctor.**

*Before you start to take it*

**Tell your doctor if you are pregnant or plan to become pregnant.**

Carbimazole Link is generally not recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

**Tell your doctor if you have any other health problems, especially the following:**

- mild or moderate liver disorder
- blood disorder.

**Tell your doctor if you are currently being given a course of iodine as part of your treatment.**

**Tell your doctor you are allergic to any other medicines, foods, dyes or preservatives.**

If you have not told your doctor about any of the above, tell them before you start taking Carbimazole Link.

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with Carbimazole Link.

These include:

- iodine or any preparation containing iodine
- theophylline used to treat asthma or breathing problems
- medicines called anticoagulants, which are used to thin blood e.g. warfarin.

These medicines may be affected by Carbimazole Link, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Carbimazole Link.

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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## **How to take Carbimazole Link**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

### *How much to take*

**Take Carbimazole Link exactly as your doctor has prescribed.**

Your doctor will tell you how many Carbimazole Link tablets to take each day.

Your dose of Carbimazole Link may also change from time to time, according to your progress.

**Be sure to keep your appointments with your doctor so that your progress can be checked.**

### *How to take Carbimazole Link*

**Swallow tablets whole with a glass of water.**

**Do not chew the tablets.**

### *When to take Carbimazole Link*

**Take your Carbimazole Link at about the same time each day.**

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the tablets.

### *How long to take Carbimazole Link*

**Continue taking Carbimazole Link until your doctor tells you to stop.**

### *If you forget to take Carbimazole Link*

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

Do not take a double dose to make up for the dose that you missed.

**Otherwise, take it as soon as you remember and then go back to taking it as you would normally.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering your dose, ask your pharmacist for some hints.**

### *In case of an overdose*

**Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Carbimazole Link. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

The following are some symptoms which may or may not occur:

- skin rash
- fever
- severe chills
- sore throat
- mouth ulcers

**Keep telephone numbers for these places handy.**

**If you are not sure what to do, contact your doctor or pharmacist.**

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## **While you are taking Carbimazole Link**

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### *Things you must do*

**Tell all doctors, dentists and pharmacists who are treating you that you are taking Carbimazole Link.**

**Tell your doctor if you become pregnant while taking Carbimazole Link.**

**Tell your doctor that you are taking Carbimazole Link if you are going to have any laboratory tests.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**Tell your doctor if you feel the tablets are not helping your condition.**

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor may want to do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

### *Things you must not do*

**Do not stop taking Carbimazole Link or change the dose without first checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

**Do not give Carbimazole Link to anyone else even if they have the same condition as you.**

**Do not use Carbimazole Link to treat other complaints unless your doctor says to.**

**Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Carbimazole Link affects you.**

However, Carbimazole Link is not expected to affect your ability to drive a car or operate machinery.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Carbimazole Link.**

Carbimazole Link helps most people with hyperthyroidism but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- nausea
- headache
- stomach upsets
- skin rashes
- pain in joints
- hair loss
- itchiness
- hives (nettle rash)
- loss of taste
- angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat
- lung problems, with symptoms that include shortness of breath or cough
- kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine.

These are the more common side effects of Carbimazole Link.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- sore throats
- mouth ulcers
- high temperature or fever

- increased bruising or bleeding tendency
- you are feeling generally unwell or think that you may have an infection.

**Stop taking Carbimazole Link until you have consulted your doctor.**

Some tests should be performed to check for bone marrow depression before restarting your treatment. Bone marrow depression 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.

**If you experience muscle aches or pains or notice yellowing of your skin or the whites of your eyes consult your doctor immediately.**

Carbimazole Link can affect the liver (causing jaundice and inflammation of the liver) or the muscles. Under medical supervision, the medicine should be stopped and blood tests performed.

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

This is not a complete list of all possible side effects. Others may also occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

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## After taking Carbimazole Link

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### *Storage*

**Keep your tablets in the blisters and original packaging until it is time to take them.**

If you take the tablets out of the blister they may not keep well.

**Keep Carbimazole Link in a cool dry place where the temperature stays below 25°C.**

**Do not store it, or any other medicine, in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep Carbimazole Link where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking Carbimazole Link, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.**

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## Product description

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### *Availability*

Carbimazole Link comes in a tablet strength of 5 mg.

Carbimazole Link comes in a blister pack of 100 tablets.

### *What Carbimazole Link looks like*

The tablets are white, round convex and scored on one side.

### *Ingredients*

Carbimazole Link contains 5 mg of carbimazole as the active ingredient.

It also contains:

- mannitol
- microcrystalline cellulose
- maize starch
- citric acid
- sodium starch glycollate type A
- magnesium stearate.

Carbimazole Link tablets do not contain lactose or gluten.

### *Sponsor*

**Link Medical Products Pty Ltd**  
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Warriewood NSW 2102  
Australia

### **Australian Registration Number:**

AUST R 254132

This leaflet was last prepared in August 2016.