



Carbimazole 2.5mg/ml Oral Solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Carbimazole Oral Solution is and what it is used for

What Carbimazole Oral solution is
Carbimazole Oral solution (this will be referred to carbimazole throughout the leaflet) contains the active substance carbimazole.

Carbimazole belongs to a group of medicines called anti-thyroid agents. Carbimazole is used to reduce the formation of thyroid hormones in adults and children with an overactive thyroid gland. The condition is called hyperthyroidism. Carbimazole is also used in more serious cases, for example, to restore the normal function of the thyroid before its partial removal by surgery. It may also be used together with other treatments for hyperthyroidism.

2. What you need to know before you take Carbimazole Oral Solution

Do not take carbimazole

- If you are allergic to carbimazole or any of the ingredients of this medicine (listed in section 6).
- If you have a serious blood disorder.
- If you have a severe liver disorder.
- If you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.

Warnings and precautions

Talk to your doctor or pharmacist before taking carbimazole

- If you have a swelling in your neck called an ‘intrathoracic goitre’.
- If you have bone marrow depression.
- 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 unable to comply with the instructions for use or cannot be monitored regularly.
- If you are pregnant, think you may be pregnant or are trying to become pregnant.
- If you have mild or moderate liver problems.
- Tell your doctor straight away if you develop fever or abdominal pain, which may be signs of inflammation of the pancreas (acute pancreatitis). Carbimazole may need to be discontinued.
- Carbimazole can cause harm to an unborn baby. If you could get pregnant, use reliable contraception from the time you start treatment and during treatment.

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

Children

Do not give this medicine to children aged two years or below because it may not be safe or effective.

Other medicines and carbimazole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription, including herbal medicines. This is because carbimazole can affect the way some medicines work. Also, some medicines can affect the way carbimazole works.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Theophylline used to treat asthma or breathing problems
- Medicines called anticoagulants, which are used to thin the blood e.g. warfarin
- Steroids such as prednisolone
- An antibiotic called erythromycin
- A medicine for heart failure called digoxin
- Medicines for high blood pressure called beta-blockers
- Any other medicine that could affect your white blood cell count.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Carbimazole can cause harm to an unborn baby. If you could get pregnant, use reliable contraception from the time you start treatment and during treatment. However, to reduce the possibility of any effects on your baby:

- Your doctor should prescribe the lowest dose possible.
- Your treatment may be discontinued three to four weeks before you are due to give birth.

Your treatment with carbimazole may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

Breast-feeding

You should not breast-feed if you are using carbimazole. This is because small amounts may pass into the mother’s milk.

Driving and using machines

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

Carbimazole Oral Solution contains:

This medicine contains peppermint oil (3mg/ml) which should not be used at levels over 1.62 mg/Kg/day. This is equivalent to 7.5 mL oral solution per day for children of 3 years and over and 38.0 mL oral solution per day for an adult.

3. How to take Carbimazole Oral Solution

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

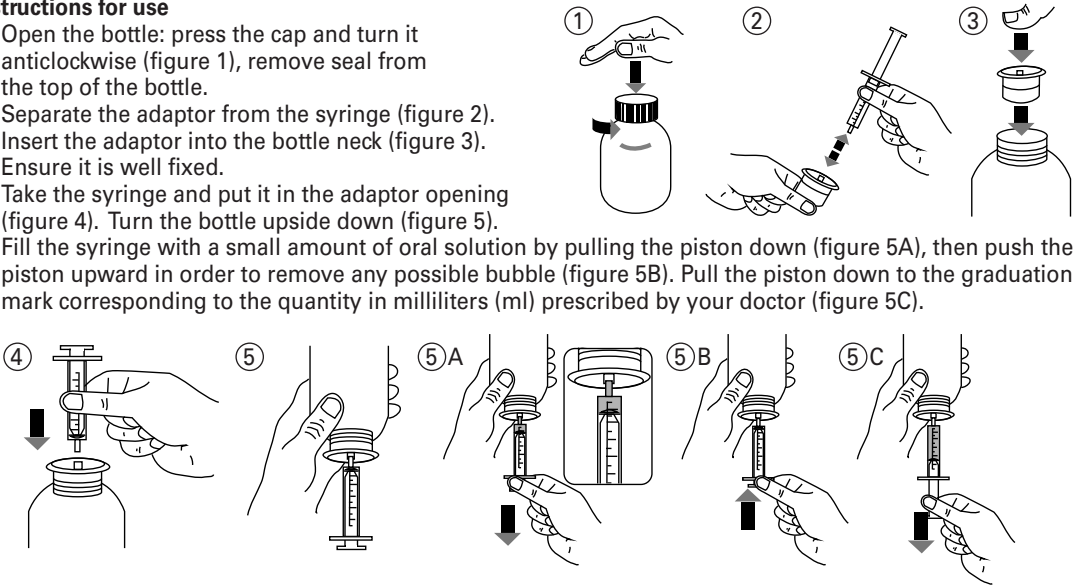
- The oral solution should be taken by mouth.
- You can take the oral solution before, after or during meals.
- Each day’s dose may be divided into two (morning and evening) or three daily doses (morning, noon and night).
- The dose of Carbimazole oral solution should be taken with a glass of water.

Adults and the elderly: The recommended starting dose is 8 ml (20 mg) to 24 ml (60 mg) daily. Once control is achieved your doctor will gradually reduce your dose to 2 ml (5 mg) to 6 ml (15 mg) each day.

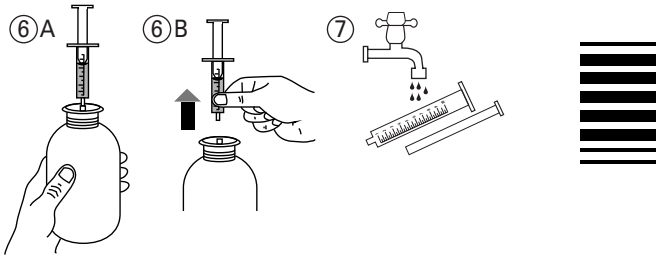
Use in children and adolescents (3 to 17 years of age): The recommended starting dose is 6 ml (15 mg) oral solution daily.

Instructions for use

- Open the bottle: press the cap and turn it anticlockwise (figure 1), remove seal from the top of the bottle.
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.
- Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).
- Fill the syringe with a small amount of oral solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).
- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe into your mouth.
- After dosing, wash the syringe with water only (figure 7).



The dosage will be decided by your doctor according to your individual needs, and may be changed at intervals during treatment.

Do not change the dosage without consulting your doctor first.

Your doctor may decide to add levothyroxine, to help control your condition.

Some improvement is usually felt within one to three weeks. However, full beneficial effects usually take four to eight weeks.

In order to maintain control of the thyroid gland, you may need to continue to take carbimazole for several months. Your doctor will decide when treatment can be stopped. They may ask you to have occasional blood tests to help them to determine how you are responding to treatment.

Radio-iodine is another treatment for hyperthyroidism. If you need radioiodine treatment, your doctor will tell you to stop taking carbimazole temporarily.

If you take more carbimazole than you should

If you take more carbimazole than you should, contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining solution with you.

If you forget to take carbimazole

If you forget to take carbimazole take the next dose as soon as you remember. If your next dose is due, take both doses together.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, stop taking carbimazole and see a doctor straight away. The signs may include: sudden rash, swelling or difficulty breathing.

Stop taking carbimazole and see a doctor straight away if you notice any of the following side effects:

- 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
- Stevens-Johnson syndrome, a serious illness with blistering of the skin, mouth, eyes and genitals
- angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat.

In addition, if you experience any of these symptoms while taking carbimazole you should also contact your doctor immediately:

- Muscle pain or weakness
- Nerve pain
- Swelling of lymph nodes
- Swelling of glands in your mouth
- Feeling faint (low blood sugar)
- Yellowing of your skin or whites of your eyes.
- Kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention, blood in the urine.

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.

Do not stop taking carbimazole until you have consulted your doctor.

Carbimazole can sometimes 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.

The following side effects are reported with a not known frequency (frequency cannot be estimated from the available data):

- feeling sick
- headache
- skin rashes, including urticaria (nettle rash)
- itching
- stomach upset
- painful joints.
- hair loss
- loss of taste
- inflammation of the pancreas (acute pancreatitis)
- lung problems, with symptoms that include shortness of breath or a cough.

Reporting of side effects

If you get any 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 directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Carbimazole Oral Solution

Keep this medicine out of the sight and reach of children.

Store the bottle in the carton in order to protect from light. Do not refrigerate or freeze. Do not store above 25°C.

After first opening the bottle, discard after 30 days.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Carbimazole Oral solution contains

- The active substance is carbimazole. Each ml of oral solution contains 2.5 mg of carbimazole.
- The other ingredients are: butylhydroxyanisole (E 320), peppermint oil and triglycerides, medium chain.

What Carbimazole Oral solution looks like and contents of the pack

Carbimazole Oral solution is a clear, colorless oily liquid free from visible particulate matter.

Carbimazole Oral solution, is packaged in a HDPE bottle with a child-resistant, tamper-evident, PP closure. Pack size of 150 ml. The pack contains a 10 ml oral syringe (PP barrel, purple HDPE plunger, graduations at 0.25 ml, numbered every ml) and an LDPE bottle adaptor.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

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If you would like this leaflet in different format information, please contact the marketing authorisation holder listed above.