Novamaze

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Novamaze?

Novamaze contains the active ingredient carbimazole. Novamaze is used to treat hyperthyroidism or overactive thyroid gland (a condition where the thyroid gland produces too much thyroid hormone).

For more information, see Section 1. Why am I taking Novamaze? in the full CMI.

2. What should I know before I take Novamaze?

Do not take if you have ever had an allergic reaction to Novamaze or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take Novamaze? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Novamaze and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Novamaze?

Your doctor will tell you how many Novamaze tablets to take each day and when. Take your tablets at about the same time each day. Swallow the tablets whole with a glass of water – do not chew them.

More instructions can be found in Section 4. How do I take Novamaze? in the full CMI.

5. What should I know while taking Novamaze?

Things you	Remind any doctor, dentist or pharmacist you visit that you are taking Novamaze.	
should do	Call your doctor straight away if you:	
	 become pregnant while taking Novamaze develop fever or abdominal pain develop fatigue, weight loss and muscle and joint pain. 	
Things you should not do	 Do not stop taking Novamaze or change the dose without checking with your doctor. Do not let yourself run out of Novamaze over a weekend or on holidays. 	
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Novamaze affects you.	
Looking after your medicine	Keep Novamaze tablets in the bottle until it is time to take them.	
	• Store Novamaze in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C. Protect from light.	

For more information, see Section 5. What should I know while taking Novamaze? in the full CMI.

6. Are there any side effects?

- Less serious side effects: nausea, headache, pain in joints, stomach upsets, skin rashes, itchiness, loss of sense of taste, hair loss.
- Serious side effects: abdominal pain, rash on the hands and feet, facial swelling, hoarseness, difficulty breathing, blood in the urine, fever, fatigue, weight loss, muscle pain.
- Very serious side effects: liver pain or yellowing of your skin or the whites of your eyes; sore throat, mouth ulcers, high temperature or fever, increased tendency for bruising or bleeding, extreme tiredness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Novamaze

Active ingredient: carbimazole

Consumer Medicine Information (CMI)

This leaflet provides important information about using Novamaze. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Novamaze.

Where to find information in this leaflet:

- 1. Why am I taking Novamaze?
- 2. What should I know before I take Novamaze?
- 3. What if I am taking other medicines?
- 4. How do I take Novamaze?
- 5. What should I know while taking Novamaze?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking Novamaze?

Novamaze contains the active ingredient carbimazole.

Novamaze belongs to a group of medicines called antihyperthyroidism agents. These medicines work by reducing the production of thyroid hormones. There are different types of medicines used to treat hyperthyroidism.

Novamaze is used to treat hyperthyroidism or overactive thyroid gland (a condition where the thyroid gland produces too much thyroid hormone).

2. What should I know before I take Novamaze?

Warnings

Do not take Novamaze if:

- you are allergic to carbimazole, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

Do not take Novamaze if you have had any of the following medical conditions:

- growth of the thyroid gland downwards from the neck into the chest (retrosternal goitre)
- serious blood disorder
- severe liver disorder
- airway obstruction
- inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole.

Check with your doctor if you:

- have any other medical conditions, such as mild or moderate liver disorder
- take any medicines for any other condition
- have had an allergic reaction to thiamazole or propylthiouracil (medicines used to treat thyroid disorders).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Carbimazole is suspected to cause an increased incidence of congenital malformations when administered during pregnancy.

If you could get pregnant, use reliable contraception from the time you start treatment and while being treated with carbimazole.

Carbimazole can cause harm to an unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Carbimazole crosses the placenta and passes into breast milk. Your doctor can discuss with you the risks and benefits of using Novamaze if you are pregnant or breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Carbimazole may interfere with some medicines and affect how they work.

- · iodine or any preparation containing iodine
- theophylline, used to treat asthma or breathing problems
- anticoagulants e.g., warfarin
- prednisolone, used to treat allergic disorders, skin conditions, ulcerative colitis, arthritis, lupus, psoriasis or breathing disorders
- erythromycin, used to treat bacterial infections
- digoxin, used to treat heart conditions
- beta-blockers e.g., atenolol and sotolol.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Novamaze.

4. How do I take Novamaze?

How much to take

- Your doctor will tell you how many Novamaze tablets to take each day and when.
- Your dose may change from time to time according to your progress.
- Follow the instructions provided and take Novamaze until your doctor tells you to stop.

How to take Novamaze

- Swallow the tablets whole with a glass of water.
- Do not chew the tablets.

When to take Novamaze

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

If you forget to take Novamaze

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 you missed.

Otherwise, take Novamaze as soon as you remember and then go back to taking your tablets as you would normally.

If you use too much Novamaze

If you think that you have used too much Novamaze, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Novamaze?

Things you should do

Call your doctor straight away if you:

- become pregnant while taking Novamaze
- develop fever or abdominal pain, as these may be signs of inflammation of the pancreas (acute pancreatitis)
- develop fatigue, weight loss and muscle and joint pain, as these may be signs of inflammation of the blood vessels (vasculitis)

You may need to stop taking Novamaze.

Remind any doctor, dentist or pharmacist you visit that you are taking Novamaze.

Things you should not do

- Do not stop taking Novamaze or change the dose without checking with your doctor.
- Do not let yourself run out of Novamaze over a weekend or on holidays.
- Do not take Novamaze to treat any other complaints unless your doctor tells you to.
- Do not give Novamaze to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Novamaze affects you.

Looking after your medicine

Keep Novamaze tablets in the bottle with the childresistance cap until it is time to take them. If you take the tablets out of the bottle they may not keep well.

Keep Novamaze in a cool dry place where the temperature stays below 25°C. Protect from light.

Follow the instructions on the label on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 nausea headache pain in joints stomach upsets skin rashes itchiness loss of sense of taste hair loss abdominal pain rash on the hands and feet hoarseness fatigue weight loss muscle pain 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 liver pain yellowing of your skin or the whites of your eyes sore throat mouth ulcers high temperature fever increased tendency for bruising or bleeding extreme tiredness facial swelling difficulty breathing blood in the urine 	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side affects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Novamaze contains

Active ingredient (main ingredient)	Carbimazole
Other ingredients (inactive ingredients)	Lactose Croscarmellose sodium Magnesium stearate
Potential allergens	Sugars as lactose

Do not take Novamaze if you are allergic to any of these ingredients.

What Novamaze looks like

Each 5 mg tablet is white, round, uncoated tablets debossed with "CARB" on one side and "5" on the other side, containing 5mg carbimazole.

AUST R 397412

Who distributes Novamaze

Nova Pharmaceuticals Australasia Pty Ltd Suite 305, 10 Norbrik Drive Bella Vista, NSW 2153 Toll free 1800 002 171

This leaflet was prepared in August 2023.