

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 using Duromine?

Duromine contains the active ingredient phentermine. Duromine is used to reduce body weight in obese or overweight patients. For more information, see Section [1. Why am I using Duromine?](#) in the full CMI.

2. What should I know before I use Duromine?

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

There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before taking Duromine (see the full CMI for more details).

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 use Duromine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Duromine 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 use Duromine?

- Carefully follow all directions given by your doctor or other healthcare professionals and never change the dose yourself.
- The usual dose of Duromine is one capsule a day.
- Swallow the capsule whole with plenty of water. Do not chew or open the capsules.

More instructions can be found in Section [4. How do I use Duromine?](#) in the full CMI.

5. What should I know while using Duromine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Duromine.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Duromine.• Stop taking and contact your doctor immediately if you become pregnant while taking Duromine.• Tell your doctor immediately if you experience sudden or rapid weight loss, difficulty breathing, chest pain, fainting, and swelling of the lower limbs or if you cannot exercise as much as you usually can.
Things you should not do	<ul style="list-style-type: none">• Do not take Duromine to treat any other conditions unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Duromine affects you.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol whilst taking Duromine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the blister-foil pack until it is time to take them.• Store in a cool dry place where the temperature stays below 30°C and keep out of reach of children.

For more information, see Section [5. What should I know while taking Duromine?](#) in the full CMI.

6. Are there any side effects?

Common side effects include changes in your heartbeat, high blood pressure, restlessness, trouble sleeping, nervousness, tremor, headache, dizziness, fainting, nausea, vomiting, diarrhoea or constipation, stomach cramps, dry or unpleasant taste in mouth, trouble urinating, skin rashes, sexual function problems, feelings of extreme happiness followed by depression and tiredness.

Serious side effects include heart attack, stroke, chest pain, myocardial infarction and difficulty breathing.

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.

Duromine[®] (dure-o-mean)

Active ingredient(s): Phentermine (fen-ter-mean)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Duromine. **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 Duromine.**

Where to find information in this leaflet:

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

1. Why am I taking Duromine?

Duromine contains the active ingredient phentermine.

Phentermine is combined with a resin which slowly releases the phentermine so the effect of Duromine lasts all day.

Duromine is used to reduce body weight in obese or overweight patients.

Duromine is an appetite suppressant that works by directly affecting the area of the brain that controls your appetite making you feel less hungry.

Duromine should be used as a part of an overall weight management plan, which includes a medically controlled diet and exercise program.

Your doctor will assess whether Duromine is suitable for you.

2. What should I know before I take Duromine?

Warnings

Do not use Duromine if:

- You are allergic to phentermine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue, or other parts of the body
 - rash, itching or hives on the skin.
- You are taking any similar medicines to reduce weight.

- You have any of the following medical conditions:
 - very high blood pressure
 - high blood pressure in the lungs
 - problems with your heart valves
 - disease related to blood vessels in the brain
 - severe heart disease including changes in the rhythm or rate of the heartbeat
 - narrowing of the blood vessels due to thickening or hardening of the blood vessel wall
 - overactive thyroid gland
 - psychiatric illness including anorexia nervosa (loss of appetite) and depression
 - glaucoma (high pressure in the eye).
- It is past the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- You are a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.
- You are elderly.
- You are currently taking, or have taken within the last 14 days, antidepressant medicines called mono-amine oxidase inhibitors (MAOIs).
- You have previously misused drugs or alcohol.

Check with your doctor if you:

- Have any other medical conditions including:
 - high blood pressure
 - heart disease such as angina (chest pain)
 - diabetes
 - epilepsy
- Take any medicines for any other condition.

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.

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

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.

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

These include:

- other medicines for weight reduction
- medicines for depression or obsessive-compulsive disorder or other mental illness
- ergot-like medicines for migraine
- some cough and cold remedies
- thyroid hormones
- medicines for lowering high blood pressure.

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

4. How do I take Duromine?

How much to take

- The usual dose is one capsule a day, however your doctor will prescribe the right dose for you.
- Swallow the capsules whole with plenty of water. Do not chew or open the capsules.
- Carefully follow the instructions provided and use Duromine until your doctor tells you to stop.

Increasing the dose may not necessarily make you lose more weight or make you lose weight faster. However, you will more likely experience side effects. Your doctor will tell you how long you are to take Duromine for.

When to take Duromine

- Take Duromine first thing in the morning, at breakfast time so that it does not keep you awake at night.
- Taking Duromine at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.
- Do not change the dose unless your doctor tells you to do so.

If you forget to use Duromine

Duromine should be used regularly at the same time each day. If you miss your dose at breakfast, take it no later than lunchtime.

If you take Duromine any later than lunchtime you may have trouble sleeping at night.

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.

If you use too much Duromine

If you think that you have taken too much Duromine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand), 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 Duromine?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking Duromine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Duromine.

- Check with your doctor or pharmacist before you start to take any cough or cold medication.

Call your doctor straight away if you:

- Become pregnant while taking this medicine.
- Experience sudden or rapid weight loss, difficulty breathing, chest pain, fainting, and swelling of the lower limbs and if you cannot exercise as much as you usually can.

Things you should not do

- Do not take Duromine to treat any other conditions unless your doctor tells you to.
- Do not give your medicine 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 Duromine affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol whilst taking Duromine.

Looking after your medicine

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

- Keep your capsules in the blister-foil in the carton until it is time to take them.
- Store Duromine below 30°C 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
<ul style="list-style-type: none">• feeling more awake than usual and trouble sleeping• your heart seems to beat faster and harder• your blood pressure may be raised slightly• irregular heart beats• feeling restless	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> feelings of extreme happiness followed by depression and tiredness nervousness tremor (shaking) headache dizziness fainting nausea vomiting diarrhoea or constipation stomach cramps dry mouth or an unpleasant taste in your mouth if you cannot exercise as much as you usually can difficulty passing urine skin rashes impotence changes in sexual drive swelling of the lower limbs swelling of the face sudden or rapid weight loss 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> heart attack stroke chest pain myocardial infarction difficulty breathing 	<p>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.</p>

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 effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia, or Medsafe at www.medsafe.govt.nz/safety/report-a-problem.asp in New Zealand.

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 Duromine contains

Active ingredient (main ingredient)	Phentermine
Other ingredients (inactive ingredients)	lactose monohydrate liquid paraffin magnesium stearate gelatin capsules hard PI (1947) titanium dioxide iron oxide black (CI 77499) sodium polystyrene sulfonate <u>In addition:</u> <u>Duromine 15 mg contains:</u> brilliant blue FCF (CI 42090) iron oxide yellow (CI 77492) <u>Duromine 30 mg contains:</u> iron oxide red (CI 77491) <u>Duromine 40 mg contains:</u> erythrosine (CI 45430) sunset yellow FCF (CI 5985)
Potential allergens	Contain sugars as lactose monohydrate

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

Duromine capsules are gluten-free.

What Duromine looks like

Duromine capsules are available in three strengths in packs of 30 capsules:

15 mg - AUST R 10941

Grey and green and marked DUROMINE 15

30 mg - AUST R 76680

Grey and reddish brown and marked DUROMINE 30

40 mg - AUST R 10942

Grey and orange and marked DUROMINE 40

Duromine capsules are available in two strengths in packs of 7 capsules:

15 mg - AUST R 10941

Grey and green and marked DUROMINE 15

30 mg - AUST R 76680

Grey and reddish brown and marked DUROMINE 30

Who distributes Duromine

Australia

iNova Pharmaceuticals (Australia) Pty Limited
 Level 10, 12 Help Street
 Chatswood NSW 2067
 Tel: 1800 630 056

New Zealand

iNova Pharmaceuticals (New Zealand) Pty Limited

Auckland

Tel: 0508 375 394

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