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 Phenterin?

Phenterin contains the active ingredient Phentermine. Phenterin is used to reduce body weight in obese or overweight patients.

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

2. What should I know before I use Phenterin?

Do not use if you have ever had an allergic reaction to Phenterin 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 use Phenterin? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Phenterin 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 Phenterin?

• The usual dose of Phenterin is one capsule every day. Take Phenterin first thing in the morning, at breakfast time so that it does not keep you awake at night. Swallow the capsules whole with water. Do not chew or open the capsules.

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

5. What should I know while using Phenterin?

Things you should do	 Remind any doctor, dentist or pharmacist, surgeon/anaesthetist you visit that you are using Phenterin. If you become pregnant while taking this medicine, tell your doctor immediately. Tell your doctor immediately if you 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 Phenterin to treat any other complaints unless your doctor tells you. Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	Be careful driving or operating machinery until you know how Phenterin affects you.
Drinking alcohol	Do not drink alcohol while using Phenterin.
Looking after your medicine	 Keep your capsules in the blister foil until it is time to take them. Keep Phenterin in a cool, dry place where the temperature says below 30°C.

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

6. Are there any side effects?

Common side effects include feeling more awake than usual, trouble sleeping, heart seems to beat harder and faster, blood pressure may be raised, irregular heartbeats, chest pain, feeling restless, feelings of extreme happiness followed by depression and tiredness, nervousness, tremor (shaking), headache, dizziness, nausea, vomiting, diarrhoea or constipation, stomach cramps. Serious side effects can include heart attack, stroke, angina and myocardial infarction.

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.

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PhenterinTM (fen-ter-in)

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

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Phenterin?

Phenterin contains the active ingredient phentermine, which is combined with a resin to slowly release the phentermine so the effect lasts all day. Phenterin works by directly affecting the area of the brain that controls your appetite making you feel less hungry.

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

2. What should I know before I use Phenterin?

Warnings

Do not use Phenterin if:

- you are allergic to phentermine, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any other similar medicines used to reduce weight.
- you have very high blood pressure.
- · you have high blood pressure in the lung.
- you have disease related to blood vessels in the brain.
- you have severe heart disease including changes in the rhythm or rate of the heart rate.
- you have narrowing of the blood vessels due to thickening or hardening of the blood vessel wall.
- you have an overactive thyroid gland.
- you have psychiatric illness including anorexia nervosa (loss of appetite) and depression.
- you have glaucoma (high pressure in the eye).
- you are currently taking, or have taken within the last 14 days antidepressant medicines from the monoamine oxidase inhibitor (MAOI) class such as phenelzine (e.g. Nardil) or tranylcypromine (e.g. Parnate).
- you have previously misused drugs or alcohol.

Check with your doctor if you:

- have high blood pressure.
- have heart disease such as angina (chest pain).
- have diabetes.
- have epilepsy.
- have allergies to any medicines, foods, preservatives or dyes.

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 <u>6</u>. <u>Are there any side effects?</u>

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.

Specific situations

- do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.
- do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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 Phenterin and affect how it works. These include:

- any medicines for weight reduction.
- any medicines for depression or obsessive compulsive disorder such as fluoxetine (e.g. Prozac, Erocap, Lovan, Zactin); sertraline (e.g. Zoloft); paroxetine (e.g. Aropax); clomipramine (e.g. Anafranil, Placil).
- ergot-like medicines for migraine such as ergotamine (e.g. Cafergot, Ergodryl, Migral).
- any cough and cold remedies containing pseudoephedrine, phenylpropanolamine or phenylephrine.
- thyroid hormones.
- any medications for mental illness
- medicines for lowering high blood pressure including clonidine, methyldopa or guanethidine.

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

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4. How do I use Phenterin?

How much to take

- In adults and adolescents over 12 years, the usual dose of Phenterin is one capsule every day. However, your doctor will prescribe the right dose for you.
- Follow the instructions provided and use Phenterin until your doctor tells you to stop. Increasing the dose may not necessarily make you lose more weight faster. However, you will most likely experience more side effects.

When to take Phenterin

- Phenterin should be taken in the morning, at breakfast time so that it does not keep you awake at night.
- Swallow the capsules whole with plenty of water. Do not chew or open the capsules.
- Taking it 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.

If you forget to use Phenterin

Phenterin 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 Phenterin 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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much Phenterin

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26)
- · contact your doctor
- 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 using Phenterin?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

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

Remind any doctor, dentist, pharmacist or surgeon and anaesthetist that you are using Phenterin.

Things you should not do

- Do not take Phenterin to treat any other complaints 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 Phenterin affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol whilst taking Phenterin.

Looking after your medicine

- Keep your capsules in the blister foil in the carton until it is time to take them. If you take the capsules out of the blister pack they may not keep well.
- Keep Phenterin is a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton 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 window sills.

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
 Feeling more awake than usual Trouble sleeping Your heart seems to beat harder and faster Your blood pressure may be raised slightly Irregular heart beats Chest pain Feeling restless Feelings of extreme happiness followed by depression and tiredness Nervousness Tremor (shaking) Headache Dizziness Diarrhoea or constipation Stomach cramps 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects • Sudden or rapid weight loss • Difficulty breathing • Chest pain • Swelling of the lower limbs • if you cannot exercise as much as you usually can • dry mouth or an unpleasant taste in your mouth • difficulty passing urine • skin rashes • impotence • changes in sexual drive 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.		
 Difficulty breathing Chest pain Swelling of the lower limbs if you cannot exercise as much as you usually can dry mouth or an unpleasant taste in your mouth difficulty passing urine skin rashes impotence changes in sexual drive straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. 	Serious side effects	What to do
• swelling of the face	 Difficulty breathing Chest pain Swelling of the lower limbs if you cannot exercise as much as you usually can dry mouth or an unpleasant taste in your mouth difficulty passing urine skin rashes impotence 	straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious

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. 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 Phenterin contains

Active ingredient (main ingredient)	Phentermine (as phentermine hydrochloride)
Other ingredients (inactive ingredients)	Lactose, liquid paraffin, magnesium stearate, gelatin, titanium dioxide, sodium polystyrene sulfonate, indigo carmine (15mg, 30mg), iron oxide yellow (30mg, 40mg), iron oxide red (40mg), carmoisine (40mg)
Potential allergens	Lactose

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

What Phenterin looks like

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

15mg - (AUST R 375865)

Blue cap and white body.

30mg - (AUST R 375864)

Dark green cap and white body.

40mg - (AUST R 375862)

Scarlet cap and white body.

Who distributes Phenterin

Nova Pharmaceuticals Australasia Pty Ltd Suite 305, 10 Norbrik Drive, Bella Vista NSW 2153 novapharm.com.au

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