

Phentodur 15 mg and 30 mg Modified Release Capsules

Phentermine (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Phentodur.

This leaflet answers some common questions about Phentodur. 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 using Phentodur against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Phentodur is used for

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

PHENTODUR is used to reduce body weight in obese or overweight patients. Your doctor will assess whether PHENTODUR is suitable for you. PHENTODUR works by directly affecting the area of the brain that controls your appetite making you feel less hungry.

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

Your doctor may have prescribed Phentodur for another reason.

Ask your doctor if you have any questions about why Phentodur has been prescribed for you.

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

Before you use Phentodur

When you must not use it

Do not take PHENTODUR if you have an allergy to:

- any medicine containing phentermine
- any of the ingredients listed at the end of this leaflet
- any other similar medicines used to reduce weight

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

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 if you have any of the following medical conditions:

- very high blood pressure
- high blood pressure in the lung
- problems with the valves in your heart
- disease related to blood vessels in the brain
- severe heart disease including changes in the rhythm or rate of the heart beat
- 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)

Do not use this medicine:

- if you are currently taking, or have taken within the last 14 days, antidepressant medicines from the mono-amine oxidase inhibitor (MAOI) class such as phenelzine (eg Nardil) or tranylcypromine (eg Parnate).
- if you have previously misused drugs or alcohol

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if:

Tell your doctor if you have allergies to any medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

Tell your doctor if you:

- have high blood pressure
- have heart disease such as angina (chest pain)
- have diabetes
- have epilepsy

If you have not told your doctor about any of the above, tell him/ her before you start taking PHENTODUR.

Taking other medicines

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

Some medicines and PHENTODUR may interfere with each other. These include:

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

These medicines may be affected by PHENTODUR or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine

How to use Phentodur

How much to take

In adults and adolescents over 12 years, the usual dose of PHENTODUR is one capsule every day. However, your doctor will prescribe the right dose for you.

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

Swallow the capsules whole with plenty of water. Do not chew or open the capsules.

When to take it

Take PHENTODUR first thing in the morning, at breakfast time so that it does not keep you awake at night.

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.

PHENTODUR is not recommended for elderly patients or for children younger than twelve years.

How long to take it

Take this medicine as long as your doctor tells you to.

If you forget to take it

If you forget to take your PHENTODUR dose at breakfast take it no later than lunchtime.

Alternatively, skip the dose you missed and take your next dose at the normal time on the next day.

If you take PHENTODUR any later than lunch-time you may have trouble sleeping at night.

Never take a double dose to make up for a dose you have missed.

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

While you are using Phentodur

Things you must do

If you are about to be started on any new medicine remind your doctor and pharmacist that you are taking PHENTODUR.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

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 must not do

Do not take PHENTODUR 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.

Things to be careful of

Be careful driving or operating machinery until you know how PHENTODUR affects you.

DO NOT drink alcohol whilst taking PHENTODUR.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Phentodur

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Phentodur.

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 adverse effects.

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience:

- heart attack
- stroke
- angina
- myocardial infarction

The above list includes very serious side effects. You may need urgent medical attention or hospitalization.

These side effects are rare.

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

- feeling more awake than usual
- trouble sleeping
- your heart seems to beat faster and harder
- 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
- nausea
- vomiting
- diarrhoea or constipation
- stomach cramps

Tell your doctor as soon as possible if you notice any of the following:

- sudden or rapid weight loss
- difficulty breathing
- chest pain
- fainting
- swelling of the lower limbs
- or 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
- swelling of the face

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Phentodur

Storage

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 pack they may not keep well.

Keep PHENTODUR in a cool dry place where the temperature stays below 25°C.

Do not store PHENTODUR or any other medicine in the bathroom or near a sink. Do not leave them on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep them where children cannot reach them.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

PHENTODUR capsules are available in three strengths in PVC/PVDC/Aluminium blister packs of 30 capsules:

15 mg - AUST R 310850

Grey and green and marked with PHE15

30 mg - AUST R 310861

Grey and reddish brown and marked with PHE30

Ingredients

PHENTODUR capsules contain:

Active ingredient(s):

phentermine (as hydrochloride)

Inactive ingredients:

- sodium polystyrene sulfonate
- lactose monohydrate
- liquid paraffin
- magnesium stearate
- gelatin
- titanium dioxide
- iron oxide black (CI 77499)
- TekPrint SW-9008 Black ink (ARTG2328)

In addition:

PHENTODUR 15 mg contains:

- brilliant blue FCF (CI 42090)
- iron oxide yellow (CI 77492)

PHENTODUR 30 mg contains:

- iron oxide red (CI 77491)

PHENTODUR capsules are gluten free. Contain sugars as lactose. May contain traces of sulphites.

Sponsor Details

Phentodur is supplied in New Zealand by:

Distributor:

Pharmacy Retailing (NZ) Ltd trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

Sponsor:

Arrotex Pharmaceuticals (NZ) Ltd
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