

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PHENTOLENE 15 mg hard capsules

PHENTOLENE 30 mg hard capsules

Phentermine

Contains sugar as sucrose:

PHENTOLENE 15: Sucrose 208,5 mg per capsule

PHENTOLENE 30: Sucrose 192,0 mg per capsule

Read all of this leaflet carefully before you start using PHENTOLENE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PHENTOLENE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What PHENTOLENE is and what it is used for

PHENTOLENE works by directly affecting the area of the brain that controls your appetite making you feel less hungry.

PHENTOLENE is used to reduce body weight in obese or overweight patients. Your doctor will assess whether PHENTOLENE is suitable for you.

2. What you need to know before you take

PHENTOLENE Do not take PHENTOLENE:

- If you are hypersensitive (allergic) to phentermine, as in PHENTOLENE, or any of the other ingredients of PHENTOLENE (listed in section 6).
- If you have high blood pressure.
- If you have problems with the valves in your heart.
- If you have a heart disease including changes in the rhythm or rate of your heartbeat.
- If you have narrowing of the arteries.
- If you have an overactive thyroid gland.
- If you have psychiatric illness including anorexia nervosa (loss of appetite) and depression.
- If you have glaucoma (high pressure in the eye).
- If you have a history of drug /alcohol abuse.
- If you have a condition in which the flow of your urine is blocked.
- If you have epilepsy.
- If you if you are currently taking, or have taken within the last 14days, antidepressant medicines from the mono-amine oxidase inhibitor (MAOI) class.
- If you are pregnant or breastfeeding your baby.
- If you are allergic to sympathomimetic medicines such as included in cough remedies.

Warnings and precautions

Special care should be taken with PHENTOLENE, and you should tell your doctor or health care provider.

- If you are taking any medicines for depression such as fluoxetine, or ergot-like medicines for migraine such as ergotamine, when co-administered with PHENTOLENE, it may cause damage to your heart valves.
- When you are taking any medicines for weight reduction.
- If you experience a sudden shortness of breath, a tight chest, or severe chest pain, fainting and swelling of the lower limbs and if you cannot exercise as much as you usually can.
- If you have high blood pressure or problems with your kidneys.
- If you have diabetes.
- When you experience sudden or rapid weight loss, and any chest pain, difficulty breathing or fainting.
- If you use any medication for lowering your high blood pressure, or for a mental illness.
- When you have epilepsy.

Elderly

PHENTOLENE is not recommended for use in the elderly.

Children

The safety of PHENTOLENE has not been established in patients under the age of 12 years, therefore treatment with PHENTOLENE is not recommended for children.

Other medicines and PHENTOLENE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

- Any cough and cold remedies containing pseudoephedrine, phenylpropanolamine, or phenylephrine.
- Medicines for lowering high blood pressure including clonidine, methyldopa or guanethidine.
- Any medicines for depression or mental illness.
- Thyroid hormones.

PHENTOLENE with alcohol

Alcohol may increase the side effects of PHENTOLENE and should be avoided while you are being treated with PHENTOLENE.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking PHENTOLENE.

Driving and using machines

PHENTOLENE may impair the ability to perform activities requiring mental alertness, such as driving and operating machinery.

It is not always possible to predict to what extent PHENTOLENE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PHENTOLENE affects you.

PHENTOLENE contains sucrose

PHENTOLENE contains sucrose. If you have been told that you have an intolerance to some sugars, you should not take PHENTOLENE.

3. How to take PHENTOLENE

Do not share medicines prescribed for you with any other person.

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

The usual dose is one capsule every day, swallowed whole. Take PHENTOLENE first thing in the morning, at breakfast time so that it does not keep you awake at night.

Your doctor will tell you how long your treatment with PHENTOLENE will last. Do not stop treatment early or combine the treatment with any other appetite suppressants. If you have the impression that the effect of PHENTOLENE is too strong or too weak, tell your doctor or pharmacist.

If you take more PHENTOLENE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PHENTOLENE

If you forget to take your PHENTOLENE 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 PHENTOLENE any later than lunchtime you may have trouble sleeping at night. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PHENTOLENE can have side effects.

Not all side effects reported for PHENTOLENE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PHENTOLENE please consult your health care provider for advice.

If any of the following happens, stop taking PHENTOLENE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- you experience a sharp pain in the left side of your chest near your heart.
- a stroke
- angina

These are all very serious side effects. If you have them, you may have had a serious reaction to PHENTOLENE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- irregular heartbeats, or your heart seems to beat faster and harder
- your blood pressure may be raised slightly

Less frequent

- feelings of extreme happiness followed by depression and tiredness
- reality judgment is severely affected, and you are hearing, seeing, feeling, smelling, or even tasting things that are not real
- stroke
- chest pain
- the heart suddenly stops beating
- sudden shortness of breath

Frequency unknown

- blurred vision
- nausea
- vomiting
- stomach cramps
- diarrhoea or constipation
- dry mouth or an unpleasant taste in your mouth

- skin rashes
- difficulty passing urine
- swelling of the face
- impotence
- changes in sexual drive
- feeling more awake than usual
- feeling restless
- nervousness
- trouble sleeping
- experience trembling or shaking
- dizziness and headache

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of PHENTOLENE.

5. How to store PHENTOLENE

Store all medicines out of reach of children.

- Store at or below 30 °C
- Keep the blisters in the original container until required for use.
- Do not use after the expiry date stated on the blister / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PHENTOLENE contains

- The active substance is phentermine.

PHENTOLENE 15: Each capsule contains 15 mg phentermine.

PHENTOLENE 30: Each capsule contains 30 mg phentermine.

- The other ingredients are dewaxed shellac, gelatin capsule, povidone Type K29-32, sugar spheres (containing sucrose and maize starch), talc.

What PHENTOLENE looks like and contents of the pack

PHENTOLENE 15: Size 2 gelatin capsules, with P15 imprint on the capsule, with a red cap and a neutral transparent body.

PHENTOLENE 30: Size 2 gelatin capsules, with P30 imprint on the capsule, with a dark blue cap and a natural transparent body.

PHENTOLENE is packed in 30's in white high-density polyethylene (HDPE) bottles, with a white low density polyethylene (LDPE) cap. One pack with 30 capsules are packed in a cardboard carton.

Holder of Certificate of Registration

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