

DUROMINE® CAPSULE

Phentermine (15mg; 30mg)

What is in this leaflet

1. What Duromine Capsule is used for
2. How Duromine Capsule works
3. Before you use Duromine Capsule
4. How to use Duromine Capsule
5. While you are using it
6. Side effects
7. Storage and disposal of Duromine Capsule
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Duromine Capsule is used for

Duromine Capsule capsules contain the active ingredient, phentermine.

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

Duromine Capsule is used to reduce body weight in obese or overweight patients. Your doctor will determine if you are overweight enough to use Duromine Capsule.

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

Duromine Capsule is only available with a doctor's prescription. It has been prescribed for you only.

Do not give it to anyone else even if their condition is the same as yours.

Ask your pharmacist or doctor if you have any questions about this medicine.

How Duromine Capsule works

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

Before you use Duromine Capsule

-When you must not use it

Do not take this medicine 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:

- High blood pressure in the lung;
- Problems with the valves in your heart;
- Moderate to high blood pressure;
- 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)
- If you are currently taking, or have taken within the last 14 days, antidepressant medicines from the mono-amine oxidase inhibitor (MAOI) class

- 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 you are not sure whether you should start using this medicine, talk to your pharmacist or doctor.

-Before you start to use it

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

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

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 pharmacist or doctor about any of the above, tell him/her before you start using Duromine Capsule.

-Taking other medicines

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

Some medicine and Duromine Capsule may interfere with each other. These include

- Sympathomimetic drugs
- Adrenergic neurone blocking drugs such as clonidine, methyl dopa and guanethidine.
- Monoamine Oxidase Inhibitors.
- Thyroid hormones

- Alcohol

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

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

How to use Duromine Capsule

Follow all directions on the pack or those given to you by your pharmacist or doctor carefully.

If you do not understand the instructions on the box, ask your pharmacist or doctor for help.

-How much to use

In adults and children over 12 years, the usual dose of Duromine Capsule is one 30mg capsule every day. However, your doctor will prescribe the right dose for you.

The recommended starting dose is 30mg daily. Depending on the response, you doctor may prescribe 15 or 30mg daily as maintenance dose, either continuously or intermittently.

Follow your doctor's instructions exactly and never change the dose yourself.

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 Duromine Capsule for.

-When to use it

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

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

Take 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.

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

-How long to use it

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

-If you forgot to use it

If you forget to take your Duromine Capsule 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 Duromine Capsule 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.

-If you take too much (overdose)

Immediately telephone your doctor for advice, or go the Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Duromine Capsule. Do this even if there are no signs of discomfort or poisoning.

While you are using it

-Things you must do

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

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 in breathing, chest pain, fainting, and swelling of the lower limbs and if you can not exercise as much as you usually can.

-Things you must not do

Do not take Duromine Capsule to treat any other complaints unless your pharmacist or 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 Duromine Capsule affects you.

Do not drink alcohol whilst taking Duromine Capsule. Check with your doctor or pharmacist before you start to take any cough or cold medication.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Duromine Capsule.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

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

- Your heart seems to beat faster and harder
- Your blood pressure may be raised slightly
- Overstimulation
- Feeling restless
- Nervousness
- Insomnia
- Tremor
- Dizziness
- Headache

- Nausea
- Vomiting
- Dry mouth
- Abdominal cramp
- Unpleasant taste
- Diarrhoea
- Constipation
- Disturbance in urination
- Rash
- Impotence
- Changes in libido
- Facial oedema

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

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website portal.bpfk.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Duromine Capsule

-Storage

Keep your medicine in the original pack until it is time to take it.

Keep your medicine in a cool dry place where the temperature stays below 30° C.

Do not store Duromine Capsule or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

-Disposal

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

Product description

-What it looks like

Duromine Capsule capsules are available in two strengths in packs of 30 capsules:

15mg – Opaque green cap and opaque light grey body marked Duromine 15/Duromine 15

30mg – Opaque reddish brown cap and opaque light grey body marked Duromine 30/Duromine 30

-Ingredients

-Active ingredient(s)

Each Duromine Capsule 15mg contains:

- Phentermine 15mg as ion-exchange resin complex.

Each Duromine Capsule 30mg contains:

- Phentermine 30mg as ion-exchange resin complex.

-Inactive ingredients

- Magnesium stearate
- Liquid paraffin
- Lactose

-MAL Number

MAL18086157ACSZ (15mg)

MAL18086158ACSZ (30mg)

Manufacturer

Bausch Health Companies Inc
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Product Registration Holder

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