SCHEDULING STATUS

S5

DUROMINE 15/ DUROMINE 30 capsules

Phentermine 15 mg

Contains sugar: lactose monohydrate 211,30 mg/capsule

Phentermine 30 mg

Contains sugar: lactose monohydrate 135,75 mg/capsule

Read all of this leaflet carefully before you start taking DUROMINE

- 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.
- DUROMINE 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 DUROMINE is and what it is used for
2. What you need to know before you take DUROMINE
3. How to take DUROMINE
4. Possible side effects

5. How to store DUROMINE

6. Contents of the pack and other information

1. WHAT DUROMINE IS AND WHAT IT IS USED FOR

Duromine capsules contain 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. Your doctor will assess whether Duromine is suitable for you. Duromine 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 should include a medically controlled diet and exercise program.

Duromine is available only with a doctor's prescription. Your doctor may prescribe Duromine for another purpose. If you are not sure why you are taking this medicine ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DUROMINE

Do not take DUROMINE:

- If you are hypersensitive (allergic) to Phentermine or any of the other ingredients of DUROMINE.
- If you have an allergy to any other similar medicines used to reduce weight

Do not take DUROMINE 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 take DUROMINE 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) OR if you have previously misused drugs or alcohol

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years and in the elderly have not been established.

WARNINGS AND PRECAUTIONS

Take special care with DUROMINE:

Tell your doctor if you:

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

DUROMINE contains lactose monohydrate (a sugar)

Take special care with DUROMINE if you have problems of galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

Other medicines and DUROMINE

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

Please consult your doctor, pharmacist, or other healthcare professional for advice prior to taking DUROMINE if you are currently taking any of the following:

- any medicines for weight reduction,
- any medicines for depression or obsessive-compulsive disorder such as fluoxetine; sertraline; paroxetine; clomipramine
- ergot-like medicines for migraines such as ergotamine,
- 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 Duromine or may affect how well it

works. You may need different amounts of your medicines, or you may need to take different medicines.

Taking DUROMINE with food and drink:

There are no known interactions with food. DUROMINE capsules should be swallowed with cold water.

Do not drink alcohol whilst taking DUROMINE.

Pregnancy and Breastfeeding:

DUROMINE is not suitable for use during pregnancy and while breastfeeding at the recommended dosage.

If you are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machinery:

It is not always possible to predict to what extent DUROMINE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DUROMINE affects them.

3. HOW TO TAKE DUROMINE

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

Always take DUROMINE exactly as your doctor has told you. You should check with your doctor if you are unsure.

Your doctor will tell you how long your treatment with DUROMINE will last. If you have the impression that the effect of DUROMINE is too strong or too weak, tell your doctor or pharmacist.

The usual dose is as follows:

Adults and adolescents 12 years and older: Swallow one capsule with water daily.

Take DUROMINE 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.

Do not chew or open the capsules.

Do not exceed the prescribed dosage.

If you take more DUROMINE than you should:

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

Symptoms: Initially irritability, rapid respiration, agitation, euphoria, restlessness, over responsive reflexes, disorientation and tremor, aggressiveness, hallucinations and panic states may occur, followed by irregular heartbeat, convulsions, fatigue, central nervous system depression and coma. Cardiovascular effects include irregular heartbeat, high or low blood pressure. Gastrointestinal symptoms include nausea, vomiting, diarrhea and abdominal cramps.

Your doctor will manage the overdosage.

If you forget to take DUROMINE

Do not use a double dose to make up for a forgotten individual dose.

4. POSSIBLE SIDE EFFECTS

DUROMINE can have side effects.

Not all side effects reported for DUROMINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DUROMINE, please consult your doctor, pharmacist or other healthcare professional for advice.

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

Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

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

- 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
- 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

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 or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction 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 about the safety of DUROMINE.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000.

Website: www.inovapharma.co.za.

5. HOW TO STORE DUROMINE

Store all medicines out of reach of children.

Store at or below 30 °C. Store blisters in carton and protect from sunlight.

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

Other ingredients include liquid paraffin, magnesium stearate.

The capsule shells contain: colloidal silicon dioxide, Colourcon black or Colorcon white, FD&C blue, gelatin, sodium lauryl sulphate,

yellow iron oxide

What DUROMINE looks like and contents of the pack

15 mg capsule: Size 3 locking capsule, opaque green cap with opaque light grey body with marking DUROMINE 15/DUROMINE 15, printed in black ink on both the body and cap.

30 mg capsule: Size 3 locking capsule, opaque reddish-brown cap with opaque light grey body with marking DUROMINE 30/DUROMINE 30, printed in white ink on both the body and cap.

DUROMINE is packed in blister packs of 10 capsules each, and cartons containing 30 capsules

HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd,

15e Riley Road,

Bedfordview

2007

Tel: +27 11 087 0000

REFERENCE NUMBER

15 mg: B657 (Act 101/1965)

30 mg: B658 (Act 101/1965)

This leaflet was last revised in:

To be allocated

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION FOR HEALTHCARE PROFESSIONALS

Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals.