

Reductil(R)

10mg and 15mg capsules

sibutramine hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before starting Reductil.

This leaflet answers some common questions about Reductil. It does not contain all of 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 considered the risks and benefits of you taking Reductil.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Reductil is used for

Reductil contains the active ingredient sibutramine hydrochloride.

Reductil belongs to a group of medicines called serotonin and noradrenaline reuptake inhibitors.

Reductil is used to treat very overweight (obese) patients who have not been able to lose weight using a low calorie diet and exercise.

Your ideal weight may not be achieved even with Reductil.

Reductil is a medicine used to help you lose and maintain weight loss. It

works by making you feel satisfied with less food. It helps control how much you eat. You should still get hungry but feel full with less food than before. By eating less, it should be easier for you to lose weight - even if you haven't been able to before.

Reductil does not work in the same way as traditional appetite suppressants. It works by altering the level of two chemicals in the brain, serotonin and noradrenaline, which help regulate energy intake and output.

The result is:

- (1) you will not need to eat as much during your meals before you feel full, and
- (2) Reductil stops your metabolic rate from falling as much as it normally would. Metabolic rate normally falls during weight loss as you reduce your intake of food, making it harder to keep losing weight. However, there will still be fluctuations in your weight loss as the body uses many mechanisms to maintain your weight. This could be a reason some people do not achieve any benefit from Reductil.

For the best results Reductil should be used in combination with a calorie controlled diet and a regular exercise routine. The intent of Reductil is to assist with moderate weight loss over 6 months (5-10%) – 9 months for diabetics – when used with a diet and exercise programme. This is in accordance with modern weight-loss practice, which emphasises that

moderate weight loss achieves significant health improvement. Losing even modest amounts of weight (5-10% of your initial weight) and keeping it off has been found to reduce risks for diseases such as heart disease and diabetes.

Set yourself realistic goals for weight loss and maintenance. Losing weight means changing habits and changing them for good. Your doctor is there to help and give you regular check-ups.

For best results, Reductil should be used together with a low fat diet and moderate exercise supervised by your doctor. If this is followed, you should notice some weight loss by the end of the first month of treatment. If you have not lost at least 2kg in the first four weeks of treatment, speak to your doctor.

Reductil is NOT meant to result in "overnight" weight-loss. A healthy rate of weight-loss is half to 1kg per week. Even though some people notice an effect on the size of their meals within a few days, it can take longer for others. Weight loss normally starts within 2 weeks and continues for up to 6 months (although in some people eg diabetics, it could take longer).

Reductil is not addictive or habit forming and has been approved for long-term use in weight management.

Reductil is only available with a doctor's prescription.

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

Before you take Reductil

When you must not take Reductil

Do not take Reductil if:

- **you are elderly (over the age 65) or a child (under the age of 18).**
There is not enough experience with the use of Reductil in these groups.
- you have an allergy to Reductil or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include an itchy rash and skin blisters.
- you are or intend to become pregnant or breast-feed. Like most medicines, Reductil is not recommended for use during pregnancy or breast-feeding.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering or if the capsules look damaged.

Do not take Reductil if you have one of the following medical conditions:

- You have an eating disorder such as anorexia nervosa or bulimia nervosa.
- Your overweight or obesity is due to a disease.
- You have a psychiatric or mental illness, eg bipolar disease (manic-depression).
- You have hyperthyroidism (i.e. an overactive thyroid gland).
- You have high blood pressure not controlled by drugs.
- You have severe liver or kidney disease.
- You have heart disease caused by poor blood flow in the blood vessels of the heart (e.g. angina).
- You have disease of the heart with shortness of breath, and swelling of the feet or legs due to fluid build up.

- You have changes in heart rate (fast, slow or irregular).
- You have had a stroke.
- You have a swelling of the prostate gland that makes it difficult to pass urine.
- You have a tumour of the adrenal gland, which sits near the kidney.
- You have narrow angle glaucoma. A condition in which the pressure of fluid in the eye may be high.
- You have a history of drug, medication or alcohol abuse.
- You suffer from Gilles de la Tourette's syndrome.
- **You have had seizures (epilepsy or convulsions).**

Do not take Reductil if you are taking one of the following medications:

- **You are taking any medicine for depression.**
Check with your doctor or pharmacist if you are unsure as to whether or not you are taking an antidepressant.
- **You are taking another medicine to lose weight.**
This includes over-the-counter medicines or herbal products.
- **You are taking a medicine that affects your alertness**
(i.e. keeps you awake or makes you sleepy) e.g. tranquillisers, antidepressants or tryptophan.

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

Before you start to take Reductil

Tell your doctor if

- 1. You are allergic to foods, dyes, preservatives or any other medicines.**
- 2. You are or intend to become pregnant or breast-feed.**
The use of Reductil is not recommended during pregnancy or breast-feeding.

3. You have any medical conditions, especially the following:

- high blood pressure
- kidney or liver disease
- seizures, fits or convulsions
- motor or verbal tics
- gallstones
- open angle glaucoma
- have a family history of raised pressure in the eye.

If you have not told your doctor about any of the above, tell them before you start taking Reductil.

Taking other medicines

Because weight loss has many beneficial effects, it may also affect the dose of medication you take for other conditions such as cholesterol, diabetes and thyroid. Make sure you discuss all the medications that you are taking with your doctor. Losing weight may mean your doctor may make adjustments to these medications.

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

Some medicines and Reductil may interfere with each other.

These include:

- ketoconazole, a medicine used to treat fungal infections.
- erythromycin or rifampicin, used to treat infections.
- cyclosporin, a medicine used to prevent organ transplant rejections or to treat certain problems with the immune system.
- carbamazepine, phenobarbitone, and phenytoin, medicines to treat epilepsy.
- dexamethasone, a medicine used to treat inflammation.
- lithium, a medicine used to treat mood swings.
- tryptophan, an amino acid.

- sumatriptan succinate, dihydroergotamine, medicines used to treat migraines.
- medicines used to treat severe pain.
- certain medicines used to relieve symptoms of coughs, colds and allergies (e.g. dextromethorphan).
- other medicines used for weight loss. This includes over-the-counter medicines or herbal products.

These medicines may be affected by Reductil, or may affect how well it works. Your doctor will be able to tell you what to do when taking Reductil with other medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Reductil.

How to take Reductil

How much to take

The usual dosage is one capsule taken once each day.

Follow all directions given to you by your doctor carefully.

These directions may differ from the information contained in this leaflet.

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

How to take Reductil

Swallow one capsule whole every day with a glass of water. Start with the capsule marked "Begin with this capsule" on each tray, followed, on the next day, with the capsule marked with that day of the week. Continue to take one capsule daily until all the capsules in the tray have been taken. All capsules are the same. They are marked with the day of the week to help you keep track of whether you have taken your dose each day.

When to take Reductil

Take Reductil at about the same time each day.

It does not matter if you take Reductil before or after food.

If you forget to take Reductil

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist.

How long to take Reductil

Continue taking Reductil for as long as your doctor tells you.

In case of an overdose

Immediately telephone your doctor or the Poisons Information Centre (telephone in Australia 13 11 26, in New Zealand 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Reductil. Do this even if there is no sign of discomfort or poisoning.

You may need urgent medical attention.

While you are using Reductil

Things you must do

Tell your doctor if you experience a rapid onset of shortness of breath.

Have your weight checked when your doctor requests, to make sure that Reductil is working.

Have your blood pressure and weight checked when your doctor requests. In the first 3 months of treatment, your doctor should perform a check every 2 weeks, thereafter at least once every three months.

Women should use an effective birth control method whilst taking Reductil eg the oral contraceptive pill (the pill).

If you become pregnant while taking Reductil, stop taking it and tell your doctor immediately.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Reductil.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Reductil, as with all your other medicines.

For best results, Reductil should be used together with a low fat diet and moderate exercise.

Tell your doctor if you feel that Reductil is not working for you.

Tell your doctor if you have not taken your medicine exactly as prescribed.

Things you must not do

Do not stop taking Reductil or change the dosage without checking with your doctor.

Do not give Reductil to anyone else, even if they have the same condition as you.

Do not take Reductil to treat any other complaints unless your doctor tells you.

Things to be careful of

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

Like other medicines, Reductil may cause light-headedness or dizziness in some people. Make sure you

know how you react to Reductil before you drive a car or operate machinery, or do anything else that may be dangerous if you are dizzy or light-headed. If this occurs do not drive.

If you drink alcohol, light-headedness or dizziness may be worse. It is important to remember that the consumption of alcohol is not consistent with a calorie controlled weight loss program. Your doctor is the best person to discuss whether you should drink alcoholic beverages while on Reductil.

Side effects

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

Tell your doctor as soon as possible if you do not feel well while taking Reductil.

Reductil helps most overweight people lose weight, but it may have unwanted side effects in a few people. All medicines can have serious side effects. Some times they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions that you may have.

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

- dry mouth
- headache
- hot flushes
- constipation
- feeling sick, also called nausea
- haemorrhoids get worse
- inability to sleep
- dizziness
- tingling or numbness of the hands or feet
- sweating
- loss or change in taste sensation

- feeling anxious

These side effects are generally not serious.

Tell your doctor immediately if you notice any of the following:

- increase in high blood pressure
- fast or irregular heart beats
- changes in frequency of urination or volume of urine
- unusual bleeding or bruising under the skin
- blurred vision
- short-term memory loss

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

- convulsions, fits or seizures

This is a very serious side effect and is very rare. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Ask your doctor or pharmacist if you do not understand anything in this list.

After taking Reductil

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they will not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25 degrees C.

Do not store Reductil or any other medicine in the bathroom or near a sink.

Do not leave Reductil in a car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

Disposal

If your doctor tells you to stop taking Reductil or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What Reductil looks like

Reductil comes in two types of capsules:

Reductil 10mg – blue/yellow capsule with “Reductil” and “10” printed on it.

Reductil 15mg – blue/white capsule with “Reductil” and “15” printed on it

Each box contains 30, 60 or 90 capsules presented as two, four or six “trays” respectively. Individual trays contain 15 capsules each.

The 30 pack presentation is intended for initiation of Reductil therapy.

Ingredients

Active ingredient:

Each capsule contains 10mg or 15mg of sibutramine hydrochloride.

Inactive Ingredients:

- lactose
- cellulose – microcrystalline
- silica colloidal anhydrous
- magnesium stearate
- gelatine
- titanium dioxide
- shellac
- lecithin
- dimethicone
- sodium lauryl sulphate
- indigo carmine CI73015
- iron oxide black CI77499

- quinoline yellow CI47005 (10mg capsule only)

Distributor

Reductil is distributed by:
Abbott Australasia Pty Ltd
32-34 Lord Street
Botany NSW 2019
Australia
Free phone 1800 225 311

Abbott Laboratories (NZ) Ltd
4 Pacific Rise
Mt Wellington
Auckland
New Zealand
Free phone 0800 73 72 71

Reductil 10mg – AUST R 68115

Reductil 15mg – AUST R 68116

For further information on Reductil
and additional support information
please visit:

Australia:

www.reductil.com.au

New Zealand:

www.reductil.co.nz

Date of preparation

28 April 2008

Version 08