To the patient
The following instructions for use tell you what you need to know about taking this medicine. Please read this leaflet carefully and consult your doctor or pharmacist if you require more information.

Instructions for use

Reductil® 10 mg

Active substance: sibutramine hydrochloride monohydrate

Composition
1 Reductil® 10 mg capsule contains:

– Active substance:
10 mg of sibutramine hydrochloride monohydrate

– Other ingredients:
Quinoline yellow (E 104), dimeticone, iron oxides and hydroxides (E 172), gelatin, colloidal anhydrous silica, indigo carmine (E 132), lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, shellac, soybean lecithin (E 322), titanium dioxide (E 171).

Presentation and contents
Each pack contains 28 capsules.

Reductil is for the treatment of obesity counting as an illness.

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Indications
Reductil 10 mg is for supportive treatment within a weight management programme of
- Patients with alimentary obesity and a BMI (Body Mass Index) of 30 kg/m² or above.
- Patients with alimentary excess weight and a BMI of 27 kg/m² or above who have obesity-related risk factors like type II diabetes or dyslipidaemia (disorders of lipid metabolism).

Note:
Reductil 10 mg may only be used by patients who have failed to respond or shown inadequate response to appropriate weight reducing measures alone, that is, who have lost less than 5 kg in weight within three months.
Treatment with Reductil 10 mg should only be undertaken as part of a comprehensive therapeutic approach to weight management under the supervision of a doctor with experience in the treatment of obesity. An appropriate therapeutic approach involves diet, behavioural modification and increased physical activity. This type of comprehensive approach is the basis for the lasting modification of eating habits and behaviour patterns that is essential to maintaining weight loss after stopping treatment. Reductil 10 mg should not be taken indefinitely.

Contraindications
When should I not take Reductil 10 mg?
- If you know you are hypersensitive to sibutramine hydrochloride monohydrate or one of the other constituents of the medicine
- If your obesity is caused by organic dysfunction
- If you have a prior history of, or an existing, eating disorder such as anorexia nervosa (slimmer's disease) or bulimia nervosa (compulsive eating and vomiting).
- If you suffer from mental illness
  If you have Gilles de la Tourette's syndrome (a special type of tic disorder)
- If you are currently taking, or have taken during the past 2 weeks, monoamine oxidase inhibitors (MAO inhibitors, medicines for the treatment of depression) or other medicines acting on the central nervous system for the treatment of mental disorders (such as antidepressants or antipsychotics), for sleep disorders (tryptophan) or for weight reduction.
- If you have a prior history of, or existing, coronary artery disease, congestive heart failure (weak heart), tachycardia (accelerated heart beat), occlusive artery disease (a specific type of serious blood flow disorder), heart rhythm disorder, or cerebrovascular disease (impairment of blood flow to the brain) such as stroke or TIA (transient ischaemic attack – recurrent impairment of blood flow to the brain)
- If you have inadequately controlled high blood pressure (greater than 145/90 mm Hg) [see "Precautions for use and warnings"]
- If you suffer from hyperthyroidism (excessive production of hormones by the thyroid gland)
- If you have severely impaired liver function
- If you have severely impaired kidney function
- If you have benign prostatic hyperplasia (enlargement of the prostate) with urine retention
  If you have phaeochromocytoma (a hormone-producing tumour of the adrenal cortex)
- If you suffer from narrow angle glaucoma
- If you misuse drugs, medicines or alcohol or have done so in the past
- If you are pregnant or breastfeeding.

Can I take Reductil if I am pregnant?
As existing data is insufficient to demonstrate the safety of Reductil 10 mg for the unborn child, Reductil 10 mg may not be used during pregnancy.
Women of childbearing potential should therefore use a suitable method of contraception while taking Reductil 10 mg.

Can I take Reductil if I am breastfeeding?
It is not known whether sibutramine passes into breast milk. Therefore, do not take Reductil 10 mg if you are breastfeeding a baby.

What about children and elderly people?
As existing data is insufficient to demonstrate the safety of Reductil 10 mg in children and young people under 18 and in persons aged 65 years and older, Reductil 10 mg may not be used by these age groups.

Precautions for use and warnings
A description of when you may take Reductil 10 mg only under certain conditions and only with particular caution is given below. Please ask your doctor about this. You should also check with your doctor if the conditions used to apply to you.

What precautions are necessary?
Although sibutramine has never been linked with primary pulmonary hypertension (high blood pressure in the arteries of the lung), general experience with medicines for weight reduction suggests that close follow-up is indicated to watch for signs such as progressive dyspnoea (worsening shortness of breath), chest pain, and ankle oedema (swollen ankles). If you notice any such symptoms, call your doctor immediately.
Reductil 10 mg should be used with caution in patients prone to epileptic fits or seizures.
Studies with sibutramine showed raised plasma levels in patients with mild to moderate impairment of liver function. Although no unwanted effects were seen, Reductil 10 mg should be used with caution in these patients.
Although only inactive drug is eliminated through the kidneys, Reductil 10 mg should be used with caution in patients with mild to moderate impairment of kidney function.
Reductil 10 mg should be used with caution in patients with a family history of motor and verbal tics (involuntary twitching and jerking of the muscles, vocal tics).
Women of childbearing potential should use a suitable form of contraception while taking Reductil 10 mg.
For more information on possible risks associated with use along with cough and cold medications, see "Interactions with other medicines".

Warnings:
Blood pressure and pulse must be closely monitored in all patients during treatment with Reductil 10 mg. Monitoring should take place at least every 14 days during the first two months of treatment, thereafter monthly. These checks should be performed with particular care and, as necessary, more frequently in hypertensive patients whose blood pressure is currently well controlled (at or below 145/90 mm Hg). Treatment is to be stopped in patients with blood pressures above the 145/90 mm Hg threshold in two consecutive readings (see "Side effects, cardiovascular changes").
Caution is required when Reductil 10 mg is taken along with medications which prolong the QTc interval. These medications include astemizole, terfenadine (anti-allergy medications), QTc-prolonging antiarrhythmics (medications to treat disorders of heart rhythm [amiodarone, quinidine, flecainide, mexiletine, propafenone, sotalol]), cisapride (medication used to treat gastrointestinal disorders), pimozide, sertindole and tricyclic antidepressants (drugs used to treat certain psychological illnesses). Caution is also required in patients with conditions liable to prolong the QT interval, such as hypokalaemia and hypomagnesaemia (low potassium and magnesium levels in the blood) [See also "Interactions with other medicines"].

What must I do when driving or working with machinery and when working under hazardous conditions?
Drugs that act on the central nervous system are capable of affecting judgement, thinking processes and reaction time. Although sibutramine did not affect these functions in research studies, the ability to drive, operate machinery and work under hazardous conditions may be impaired while taking Reductil 10 mg.

Interactions with other medicines
What other medicines influence the effect of Reductil 10 mg and how does Reductil 10 mg influence the effect of other medicines?
Reductil 10 mg should be used only with caution together with certain medicines that are also metabolized in the liver:
Inhibition of sibutramine metabolism may be caused by ketoconazole (a drug used to treat fungal infections), erythromycin, troleandomycin (drugs used to treat infections) and cyclosporin (a drug used to suppress immune reactions, for example, in recipients of organ transplants). Simultaneous administration of sibutramine with ketoconazole and erythromycin led to a rise in plasma levels of sibutramine degradation products.
The heart rate rose by up to 2.5 beats per minute more than in subjects on sibutramine alone. Clinically irrelevant rises in QTc intervals of up to 9.5 milliseconds were observed.
An acceleration of sibutramine metabolism is possible when used together with rifampicin (a drug used to treat tuberculosis), macrolide antibiotics (drugs used to treat infections), phenytoin, carbamazepine, phenobarbital (drugs used to treat epilepsy) and dexamethasone (a glucocorticoid used to treat inflammatory reactions).
The simultaneous use of several drugs each of which increases levels of serotonin in the blood (serotonin is a natural transmitter) may give rise to serious interactions. This phenomenon is called serotonin syndrome and may occur in rare cases in connection with the simultaneous use of a specific type of antidepressant (selective serotonin reuptake inhibitor [SSRI]) together with certain antimigraine drugs (such as sumatriptan, dihydroergotamine), strong painkillers (such as pentazocine, pethidine, fentanyl), cough medications (such as dextromethorphan), or in the case of simultaneous use of two SSRIs.
As sibutramine inhibits serotonin reuptake (among other effects), Reductil 10 mg should not be used by patients taking other drugs which also raise serotonin levels.
The simultaneous administration of Reductil 10 mg and other medicines which affect the blood pressure or heart rate has not been systematically investigated to date. Such medicines include certain types of cough, cold and allergy remedies as well as certain anti-inflammatory drugs. Caution is therefore urged in the case of simultaneous use.
Reductil 10 mg does not impair the effectiveness of oral contraceptives ("the pill").
Please note that this information may also apply to medicines taken recently.

Do I have to avoid particular foods, alcohol, tobacco?
Research studies have shown that Reductil 10 mg does not further impair the ability to react in individuals who have taken alcohol. Regardless of this fact, alcohol consumption is not compatible with the dietary measures recommended during treatment.

Dosage instructions, method and period of use
The following information applies unless otherwise prescribed by your doctor. Please keep to the instructions for use, as Reductil 10 mg cannot work properly otherwise.
General information:
Treatment with Reductil 10 mg should only be carried out as part of a comprehensive weight reduction programme under the supervision of a doctor with experience in treating obesity (see "Indications").

How much Reductil 10 mg should I take and how often should I take it?
Adults: The starting dose is one Reductil 10 mg capsule (equivalent to 10 mg of sibutramine hydrochloride monohydrate) once daily.
Patients who respond unsatisfactorily to Reductil 10 mg (i.e. less than 2 kg weight loss in 4 weeks) may be switched to 1 capsule of Reductil 15 mg* (equivalent to 15 mg of sibutramine hydrochloride monohydrate) once daily, provided Reductil 10 mg was well tolerated. Treatment must be discontinued in patients who respond unsatisfactorily to Reductil 15 mg* (i.e. less than 2 kg weight loss in four weeks).
*Reductil is also available in a 15 mg dose.

How and when should I take Reductil 10 mg?
Take the capsule in the morning whole and unchewed with plenty of liquid (a glass of water, for example). It can be taken with or without food.

How long should I take Reductil 10 mg for?
Treatment should be stopped after three months in patients who fail to respond satisfactorily, that is, who have not lost 5% or more of their initial weight within three months after starting treatment.
Treatment should not be continued in patients who subsequently gain 3 kg or more after initially losing weight.
Treatment with Reductil 10 mg should not exceed one year as the safety and efficacy of treatment have not been established for periods in excess of one year.
Patients undergoing treatment with Reductil 10 mg should change their lifestyle in accordance with the goal of weight management so that they can maintain their weight loss after stopping treatment. Patients should be told that they will regain weight otherwise, and should also be aware that the continued guidance of their treating physician is necessary after treatment has been discontinued.

Overdose and other errors in use
What must I do if I take too much Reductil 10 mg (deliberate or accidental overdose)?
There is only limited experience of sibutramine overdose. No special signs of overdose are known, but a greater occurrence of side effects is likely. Please tell a doctor if you suspect an overdose.
Medical measures in case of overdose:
No special treatment is recommended and there is no specific antidote to sibutramine. General measures should be taken such as keeping the airways open, monitoring cardiovascular functions, and general symptomatic and supportive measures. Early administration of activated charcoal can retard the absorption of sibutramine. Gastric lavage may also be of benefit. In patients with high blood pressure or tachycardia (accelerated heartbeat), careful administration of beta-blockers (medicines to lower the blood pressure and slow down the pulse rate) may be indicated.

What must I do if I have taken too little Reductil 10 mg or missed a dose?
Do not take a double dose next time. Just continue to take Reductil as described in the dosage instructions.

Side effects
What side effects can occur when taking Reductil 10 mg, and what countermeasures can be taken?
Most side effects have occurred at the start of treatment (in the first 4 weeks). Their severity and frequency decreased with time. The side effects were generally not serious and went away.
The list below shows side effects classified by organ system (frequent > 10%; occasional 1–10%; rare < 1%).

Organ system	Frequency	Adverse event
Cardiovascular (see also "Cardiovascular changes")	Occasional	Tachycardia (pathologically accelerated heartbeat) Palpitations Raised blood pressure/hypertension Vasodilation (flush [reddening of the skin with sensation of heat])
Gastrointestinal	Frequent	Loss of appetite Constipation
	Occasional	Nausea Haemorrhoids
Central nervous system	Frequent	Dry mouth Insomnia
	Occasional	Dizziness Paraesthesias (abnormal skin sensations) Headache Anxiety
Skin	Occasional	Sweating
Senses	Occasional	Taste disturbance

The following clinically significant adverse events occurred in individual cases under treatment with sibutramine:
- Acute interstitial nephritis, mesangiocapillary glomerulonephritis (certain types of kidney inflammation)
- Henoch-Schoenlein purpura (blotchy skin haemorrhages)
- Seizures
- Thrombocytopenia (reduction in platelet count)
- Temporarily raised liver enzyme activity
- Acute psychotic attack after treatment in one patient with schizoaffective disorder which presumably existed prior to treatment

Withdrawal symptoms such as headache and increased appetite have rarely been observed. There have been no signs of withdrawal or abstinence syndrome or mood swings on discontinuing treatment.

Cardiovascular changes
A mean increase in resting blood pressure of between 1 and 3 mmHg and a mean increase in pulse rate of 3 to 7 beats per minute have been observed.
Higher increases in blood pressure and heart rate cannot be ruled out in individual cases.
Any medically significant rise in blood pressure and heart rate tends to occur at the start of treatment (during the first 4 to 8 weeks).
Use of Reductil 10 mg in patients with high blood pressure: see "Contraindications" and "Precautions for use and warnings".
If you experience side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

Instructions and information on storing this medicine
The expiry date is marked on the blister pack and cardboard box. Do not use the medicine after this date.

How should I store Reductil 10 mg?
Do not store over 25°C.
Keep all medicines out of children's reach.

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What is obesity?
Obesity means an excess of body fat. There may be a variety of causes, but in most cases obesity is caused by overeating. Weight gain is primarily an increase in fatty mass. For example, a weight gain of 12 kg means an increase of 9 kg in body fat and 3 kg in muscle mass. The Body Mass Index (BMI) is used nowadays to determine whether a person is overweight and to what extent. Adult BMI is calculated by the following formula:

$$\text{BMI} = \frac{\text{Body weight in kg}}{(\text{Body height in m})}$$

A BMI of between 18.5 and 24.9 indicates normal weight, 25 to 29.9 indicates moderate overweight, and 30 to 39.9 indicates obesity that definitely requires treatment. Extreme obesity is indicated by a BMI of 40 and above.

What is the treatment for severe obesity?
For treatment of obesity to be successful, it is particularly important to change your present lifestyle gradually and permanently with the help of a targeted treatment programme and medical support.
The new lifestyle involves switching to a balanced diet, more physical activity, and learning new patterns of behaviour in particular situations. It often helps to join a support group. Treatment may be enhanced for a period of time by taking a medication which aids weight loss and helps you maintain your weight at a lower level.

Your doctor has prescribed Reductil 10 mg for this purpose. Reductil 10 mg mainly acts by its effects on transmitter substances in the brain which are involved in controlling hunger pangs, fullness and metabolic activity. This makes it easier to switch to healthier eating habits.

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