

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ionamin 15

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active constituent

Phentermine (as a resin complex)	15 mg
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3 PHARMACEUTICAL FORM

Modified release capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ionamin is an anorectic agent intended as an adjunctive therapy to diet in patients with obesity and a body mass index (BMI) of 30 kg/m² or higher, who have not responded to an appropriate weight reducing regimen alone.

Note: Short term efficacy only has been demonstrated with regard to weight reduction. No significant data on changes in morbidity or mortality are yet available.

4.2 Posology and method of administration

Oral administration.

Adults: 15 mg or 30 mg daily at breakfast time. Evening dosing should be avoided as Ionamin may induce nervousness and insomnia.

It is recommended that treatment should be conducted under the care of physicians experienced in the treatment of obesity.

Secondary organic causes of obesity must be excluded by diagnosis before prescribing Ionamin.

The recommended dose should not be exceeded in an attempt to increase the anorectic effect, and the drug should be discontinued in non-responsive cases.

The management of obesity should be undertaken using a overall approach which should include dietary, medical and psychotherapeutic methods.

The duration of treatment is four to six weeks and should not exceed three months. An intermittent dosage regimen consisting of treatment for up to four weeks, followed by a similar period without medication may be as effective as continuous treatment.

Children (below 12 years) and The Elderly: Ionamin is not recommended for use.

4.3 Contraindications

Pulmonary artery hypertension; severe arterial hypertension. Thyrotoxicosis, glaucoma, epilepsy. Hypersensitivity to sympathomimetic amines. Current or past medical history of cardiovascular or cerebro-vascular disease or psychiatric disorders including anorexia nervosa and depression. Propensity towards drug abuse, known alcoholism. Ionamin should not be administered to children under 12 years of age.

Combination drug therapy

Concurrent use with any other centrally acting anorectic agent is contra-indicated due to the increased risk of potentially fatal pulmonary artery hypertension. Concurrent or recent use of monoamine oxidase inhibitors (MAOI's) also contra-indicates the use of Ionamin.

4.4 Special warnings and precautions for use

Special Warnings

Cases of severe, often fatal, pulmonary artery hypertension, have been reported in patients who have received anorectics of the type in this product. An epidemiological study has shown that anorectic intake is a risk factor involved in the development of pulmonary artery hypertension and that the use of anorectics is strongly associated with an increased risk for this adverse drug reaction. In view of this rare but serious risk, it must be emphasised that:

- careful compliance with the indication and the duration of treatment is required,

- duration of treatment greater than 3 months and a BMI ≥ 30 kg/m² increase the risk of pulmonary artery hypertension.
- the onset or aggravation of exertional dyspnoea suggests the possibility of occurrence of pulmonary artery hypertension. Under these circumstances, treatment should be immediately discontinued and the patient referred to a specialist unit for investigation.

Special Precautions for Use

- Prolonged treatment may give rise to pharmacological tolerance and drug dependence, and more rarely to severe psychotic disorders in predisposed patients.
- Rarely, cases of cardiac and cerebro-vascular accidents have been reported, often following rapid weight loss. Special care should be taken to ensure gradual and controlled weight loss in obese patients, who are subject to a risk of vascular disease. Ionamin should not be prescribed in patients with current or a past medical history of cardio-vascular or cerebro-vascular disease.
- Ionamin should be used with caution in epileptic patients.

4.5 Interaction with other medicinal products and other forms of interaction

Phentermine may enhance the response to alcohol and, in combination with dieting, may alter the insulin requirements of diabetics. Caution should be exercised when Ionamin is administered with anti-hypertensive, psychotropic and sympathomimetic drugs.

4.6 Fertility, Pregnancy and lactation

Pregnancy: There is inadequate evidence of safety of Ionamin in human pregnancy. There is evidence of harmful effects in animals with amphetamines. Treatment with Ionamin should cease during pregnancy.

Lactation: No information is available.

4.7 Effects on ability to drive and use machines

Phentermine may produce mild CNS excitation and there is a theoretical risk of sedation on withdrawal of the drug. If the patient is affected, his ability to drive or operate machinery may be impaired.

4.8 Undesirable effects

Pulmonary artery hypertension

- An epidemiological study has shown that anorectic intake is a risk factor involved in the development of pulmonary artery hypertension and that the use of anorectics is strongly associated with an increased risk for this adverse drug reaction. Cases of pulmonary artery hypertension have been reported in patients treated with phentermine. Pulmonary artery hypertension is a severe and often fatal disease. The occurrence or aggravation of exertional dyspnoea is usually the first clinical sign and requires treatment discontinuation and investigation in a specialised unit (see Special Warnings).

CNS effects

- the prolonged use of this agent is associated with a risk of pharmacological tolerance, dependence and withdrawal syndrome.
- the most common adverse reactions which have been described are: psychotic reactions or psychosis, depression, nervousness, agitation, sleep disorders and vertigo.
- Convulsions, dry mouth and headache have also been reported.

Cardio-vascular effects

- the most common reported reactions are tachycardia, palpitations, hypertension, precordial pain.
- rarely, cases of cardiovascular or cerebro-vascular accidents have been described in patients treated with anorectic agents. In particular stroke, angina, myocardial infarction, cardiac failure and cardiac arrest have been reported.

Other effects

- Constipation, nausea, vomiting and rashes have been reported.

4.9 Overdose

Signs and Symptoms: CNS stimulation such as restlessness, agitation and hallucinations may occur, usually followed by fatigue and depression. Cardiovascular effects include arrhythmias, hypertension and circulatory collapse. Gastrointestinal effects include nausea, vomiting, diarrhoea and abdominal cramps. Since Ionamin is a sustained release product, effects may be slow in onset and prolonged.

Treatment: Management includes emesis or gastric lavage (depending on the clinical state of the patient) and activated charcoal. The patient should be kept quiet and chlorpromazine used if necessary for sedation. Cardiovascular function should be monitored and treated symptomatically. In serious cases, forced acid diuresis may be indicated but only after discussion with a poisons centre.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Phentermine is a sympathomimetic amine with CNS stimulant activity. It has not been established whether its anorectic action is primarily one of appetite suppression or whether other central nervous or metabolic effects may be involved.

5.2 Pharmacokinetic properties

After ingestion, phentermine is gradually released from the ion exchange resin complex providing smooth and maintained plasma concentrations.

5.3 Preclinical safety data

No remarks.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amberlite Resin*, Calcium Hydrogen Phosphate BP, Lactose BP, Magnesium Stearate BP, Purified Water BP, Titanium Dioxide (E171), Sunset Yellow (E110), Quinoline Yellow (E104), Gelatin USP, Black Iron Oxide (E172) and Black Ink.

*Sulphonated styrene - divinyl benzene copolymer

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

Tablet container with screw cap (100 capsules) or strips (4 or 28 capsules).

6.6 Special precautions for disposal

No special instructions are necessary.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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24/02/2009

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