NEW ZEALAND DATA SHEET

Phentermine Juno ER

1. PRODUCT NAME

Phentermine Juno ER 15 mg extended release tablet
Phentermine Juno ER 30 mg extended release tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Phentermine Juno ER are oral film coated extended release tablets, containing the active ingredient phentermine HCl with two different strengths 15 and 30 mg as phentermine base.

Excipients with known effect:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Modified release tablet

Phentermine Juno ER 15 mg are green film coated capsule shaped tablets.
Phentermine Juno ER 30 mg are red film coated capsule shaped tablets.

The release mechanism is controlled by hydrophobic and hydrophilic release modifiers. The tablet consists of a hydrophobic wax matrix which contains a hydrophilic release modifier and the drug substance.

When the drug product is taken, the GI tract fluids begin to dissolve the hydrophilic components. The dissolution process allows the gradual release of phentermine over time. Drug release is not dependent on pH.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Phentermine Juno ER is indicated as a short-term adjunct in a medically monitored comprehensive regimen of weight reduction based on exercise, diet (caloric restriction) and behaviour modification in obese patients with a body mass index (BMI) of 30kg/m² or greater who have not achieved an adequate clinical response to an appropriate weight-reducing regimen alone.

Phentermine Juno ER may appropriately be initiated in overweight patients with a lower BMI when risk of morbidity from other medical conditions is increased. Patients with the following co-morbidities are particular candidates for medical assistance with weight reduction, and may be considered for treatment even if their BMI does not exceed 30 kg/m^2:

- sleep apnoea
- insulin-resistant diabetes mellitus
- pre-diabetes or impaired glucose tolerance in association with obesity
- high cardiovascular risk status as a consequence of obesity.

Failure to achieve a weight reduction of 5% within a period of 12 weeks is an indication for discontinuation of treatment. Treatment may continue beyond this point provided continued monitoring of the patient occurs (for weight loss and medical conditions) and for as long as weight loss is maintained.

Secondary organic causes of obesity should be excluded by diagnosis before prescribing this agent.

4.2 Dose and method of administration

For oral administration:

Adults and children aged over 12 years

One capsule daily at breakfast, swallowed whole. Evening dosing should be avoided as this agent may induce insomnia. It is recommended that treatment should be initiated under the care of medical practitioners experienced in the treatment of obesity.

The usual starting point of therapy is 30 mg daily. For lighter framed individuals or when side effects are evident, the 15 mg strength is the recommended alternative. Maintenance therapy, either continuous or intermittent, can be effectively managed with a dose between 15 mg and 30 mg daily. The recommended dose of Phentermine Juno ER should not be exceeded and PHENTERMINE JUNO ER should not be combined with other appetite suppressants in an attempt to increase the effect. Patients require medical review after a defined course of treatment which ideally should not exceed 3 months.

Children

Phentermine Juno ER is not recommended for children under the age of twelve.

Elderly

Phentermine Juno ER is not recommended for the elderly.

4.3 Contraindications

Pulmonary artery hypertension, existing heart valve abnormalities or heart murmurs, moderate to severe arterial hypertension, cerebrovascular disease, severe cardiac disease including arrhythmias, advanced arteriosclerosis, known hypersensitivity to sympathomimetic drugs, hyperthyroidism, agitated states or a history of psychiatric illness including anorexia nervosa and depression, glaucoma, history of drug/alcohol abuse or dependence.

Concomitant treatment with monoamine oxidase (MAO) inhibitors or within 14 days following their administration.

4.4 Special warnings and precautions for use

Each Phentermine Juno ER extended release tablet contains phentermine hydrochloride. The innovator contains phentermine as an extended release ion exchange resin capsule. All clinical data in this product information are based on phentermine extended release capsule. Bioequivalence has been established between the two drug forms.

Phentermine Juno ER capsules are indicated only as short-term monotherapy for the management of exogenous obesity. The safety and efficacy of combination therapy with phentermine and any other drug products for weight loss have not been established. Therefore, co-administration of drug products for weight loss is not recommended.

Valvular heart disease

Serious regurgitant cardiac valvular disease, primarily affecting the mitral, aortic and/or tricuspid valves, has been reported in otherwise healthy persons who had taken a combination of phentermine with fenfluramine or dexfenfluramine for weight loss. The aetiology of these valvulopathies has not

been established and their course in individuals after the drugs are stopped is not known. There have been no reported cases to date of this valvular condition occurring with the use of phentermine alone.

Since the selective serotonin reuptake inhibitors (e.g. fluoxetine, sertraline, fluvoxamine, paroxetine), ergot derived drugs and clomipramine affect serotonin metabolism there remains a theoretical risk that combination of these agents with phentermine may also be associated with cardiac valvular disease, although there is no direct scientific evidence to confirm this theory.

Primary pulmonary hypertension

Cases of severe, sometimes fatal, primary pulmonary hypertension (PPH) have been reported in patients who have received anorectics. PPH has also been reported in patients receiving phentermine combined with fenfluramine/dexfenfluramine. The possibility of an association between PPH and the use of phentermine alone cannot be ruled out. There have been very rare cases of PPH in patients who reportedly have taken phentermine alone.

The initial symptom of PPH is usually dyspnoea. Other early symptoms include angina pectoris, syncope, lower extremity oedema or the unexplained onset or aggravation of diminished exercise tolerance. Under these circumstances, treatment should be immediately discontinued and the patient referred to a specialist unit for investigation.

Use with caution in the following circumstances

Phentermine Juno ER should be used with caution in patients with mild hypertension. In the first days of treatment determine that there is no loss of blood pressure control.

In patients receiving Phentermine Juno ER, response to insulin and oral hypoglycaemic agents may vary due to alterations in dietary regimens. This should be kept in mind if Phentermine Juno ER is used in diabetic patients.

Phentermine Juno ER is not recommended in patients with pre-existing valvular heart disease.

Rarely, cases of cardiac and cerebrovascular 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 have an increased risk of vascular disease.

Phentermine Juno ER should be used with caution in patients under treatment with anti-hypertensive agents, since it may cause some loss of blood pressure control, and in patients receiving psychotropic drugs, including sedatives and sympathomimetic agents. Phentermine Juno ER should be used with caution in epileptic patients.

Inappropriate use of Phentermine Juno ER and similar medicines has been reported and the possibility of this occurrence should be considered and patients managed accordingly. As a result patients should be reviewed regularly in the process of their treatment and informed of other measures to effect weight loss.

Phentermine Juno ER should not be used in men or women for loss of weight for cosmetic reasons. Those who have failed to respond to medical treatment for weight loss in the past should only be treated after review by a medical practitioner specialising in the treatment of weight loss. The ability of the patient to maintain effective lifestyle interventions of exercise and diet, and adhere to a medical regimen should be assessed before treatment is commenced.

4.5 Interaction with other medicines and other forms of interaction

Use Phentermine Juno ER with caution for patients receiving sympathomimetic agents. Response to insulin and oral hypoglycaemic agents may vary in patients receiving phentermine. Phentermine antagonises adrenergic neurone blocking drugs such as clonidine, methyldopa and guanethidine and may decrease their hypotensive effect.

The effects of phentermine are potentiated by monoamine oxidase inhibitors (see section 4.3) and may result in a hypertensive crisis.

The concurrent use of thyroid hormones with Phentermine Juno ER may increase the CNS stimulation that can occur with Phentermine Juno ER.

Alcohol may increase CNS side effects such as dizziness, light-headedness and confusion and its concurrent use should be avoided with Phentermine Juno ER.

Serotonin reuptake inhibitors and tricyclic antidepressants may interact with Phentermine Juno ER by increasing serotonin levels, and Phentermine Juno ER should be used with caution in those taking these agents. Since the selective serotonin reuptake inhibitors (e.g. fluoxetine, sertraline, fluvoxamine, paroxetine), ergot derived drugs and clomipramine affect serotonin metabolism there remains a theoretical risk that combination of these agents with phentermine may also be associated with cardiac valvular disease, although there is no direct scientific evidence to confirm this theory.

Effects on laboratory tests

There are no reports to date to suggest that phentermine interferes with laboratory or diagnostic tests.

4.6 Fertility, pregnancy and lactation

Pregnancy

Category B3

Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans. Due to inadequate evidence of safety in human pregnancy, Phentermine Juno ER should not be used in pregnant women.

Weight reduction using appetite suppressant drugs is not recommended in pregnancy.

Lactation

There are no data available on the safety of Phentermine Juno ER in lactation and as such, its use in lactating
women should be avoided.

4.7 Effects on ability to drive and use machines

Phentermine Juno ER may impair the ability to perform activities requiring mental alertness, such as driving and operating machinery, and patients therefore should be cautioned accordingly. Patients may be at risk whilst driving or operating machinery.

4.8 Undesirable effects

Cardiac disorders

(See section 4.4 regarding the onset or aggravation of exertional dyspnoea).

The most commonly reported reactions are tachycardia, palpitations, hypertension and precordial pain. Rarely, cases of cardiovascular or cerebrovascular accidents have been described in patients treated with anorectic agents. In particular stroke, angina, myocardial infarction, cardiac failure and cardiac arrest have been reported.

Nervous system disorders

Overstimulation, restlessness, nervousness, insomnia, tremor, dizziness and headache. Rarely euphoria may occur and this may be followed by fatigue and depression. Psychotic episodes and hallucinations are rare side-effects.

Gastrointestinal disorders

Nausea, vomiting, dry mouth, abdominal cramps, unpleasant taste, diarrhoea, constipation.

Renal and urinary disorders

Micturition disturbances

Reproductive system and breast disorders

Impotence, changes in libido

Skin and subcutaneous tissue disorders

Rash, facial oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose

Symptoms and Signs

Initially euphoria, restlessness, irritability, tremor, hyper-reflexia, rapid respiration, confusion, agitation, assaultiveness, disorientation, hallucinations and panic states may occur. Fatigue, central nervous system depression, convulsions and coma may follow the central stimulation.
Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse.
Gastrointestinal symptoms include nausea, vomiting, diarrhoea and abdominal cramps.

Treatment

The treatment of overdose is largely symptomatic. However, the stomach should be emptied by gastric lavage and washed out with water if the preparation has been ingested within the last three or four hours. Gastric lavage, followed by activated charcoal, may be the optimal decontamination regimen for patients expressing CNS depression. Diazepam, preferably by mouth (cautiously by intravenous injection) can be used to control marked excitement and convulsions. Provided renal function is adequate, acidification of the urine has been shown to increase elimination of phentermine. There is insufficient experience to recommend haemodialysis or peritoneal dialysis.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Centrally acting antiobesity products, ATC Code: A08AA01

Phentermine is a sympathomimetic amine chemically related to amphetamine with significant anorectic activity in animal models. Its appetite suppressant effect is generally considered to be exerted through the hypothalamus but it is not certain that this is the only effect related to weight loss. Phentermine has major effects on the dopaminergic and noradrenergic nervous systems. In addition to effects upon appetite suppression in the CNS, phentermine may also have peripheral effects related to lipid metabolism. The cardiovascular effects include a pressor response and an increase in heart rate and force of contraction.

5.2 Pharmacokinetic properties

Phentermine (phenyl tertiary butylamine) ion-exchange resin complex is quite stable, highly insoluble and without pharmacological effect until it reacts with cations (hydrogen, potassium, sodium, etc) present in the gastrointestinal fluids. Phentermine is then released from the resin complex at a rate dependent on the total concentrations of these cations. Since this concentration is fairly constant throughout the entire gastrointestinal tract, continuous and controlled ionic release occurs over a 10 to 14 hour period.

Absorption of phentermine is almost complete. The rate of absorption from the resin complex is significantly slower than that from the hydrochloride salt, resulting in a lower and later peak blood level.

Phentermine is readily absorbed from the gastrointestinal tract and approximately 70 to 80% of an oral dose is excreted unchanged in the urine. The remainder is metabolised by the liver.

The half-life of phentermine is about 25 hours. In one study in volunteers acidification of the urine reduced the half life to 7 to 8 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phentermine Juno ER 15 mg capsules

Cetostearyl alcohol
Stearic acid
Maltodextrin
Sorbitol
Magnesium stearate
Polyvinyl alcohol
Titanium dioxide
Macrogol
Talc
Brilliant blue FCF aluminium lake
Iron oxide yellow
Sunset yellow FCF aluminium lake

Phentermine Juno ER 30 mg capsules

Cetostearyl alcohol
Stearic acid
Maltodextrin
Sorbitol
Magnesium stearate
Polyvinyl alcohol
Iron oxide red
Macrogol
Talc
Titanium dioxide
Black iron oxide

Phentermine Juno ER capsules are gluten-free, preservative-free and gluten free. It does not contain materials of animal origin.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months from date of manufacture.

6.4 Special precautions for storage
Store at or below 30^0C.

Keep out of the reach of children.

6.5 Nature and contents of container
Phentermine Juno ER tablets 15 mg are supplied in pack sizes of 30 and 90 tablets.
Phentermine Juno ER tablets 30 mg are supplied in pack sizes of 30 and 90 tablets.

6.6 Special precautions for disposal
No special requirements.

7. MEDICINE SCHEDULE
Class C5 Controlled Drug

8. SPONSOR
Arrotex Pharmaceuticals (NZ) Limited:
C/o Quigg Partners
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36 Brandon Street,
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9. DATE OF FIRST APPROVAL
14 December 2023

10. DATE OF REVISION OF THE TEXT
1 August 2025

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SUMMARY TABLE OF CHANGES

Section changed	Summary of Changes
4.8	The website address to report adverse effects has been updated
4.9	Minor editorial change
8	Sponsor transfer