Professional Information for RELISLIM

SCHEDULING STATUS: S6 (RSA)

NS4 (Namibia)

1. NAME OF THE MEDICINE

ReliSlim 20 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg d-norpseudoephedrine hydrochloride.

Excipients with known effect:

Contains sugar (60 mg lactose monohydrate per tablet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Round, white tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

An aid to mass reduction when used in combination with a reduced kilojoule intake.

4.2 Posology and method of administration

Do not exceed the recommended dosage.

One to two tablets with breakfast followed by one tablet at lunchtime, taken with a little water.

Do not use for longer than 4 weeks at a time.

Method of administration

Oral.

4.3 Contraindications

- Hypersensitivity to d-norpseudoephedrine hydrochloride or to any of the excipients of ReliSlim (see section 6.1).
- Pregnancy (see section 4.6).
- Coronary thrombosis.
- Hyperthyroidism.
- Closed-angle glaucoma.
- Severe hypertension.
- Phaeochromocytoma.
- Patients undergoing anaesthesia with cyclopropane, halothane, or other volatile anaesthetics (see section 4.5).
- Patients treated with monoamine oxidase inhibitors or within two weeks of stopping such treatment (see section 4.5).
- ReliSlim should be avoided in young children.

4.4 Special warnings and precautions for use

ReliSlim should not be taken late afternoon, due to the stimulant effect which d-norpseudoephedrine has on the central nervous system.

ReliSlim tablets are liable to be abused. Use with extreme caution in patients with a history of drug or alcohol abuse and in patients with personality disorders.

Tolerance with dependence has been reported.

There is a lack of evidence for efficacy in long-term management of obesity.

ReliSlim should be given with caution to patients with:

- diabetes mellitus (you have a high incidence of atherosclerotic disease and may be at higher risk of cardiac effects; the effect on blood glucose levels should be considered),
- cardiovascular disorders (coronary insufficiency, ischaemic heart disease, cardiac dysrhythmias, obstructive cardiomyopathy, cardiac decompensation or anginal pain),
- hypertension (systolic and diastolic blood pressure may be increased, especially with high doses),
- occlusive vascular disease (these patients are at an increased risk of peripheral ischaemia),
- renal impairment,
- prostate disorders (may be at an increased risk of urinary disorders, such as urinary retention or difficulty with micturition),
- porphyria (ReliSlim should be used only when no safer alternative is available and precautions should be considered in vulnerable patients),
- elderly patients (may have a high incidence of atherosclerotic disease and may be at higher risk of cardiac effects),
- a history of psychiatric illness.

ReliSlim contains lactose monohydrate

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take ReliSlim.

4.5 Interaction with other medicines and other forms of interaction

Monoamine oxidase inhibitors (MAOIs)

Patients are advised to consult their health care provider before taking ReliSlim if they are currently taking monoamine oxidase inhibitors (MAOIs), including reversible inhibitors of monoamine oxidase (RIMAs) and sympathomimetics, as it may cause a hypertensive crisis.

Sympathomimetics

Sympathomimetics which have indirect actions, and for which the risk is particularly high include: dexamfetamine, dopamine, dopexamine, ephedrine, isometheptene, mephentermine, metaraminol, methylphenidate, phenylephrine, phenylpropanolamine and pseudoephedrine.

Volatile anaesthetics

ReliSlim should be avoided or used with care in patients undergoing anaesthesia with chloroform, cyclopropane, halothane or other volatile anaesthetics, as dangerous dysrhythmias may occur.

Digoxin

An increased risk of dysrhythmias may occur if ReliSlim is given to patients receiving digoxin.

Antidysrhythmics (including quinidine)

An increased risk of dysrhythmias may occur if ReliSlim is given to patients receiving quinidine.

Tricyclic antidepressants

Tricyclic antidepressants block the inactivation of epinephrine (adrenaline) and norepinephrine (noradrenaline) by uptake into the nerve endings and may increase their effect. An increased risk of dysrhythmias and hypertension may occur if ReliSlim is given to patients receiving tricyclic antidepressants.

Central nervous system (CNS) stimulants

ReliSlim may potentiate the effects of CNS stimulants.

Ergot alkaloids

There is an increased risk of vasoconstrictor or pressor effects in patients receiving ergot alkaloids in combination with ReliSlim.

Oxytocin

There is an increased risk of vasoconstrictor or pressor effects in patients receiving oxytocin in combination with ReliSlim.

Caffeine

ReliSlim may increase the rate of metabolism of other medicines, such as caffeine.

Thyroid hormones

Caution is required when using ReliSlim in combination with thyroid hormones.

Antihypertensive medicine or medicine that cause hypotension

ReliSlim may affect blood pressure and should be used with caution in combination with antihypertensive medicines (such as guanethidine) or medicines that cause hypotension.

Alpha blockers

Alpha blockers antagonise the effects at alpha receptors but leave the beta-mediated effects unopposed, leading to an increased risk of hypotension and tachycardia.

Beta blockers (non-selective)

Beta blockers antagonise the effects of beta receptors but leave the alpha-mediated effects unopposed, increasing the risk of hypertension and reflex bradycardia.

Antiparkinsonian medicines (e.g. levodopa and bromocriptine)

Additive cardiovascular toxicity may occur when some sympathomimetics are given with antiparkinsonian medicines, such as levodopa and bromocriptine. Severe hypertension may also occur with some sympathomimetics and selegiline, possibly due to inhibition of peripheral monoamine oxidase.

Medicines used for psychiatric or emotional conditions

Do not use ReliSlim with other medicines used to treat psychiatric or emotional conditions.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and efficacy have not been established during pregnancy and breastfeeding.

Do not use ReliSlim during pregnancy, as placental perfusion may be reduced.

Breastfeeding

Do not use ReliSlim during breastfeeding, as irritability and disturbed sleep have been reported in breastfed infants.

Fertility

No data are available on the effect of ReliSlim on fertility.

4.7 Effects on the ability to drive and use machines

Patients are advised to take special care before performing tasks requiring their attention, until they know how ReliSlim will affect them.

4.8 Undesirable effects

Psychiatric disorders

Frequent: anxiety, fear, confusion, irritability, psychotic reactions

Frequency unknown: agitation, excitability

Nervous system disorders

Frequent: restlessness, insomnia, headache

Less frequent: tremors

Frequency unknown: giddiness

Cardiac disorders

Frequent: tachycardia

Less frequent: cardiac dysrhythmias

Frequency unknown: precordial pain, palpitations, increased cardiac contractility (resulting in angina and cardiac arrest)

Vascular disorders

Less frequent: impaired circulation to the extremities, hypertension

Respiratory, thoracic and mediastinal disorders

Frequent: dyspnoea

Gastrointestinal disorders

Frequent: nausea, vomiting

Less frequent: dry mouth

Skin and subcutaneous tissue disorders

Frequency unknown: sweating

Musculoskeletal, connective tissue and bone disorders

Frequency unknown: muscular weakness

Renal and urinary disorders

Frequency unknown: difficulty in micturition, urinary retention

General disorders and administration site conditions

Frequent: weakness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of ReliSlim is important. It allows continued monitoring of the benefit/risk balance of ReliSlim. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Insomnia, paranoid psychosis, delusions, hallucinations, precordial pain, tachycardia.

Treatment of overdosage is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 11.3 Anorexigenics.

Pharmacotherapeutic group: Centrally acting antiobesity products

ATC code: A08AA07

Mechanism of action

ReliSlim is a sympathomimetic and has anorexigenic properties. The product promotes weight loss by suppressing appetite.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Magnesium stearate (E572)

Microcrystalline cellulose (E460).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Store at or below 25 °C and protect from light.

6.4 Special precautions for storage

This medicine does not require any special storage conditions.

6.5 Nature and contents of container

Securitainer packs of 30 and 90 tablets.

6.6 Special precautions for disposal and other handling

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Loock Pharmaceuticals (Pty) Ltd

39 Eagles Landing

Rock Cliff Estate

Rustenburg 0299

8. REGISTRATION NUMBER

RSA:	S6	29/11.3/0316
NAMIBIA	NS4	04/11.03/0424

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 21 December 1995

10. DATE OF REVISION OF THE TEXT

Date of revision: 1 September 2021