

**SCHEDULING STATUS:**

RSA

S6

NAMIBIA

NS1

**PROPRIETARY NAME (AND DOSAGE FORM)****RELISLIM (tablets)****COMPOSITION:**

Each tablet contains:

20 mg d-Norpseudoephedrine hydrochloride.

**PHARMACOLOGICAL CLASSIFICATION:**

A.11.3 Anorexigenics

**PHARMACOLOGICAL ACTION:**

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

**INDICATIONS:**

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

**CONTRA-INDICATIONS:**

Hypersensitivity to d-Norpseudoephedrine. RELISLIM is contra-indicated during pregnancy, coronary thrombosis, hyperthyroidism and closed-angle glaucoma. RELISLIM should not be used by patients treated with monoamine oxidase inhibitors or within two weeks of stopping such treatment.

**DOSAGE AND DIRECTIONS FOR USE:**

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.

**WARNING:**

Do not use this product without consulting your doctor or pharmacist if you are presently taking monoamine oxidase inhibitors or other medicines for depression, psychiatric or emotional conditions or hypertension.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

Large doses can produce giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, dyspnoea, difficulty in micturition, urinary retention, muscular weakness and tremors, anxiety, restlessness and insomnia. Some patients may exhibit these symptoms with the therapeutic dose.

These agents may produce psychotic reactions, fear, confusion, irritability, agitation and excitability. They should be used with caution in patients with a history of psychiatric illness. Tolerance with dependence has been reported.

Use in patients receiving chloroform, cyclopropane, halothane and other halogenated anaesthetics is not recommended.

D-Norpseudoephedrine may diminish the effects of guanethidine and may increase the possibility of arrhythmias in digitalised patients. It should be taken with caution by patients with organic heart disease cardiac decompensation or angina of effort in patients receiving digitals.

The effects of d-Norpseudoephedrine may be diminished or enhanced by tricyclic anti-depressants. In patients with prostatic enlargements, it may increase difficulty with micturition. RELISLIM should not be taken late afternoon because of its stimulant effect 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.

There is a lack of evidence for efficacy in long term management of obesity. Systolic and diastolic blood pressure may be increased, especially with high doses, and angina pain, or cardiac arrhythmias may occur. RELISLIM tablets should be administered with caution to patients suffering from cardiovascular diseases (especially from coronary insufficiency), hypertension, thyrotoxicosis and narrow angle glaucoma.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Insomnia, paranoid psychosis, delusions, hallucinations, precordial pain, tachycardia. Treatment of overdosage is supportive and symptomatic.

**IDENTIFICATION:**

Round, white tablets.

**PRESENTATION:**

Securifainer packs of 30 and 90.

**STORAGE INSTRUCTIONS:**

Store below 25 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

RSA: S6 29/11.3/0316

NAMIBIA: NS1 04/11.03/0424

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**Looek Pharmaceuticals (Pty) Ltd  
39 Eagles Landing  
Rockcliff Estate  
Rustenburg 0299PO Box 912  
Waterfall Mall  
0323**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

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