SCHEDULING STATUS: S6 (RSA)
NS4 (Namibia)

PROPRIETARY NAME AND DOSAGE FORM

ReliSlim tablet

COMPOSITION
Each tablet contains 20 mg d-norpseudoephedrine hydrochloride.
Inactive ingredients: Lactose monohydrate, magnesium stearate, microcrystalline cellulose.
Contains sugar (60 mg lactose monohydrate per tablet).

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.

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

WARNINGS AND SPECIAL PRECAUTIONS
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.

Effects on 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.

Lactose warning:
ReliSlim contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.
Patients with rare hereditary conditions of galactose intolerance, e.g. galactosaemia, the Lapp lactase deficiency or glucose-galactose malabsorption should not take ReliSlim.

INTERACTIONS
Monoamine oxidase inhibitors (MAOIs)
Patients are advised to consult their healthcare 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 adrenaline and 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.

HUMAN REPRODUCTION
Safety and efficacy have not been established during pregnancy and breastfeeding.
Do not use ReliSlim during pregnancy, as placental perfusion may be reduced.
Do not use ReliSlim during breastfeeding, as irritability and disturbed sleep have been reported in breastfed infants.

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.

SIDE 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.

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
Securitainer packs of 30 and 90 tablets.

STORAGE INSTRUCTIONS
Store at or below 25 °C and protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

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

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Loock Pharmaceuticals (Pty) Ltd
39 Eagles Landing
Rock Cliff Estate
Rustenburg 0299

DATE OF PUBLICATION OF THE PACKAGE INSERT
Date of registration: 21 December 1995
Date of amendment: Dec 2018.

LOOCK PHARMACEUTICALS

PIRELS6 06/2019

SKEDULERINGSTATUS: S6 (RSA)
NS4 (Namibië)

HANDELSNAAM EN DOSEERVORM

ReliSlim tablet

SAMESTELLING
Elke tablet bevat 20 mg d-norpseudoëfedrienhidrochloried.
Onaktiewe bestanddele: Laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose. Bevat suiker (60 mg laktosemonohidraat per tablet).

FARMAKOLOGIESE KLASSIFIKASIE
A 11.3 Eetlusdempers.

FARMAKOLOGIESE WERKING
ReliSlim is 'n simpatomimetiese middel en het eetlusdempende eienskappe. ReliSlim help met massaverlies deur die eetlus te onderdruk.

INDIKASIES
'n Hulpmiddel vir massavermindering wanneer dit in kombinasie met 'n verminderde kilojoule-inname gebruik word.

KONTRA-INDIKASIES
- Hipersensitiwiteit vir d-norpseudoëfedrienhidrochloried of vir enige van die onaktiewe bestanddele van ReliSlim (sien SAMESTELLING).
- Swangerskap (sien MENSLIKE VOORTPLANTING).
- Koronêre trombose.
- Hipertiroïdisme.
- Geslotehoekgloukoom.
- Erge hipertensie.
- Feochromositoom.
- Pasiënte wat narkose met siklopropaan, halotaan, of ander vlugtige anestetika ondergaan (sien INTERAKSIES).
- Pasiënte wat behandel word met monoamienoksidase-inhibeerders of binne twee weke nadat sodanige behandeling gestaak is (sien INTERAKSIES).
- ReliSlim moet vermy word by jong kinders.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
ReliSlim moenie laatmiddag geneem word nie, weens die stimulerende uitwerking wat d-norpseudoëfedrien op die sentrale senuweestelsel het.
Die moontlikheid bestaan dat ReliSlim tablette misbruik kan word. Dit moet uiters versigtig gebruik word by pasiënte met 'n geskiedenis van middel- of alkoholmisbruik en by pasiënte met persoonlikheidsteurings.
Toleransie met afhanklikheid is al gerapporteer.
Daar is 'n gebrek aan bewyse vir effektiwiteit in die langtermynbestuur van obesiteit.

ReliSlim moet met omsigtigheid gegee word aan pasiënte met:
- diabetes mellitus (die pasiënte het 'n hoë voorkoms van aterosklerotiese siekte en mag 'n hoër risiko vir kardiale effekte hê; die uitwerking op bloedglukosevlakke moet oorweeg word)
- kardiovaskulêre steurings (koronêre ontoereikendheid, iskemiese hartsiekte, kardiale disritmieë, obstruktiewe kardiomiopatie, kardiale dekompensasie of angina-pyn)
- hipertensie (sistoliese en diastoliese bloeddruk kan verhoog wees, veral met hoë dosisse)
- okklusiewe vaskulêre siekte (hierdie pasiënte het 'n groter risiko vir perifere iskemie)
- renale belemmering
- prostaatsteurings (mag 'n verhoogde risiko van urinêre steurings hê, soos urienterughouding of moeilike mikturisie)
- porfirie (ReliSlim moet slegs gebruik word indien daar geen veiliger alternatief beskikbaar is nie en voorsorgmaatreëls moet oorweeg word by kwesbare pasiënte)
- bejaarde pasiënte (mag 'n hoë insidensie hê van aterosklerotiese siekte en mag 'n groter risiko vir kardiale effekte hê)
- 'n geskiedenis van psigiatriese siekte.

Uitwerking op die vermoë om te bestuur en masjiene te gebruik:
Pasiënte word aangeraai om versigtig te wees voordat hulle take verrig wat konsentrasie verg, totdat hulle weet hoe ReliSlim hulle affekteer.

Laktosewaarskuwing:
ReliSlim bevat laktose wat 'n invloed op pasiënte met diabetes mellitus se glukemiese beheer mag hê.
Pasiënte met skaars oorerflike toestande van galaktose-onverdraagsaamheid, bv. galaktosemie, die Laplander-laktasegebrek of glukose-galaktosewanabsorpsie, moenie ReliSlim neem nie.

INTERAKSIES
Monoamienoksidase-inhibeerders (MAOI's)
Pasiënte word geadviseer om hul gesondheidsorgverskaffer te raadpleeg voordat hulle ReliSlim neem indien hulle tans monoamienoksidase-inhibeerders (MAOI's) neem, insluitende omkeerbare inhibeerders van monoamienoksidase en simpatomimetiese middels, aangesien dit 'n hipertensiewe krisis mag veroorsaak.

Simpatomimetiese middels
Simpatomimetika met indirekte werking, en waarvoor die risiko in besonder hoog is, sluit in: deksamfetamien, dopamien, dopeksamien, efedrien, isometepteen, mefentermien, metaraminol, metielfenidaat, fenielefrien, fenielpropanolamien en pseudoëfedrien.

Vlugtige narkosemiddels
ReliSlim moet vermy word of versigtig gebruik word by pasiënte wat narkose met chloroform, siklopropaan, halotaan of ander vlugtige anestetika ondergaan, aangesien gevaarlike disritmieë mag voorkom.

Digoksien
Daar mag 'n verhoogde risiko vir disritmieë wees indien ReliSlim gebruik word deur pasiënte wat digoksien ontvang.

Antidisritmiese middels (insluitende kinidien)
Daar mag 'n verhoogde risiko vir disritmieë wees indien ReliSlim gegee word aan pasiënte wat kinidien ontvang.

Trisikliese antidepressante
Trisikliese antidepressante blokkeer die inaktivering van adrenalien en noradrenalien deur opname in die senuwee-eindpunte in en mag die effek daarvan vergroot. Daar mag 'n verhoogde risiko vir disritmieë en hipertensie wees indien ReliSlim gegee word aan pasiënte wat trisikliese antidepressante ontvang.

Sentralesenuweestelsel (SSS)-stimulante:
ReliSlim kan die effekte van SSS-stimulante potensieer.

Ergotalkaloïede
Daar is 'n verhoogde risiko vir vasokonstriktor- of pressoreffekte by pasiënte wat ergotalkaloïede in kombinasie met ReliSlim ontvang.

Oksitosien
Daar is 'n verhoogde risiko vir vasokonstriktor- of pressoreffekte by pasiënte wat oksitosien in kombinasie met ReliSlim ontvang.

Kafeïen
ReliSlim mag die tempo waarteen ander medisynes (soos kafeïen) gemetaboliseer word versnel.

Tiroïedhormone
Versigtigheid is nodig wanneer ReliSlim in kombinasie met tiroïedhormone gebruik word.

Antihipertensiewe medisyne of medisyne wat hipotensie veroorsaak
ReliSlim mag bloeddruk affekteer en moet versigtig gebruik word in kombinasie met antihipertensiewe medisynes (soos guanetidien) of medisynes wat hipotensie veroorsaak.

Alfa-blokkers
Alfa-blokkers werk die effekte by alfa-reseptore teë, maar beïnvloed nie die beta-bemiddelde effekte nie, wat tot 'n verhoogde risiko vir hipotensie en tagikardie lei.

Beta-blokkers (nieselektief)
Beta-blokkers werk die effekte van beta-reseptore teë, maar beïnvloed nie die alfa-bemiddelde effekte nie, wat tot 'n verhoogde risiko vir hipertensie en refleksbradikardie lei.

Medisynes vir parkinsonisme (bv. levodopa en broomkriptien)
Additiewe kardiovaskulêre toksisiteit mag voorkom wanneer sommige simpatomimetiese middels gepaardgaande met antiparkinsonisme medisynes soos levodopa en broomkriptien gegee word. Erge hipertensie mag ook voorkom met sommige simpatomimetiese middels en selegilien, moontlik weens die onderdrukking van perifere monoamienoksidase.

Medisynes gebruik vir psigiatriese of emosionele toestande
Moenie ReliSlim saam met ander medisynes vir die behandeling van psigiatriese of emosionele toestande gebruik nie.

MENSLIKE VOORTPLANTING
Veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie.
Moenie ReliSlim tydens swangerskap gebruik nie, aangesien plasentale perfusie verminder mag word.
Moenie ReliSlim tydens borsvoeding gebruik nie, aangesien prikkelbaarheid en onderbroke slaap gerapporteer is by babas wat geborsvoed is.

DOSIS EN GEBRUIKSAANWYSINGS
Moenie die aanbevole dosis oorskry nie.
Een tot twee tablette met ontbyt en dan een tablet met middagete, met 'n bietjie water geneem.
Moenie vir langer as 4 weke aaneenlopend gebruik nie.

NEWE-EFFEKTE
Psigiatriese steurings
Dikwels: angstigheid, vrees, verwardheid, prikkelbaarheid, psigotiese reaksies
Frekwensie onbekend: agitasie, opgewondenheid

Senuweestelselversteurings
Dikwels: rusteloosheid, slaaploosheid, hoofpyn
Minder dikwels: tremors
Frekwensie onbekend: draaiduiseling

Kardiale versteurings
Dikwels: tagikardie
Minder dikwels: kardiale disritmieë
Frekwensie onbekend: prekordiale pyn, hartkloppings, verhoogde kardiale kontraktiliteit (wat aanleiding gee tot angina en hartstilstand)

Vaskulêre versteurings
Minder dikwels: belemmerde sirkulasie na die ekstremiteite, hipertensie

Respiratoriese, torakale en mediastinale versteurings
Dikwels: dispnee

Gastro-intestinale versteurings
Dikwels: naarheid, braking
Minder dikwels: droë mond

Vel- en subkutaneweefselversteurings
Frekwensie onbekend: sweting

Muskuloskeletale, bindweefsel- en skeletbeenversteurings
Frekwensie onbekend: spierswakheid

Nier- en urienwegversteurings
Frekwensie onbekend: moeilike urinering, urienterughouding

Algemene versteurings en toestande by die plek van toediening
Dikwels: swakheid.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Slaaploosheid, paranoïede psigose, delusies, hallusinasies, prekordiale pyn, tagikardie.
'n Oordosis word hanteer deur die simptome te behandel en die pasiënt te ondersteun.

IDENTIFIKASIE
Ronde, wit tablette.

AANBIEDING
Sekuriteitshouers wat 30 of 90 tablette bevat.

BEWARINGSINSTRUKSIES
Bêre by of onder 25 °C en beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS

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

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
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Rustenburg 0299

PUBLIKASIEDATUM VAN DIE VOUBILJET
Datum van registrasie: 21 Desember 1995
Datum van hersiening: Des 2018.

LOOCK PHARMACEUTICALS