PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S6 (RSA)

NS4 (Namibia)

RELISLIM 20 mg tablets
d-norpseudoephedrine hydrochloride
Contains sugar (60 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking RELISLIM.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RELISLIM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What RELISLIM is and what it is used for
RELISLIM is a sympathomimetic and has anorexigenic properties. The product promotes weight loss by suppressing appetite. An aid to mass reduction when used in combination with a reduced kilojoule intake.

2. What you need to know before you take RELISLIM
Do not take RELISLIM:
- If you are hypersensitive (allergic) to d-norpseudoephedrine hydrochloride or any of the other ingredients of RELISLIM.
- If you are pregnant.
- If you have coronary thrombosis (a blood clot inside blood vessels in your heart).
- If you have hyperthyroidism (an overactive thyroid).
- If you have closed-angle glaucoma (increased pressure in your eye).
- If you have severe hypertension (high blood pressure).
- If you have pheochromocytoma (cancer in your adrenal glands).
- If you are undergoing anaesthesia with cyclopropane, halothane or other volatile anaesthetics.
- If treated with monoamine oxidase inhibitors or within two weeks of stopping such treatment.
- If you are a young child.

Warnings and precautions
If you have a medical condition, seek advice from your health care provider.
RELISLIM should not be taken late afternoon, due to the stimulating effect which d-norpseudoephedrine has on the central nervous system.
RELISLIM tablets are liable to be abused. Tell your doctor if you have a history of drug or alcohol abuse or have been diagnosed with a personality disorders.
Tolerance with dependence has been reported.
There is a lack of evidence for efficacy in long-term management of obesity.

Take special care with RELISLIM:
- If you have diabetes mellitus (you may be at higher risk of cardiac effects),
- If you have cardiovascular disorders (coronary insufficiency, ischaemic heart disease, cardiac dysrhythmias, obstructive cardiomyopathy, cardiac decompensation or anginal pain),
- If you have hypertension (blood pressure may be increased),
- If you have occlusive vascular disease (blockage or narrowing of an artery),
- If you have kidney impairment,
- If you have prostate disorders,
- If you have porphyria (you may be prescribed RELISLIM when no safer alternative is available),
- If you have a history of psychiatric illness,
- If you are an elderly patient (you may have a high incidence of atherosclerotic disease and may be at a higher risk of cardiac effects).

Children and adolescents
Young children should not take RELISLIM.

Other medicines and RELISLIM
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking:
- Monoamine oxidase inhibitors (MAOI's) (used to treat depression).
- Simpathomimetics, such as dexamphetamine, dopamine, dopexamine, ephedrine, isometheptene, mephentermine, metaraminol, methylphenidate, phenylephrine, phenylpropanolamine and pseudoephedrine.
- If you are planned to receive anaesthesia with chloroform, cyclopropane, halothane or other volatile anaesthetics.
- Digoxin (used to treat heart failure and a fast heartbeat).
- Quinidine or any other medicine used to treat heart rhythm disorders.
- Tricyclic antidepressants (used to treat depression or bedwetting in children).
- Any central nervous system stimulant medicines (used to enhance cognitive ability and in cold and flu medicines).
- Ergot alkaloids (used to treat migraine).
- Oxytocin (used during or to reduce bleeding after childbirth),
- Thyroid hormones.
- Medicine for high blood pressure or medicines that cause low blood pressure.
- Alpha blockers (used to treat high blood pressure or prostate problems).
- Non-selective beta-blockers (used to treat high blood pressure, heart problems or prevent migraine).
- Antiparkinsonian medicines, such as levodopa and bromocriptine.
- Medicines used for psychiatric or emotional conditions.

RELISLIM with food, drink and alcohol
RELISLIM must be taken with food.
Do not take RELISLIM with alcohol.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. Safety during pregnancy and breastfeeding has not been established.

Driving and using machines
RELISLIM is unlikely to affect your ability to drive or operate machinery/equipment.
It is not always possible to predict to what extent RELISLIM may interfere with your daily activities.
Do not drive or operate machines until you know how RELISLIM affects you.

RELISLIM contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RELISLIM.

3. How to take RELISLIM
Do not share medicines prescribed for you with any other person.
Always take RELISLIM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Take 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.
If you have the impression that the effect of RELISLIM is too strong or too weak, tell your doctor or pharmacist.

If you take more RELISLIM than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Known symptoms of overdosage are insomnia, paranoid psychosis, delusions, hallucinations, precordial pain and tachycardia.

If you forget to take RELISLIM
Take your missed dose as soon as you remember, if within a few hours after missing a dose.
If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten individual doses. In this case just continue taking one to two tablets with breakfast followed by one tablet at lunchtime, taken with a little water.

If you stop taking RELISLIM
If you have stopped taking RELISLIM for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting.

4. Possible side effects
RELISLIM can have side effects.
Not all side effects reported for RELISLIM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RELISLIM, please consult your health care provider for advice.

If any of the following happens, stop taking RELISLIM and tell your doctor immediately or go to the casualty department at your nearest hospital.
- swelling of the hands, feet, ankles, facte, lips and mouth or throat, which may cause diffucilty in swallowing or breathing,
- rash or ithcing,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RELISLIM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- changes in the way your heart beats (beating faster or slower),
- chest pain,
- irregular heart beats.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- feeling anxious or irritable, fear, confusion, psychotic reactions,
- restlessness, sleeplessness, headache,
- difficulty breathing,
- nausea (feeling sick), vomiting (being sick),
- weakness.

Less frequent side effects:
- tremors,
- impaired blood flow to the extremities, low blood pressure,
- dry mouth.

Side effects occurring with an unknown frequency:
- feeling dizzy,
- agitation, excitability,
- sweating,
- muscular weakness,
- difficulty urinating or emptying your bladder completely.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of RELISLIM.

5. How to store RELISLIM
- Store at or below 25 °C and protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use after the expiry date stated on the outer packaging
- Return all unused or expired medicine to your pharmacist.
- Do not dispose of unused or expired medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What RELISLIM contains
The active substance is d-norpseudoephedrine hydrochloride.
The other ingredients are lactose monohydrate, microcrystalline cellulose and magnesium stearate.

What RELISLIM looks like and contents of the pack
RELISLIM are small, round, white tablets.
Available in securitainer bottles containing 30 and 90 tablets.

Holder of certificate of registration
Manufactured by Columbia Pharmaceuticals (Pty) Ltd on behalf of Loock Pharmaceuticals (Pty) Ltd.
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Access to the corresponding Professional Information
The Professional Information can be obtained from the Loock Pharmaceuticals (Pty) Ltd website at www.loockpharmaceuticals.co.za

PASIËNTINLIGTINGSVOUBILJET

SKEDULERINGSTATUS:

S6 (RSA)

NS4 (Namibië)

RELISLIM 20 mg tablette
d-norpseudoefedrienhidrochloried
Bevat suiker (60 mg laktose monohidraat per tablet).

Lees al die inligting in die voubiljet noukeurig deur voor jy begin om RELISLIM te gebruik.
- Hou hierdie voubiljet. Jy mag dit later weer wil lees.
- Vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer as jy nog vrae het.
- RELISLIM is vir jou persoonlik voorgeskryf en jy moet nie die medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie voubiljet:

1. Wat is RELISLIM en waarvoor word dit gebruik
RELISLIM is 'n simpatomimetiese middel en het anoreksigeen eienskappe. Dit help met gewigsverlies deur die eetlus te onderdruk. 'n Hulpmiddel vir massavermindering wanneer dit in kombinasie met 'n verminderde kilojoule-inname gebruik word.

2. Wat jy moet weet voordat jy RELISLIM gebruik
Moet nie RELISLIM gebruik
- As jy hipersensitief (allergies) is vir d-norpseudoefedrienhidrochloried of enige van die ander bestanddele van RELISLIM.
- As jy swanger is.
- As jy 'n koronêre trombose het ('n bloedklont in die bloedvate van die hart).
- As jy hipertiroïdisme het ('n ooraktiewe tiroïdklier).
- As jy geslotehoekgloukoom het (verhoogde okulêre druk).
- As jy ernstige hipertensie het (hoë bloeddruk).
- As jy feochromositoom het (kanker in jou bynierkliere).
- As jy narkose ondergaan met siklopropaan, halotaan of ander vlugtige anestetika.
- As jy behandel word met monoamienoksidase-inhibeerders of binne twee weke nadat sodanige behandeling gestaak is.
- As jy 'n jong kind is.

Waarskuwings en voorsorgmaatreëls
As jy 'n mediese toestand het, raadpleeg jou gesondheisorgverskaffer.
RELISLIM moet nie laatmiddag geneem word nie, weens die stimulerende uitwerking wat d-norpseudoefedrien op die sentrale senuweestelsel het. Die moontlikheid bestaan dat RELISLIM tablette misbruik kan word. Stel jou dokter in kennis as jy n geskiedenis het van middel- of alkoholmisbruik of al gediagnoseer is met persoonlikheidsteurings.
Toleransie met afhanklikheid is al gerapporteer.
Daar is 'n gebrek aan bewyse vir effektiwiteit in die langtermyn handhawing van obesiteit.

Wees veral versigtig met RELISLIM:
- As jy diabetes mellitus het (jy mag 'n groter risiko hê vir kardiale effekte),
- As jy kardiovaskulêre steurings het (koronêre ontoereikendheid, iskemiese hartsiekte, kardiale disritmieë, obstruktiewe kardiomiopatie, kardiale dekompensasie of angina-pyn),
- As jy hipertensie het (bloeddruk mag verhoog),
- As jy okklusiewe vaskulêre siektes het (vernoude of geblokte arterie),
- As jy renale belemmering het,
- As jy prostaatsteurings het,
- As jy porfirie het (RELISLIM moet slegs gebruik word as daar nie 'n veiliger alternatief beskikbaar is nie),
- As jy 'n geskiedenis het van psigiatriese siektes,
- As jy 'n bejaarde pasiënt is (mag 'n hoë voorkoms van aterosklerotiese siekte en 'n groter risiko vir kardiale effekte hê).

Kinders en adolessente
Jong kinders moenie RELISLIM gebruik nie.

Ander medisyne en RELISLIM
Stel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medikasie gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in).

Stel jou dokter in kennis indien jy enige van die volgende gebruik:
- Monoamienoksidase-inhibeerders (MAOI's) (gebruik om depressie te behandel).
- Simpatomimetiese middels soos deksamfetamien, dopamien, dopeksamien, efedrien, isometepteen, mefentermien, metaraminol, metielfenidaat, fenielefrien, fenielpropanolamien en pseudoefedrien.
- As jy narkose moet ondergaan met chloroform, siklopropaan, halotaan of ander vlugtige anestetika.
- Digoksien (gebruik om hartversaking en n verhoogde hartklop te behandel)
- Kinidien en enige ander antidisritmiese middels.
- Trisikliese antidepressante (om depressie te behandel of bednatmaak by kinders).
- Sentralesenuweestelsel-stimulante (gebruik om kognitiewe vermoë te verbeter en in verkoue en griep medikasie).
- Ergotalkaloïede (gebruik om migraine te behandel).
- Oksitosien (gebruik gedurende of om bloeding te verminder gedurende bevalling).
- Tiroïedhormone.
- Antihipertensiewe medikasie of medikasie wat hipotensie veroorsaak.
- Alfa-blokkers (gebruik om hoë bloeddruk te behandel of prostaat probleme).
- Nie-selektiewe beta-blokkers (gebruik om hoë bloeddruk te behandel, kardiale probleme of migraine the voorkom).
- Medikasie vir parkinsonisme soos levodopa en broomkriptien.
- Medikasie wat gebruik word vir psigiatriese of emosionele toestande.

RELISLIM met kos, drank en alkohol
RELISLIM moet saam met voedsel geneem word.
Moenie RELISLIM met alkohol neem nie.

Swangerskap, borsvoeding en vrugbaarheid
As jy swanger is, borsvoed, dink dat jy swanger is of van plan is om 'n baba te hê, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne gebruik.
Veiligheid tydens swangerskap en borsvoeding is nog nie vasgestel nie.

Bestuur en gebruik van masjiene
Dit is onwaarskynlik dat RELISLIM jou vermoë om te bestuur of masjinerie/toerusting te gebruik sal beïnvloed.
Dit is nie altyd moontlik om te voorspel tot in watter mate RELISLIM die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem nie, totdat hulle bewus is van die mate waarop RELISLIM hulle beïnvloed.

RELISLIM bevat laktose monohidraat
Kontak jou dokter voordat jy RELISLIM gebruik indien jy 'n intoleransie vir sekere suikers het.

3. Hoe om RELISLIM te gebruik
Moenie medikasie wat vir jou voorgeskryf is, met enige ander persoon deel nie. Gebruik RELISLIM altyd presies soos jou dokter of apteker gesê het. Raadpleeg jou dokter of apteker indien jy nie seker is nie.
Neem een tot twee tablette met ontbyt, gevolg deur een tablet teen middagete, geneem met 'n bietjie water.
Moet nie vir langer as 4 weke aaneenlopend gebruik nie.
Indien jy die indruk kry dat die effek van RELISLIM te sterk of te swak is, raadpleeg jou dokter of apteker.

As jy meer RELISLIM neem as wat jy behoort
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Bekende simptome van oordosering is slaaploosheid, paranoïese psigose, waanbeelde, hallusinasies, borspyn en tagikardie.

As jy vergeet om RELISLIM te gebruik
Neem die dosis wat jy gemis het sodra jy dit onthou, indien dit binne 'n paar uur is nadat jy die dosis gemis het. As jy slegs die volgende dag van die gemiste dosis onthou, moenie 'n dubbele dosis neem om die vergete dosis aan te vul nie. In hierdie geval moet jy net voortgaan met die gebruik van een tot twee tablette in die oggend, gevolg deur een tablet teen middagete, geneem met 'n bietjie water.

As jy ophou om RELISLIM te gebruik
As jy om een of ander rede opgehou het om RELISLIM te gebruik, veral omdat jy dink dat jy newe-effekte ervaar of weens ander siektes, is dit belangrik dat jy jou dokter kontak voordat jy weer begin.

4. Moontlike newe-effekte
RELISLIM kan newe-effekte hê.
Nie alle newe-effekte wat vir RELISLIM aangemeld is, word in die voubiljet genoem nie.
Raadpleeg jou gesondheidsorgverskaffer vir advies indien jou algemene gesondheid versleg of as jy enige ander newe-effekte ervaar met die gebruik van RELISLIM.

Indien jy enige van die volgende ervaar, stop dadelik die gebruik van RELISLIM en raadpleeg jou dokter onmiddelik of gaan na die ongevalle by jou naaste hospitaal.
- Swelling van die hande, voete, enkels, lippe, mond of keel wat veroorsaak dat jy moeilik asemhaal of sluk,
- Uitslag of jeuk,
- Duiseligheid.

Al hierdie is baie ernstige newe effekte. As jy enige van bogenoemde ervaar het jy n ernstige reaksie teenoor RELISLIM. Jy kort moontlik dringende mediese hulp of hospitalisasie.

Raadpleeg jou dokter onmiddelik of gaan na ongevalle by jou naaste hospitaal as jy enige van die volgende ervaar:
- Veranderinge in jou harttempo (klop vinniger of stadiger),
- borspyn,
- onreëlmatige hartklop.

Al hierdie is baie ernstige newe effekte. Jy kort moontlike dringende mediese hulp.

Raadpleeg jou dokter indien jy enige van die volgende ervaar:
Gereelde newe effekte:
- angstigheid, prikkelbaarheid, vrees, verwarring, psigotiese reaksies.
- rusteloosheid, slaaploosheid, hoofpyn.
- dispnee.
- naarheid (voel naar), braking (is naar),
- swakheid.

Minder gereelde newe effekte:
- tremors
- verswakte sirkulasie na die ledemate, hipotensie
- droë mond

Newe effekte met 'n onbekende frekwensie:
- duiseligheid,
- opwinding, opgewondenheid,
- sweet,
- swak spiertonus,
- probleme met urinering, urienterughouding.

Indien jy enige newe effekte ervaar wat nie in die voubiljet genoem is nie, meld dit aan by jou dokter of apteker.

Rapportering van newe-effekte
Praat met jou dokter of apteker indien jy enige newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: http://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer, kan jy help om meer inligting oor die veiligheid van RELISLIM te gee.

5. Hoe om RELISLIM te berg:
- Berg teen of onder 25 °C en beskerm teen direkte sonlig.
- BERG ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum wat op die buitenste verpakking aangedui is nie.
- Vat alle ongebruikte of vervalde medisyne na jou apteker toe.
- Moenie ongebruikte of vervalde medisyne in dreine of rioolstelsels (bv.toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting
Wat RELISLIM bevat
Die aktiewe bestanddeel is d-norpseudoefedrienhidrochloried.
Die ander bestanddele is laktose monohidraat, mikrokristallyne sellulose en magnesiumstearaat.

Hoe RELISLIM lyk en die inhoud van die verpakking
RELISLIM is klein, ronde, wit tablette.
Beskikbaar in sekuriteitshouers wat 30 en 90 tablette bevat.

Houer van registrasiesertifikaat
Vervaardig deur Columbia Pharmaceuticals (Edms) Bpk namens Loock Pharmaceuticals (Edms) Bpk.
Loock Pharmaceuticals (Edms) Bpk.
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Hierdie voubiljet is laas hersien op
Datum van registrasie: 21 Desember 1995
Datum van hersienning: 01 September 2021

Registrasienommer:
RSA: 29/11.3/0316
Namibië: 04/11.3/0424

Toegang tot die toepaslike Professionele Inligting
Die professionele inligting kan vekry word vanaf die Loock Pharmaceuticals (Edms) Bpk. webwerf op www.loockpharmaceuticals.co.za

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