SCHEDULING STATUS: S0

COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

PROPRIETARY NAME AND DOSAGE FORM
REDUVIT PLUS capsule

COMPOSITION
Each capsule contains:

Vitamin A Retinol	1377 IU (0,5 mg)	Contains sugar:
Vitamin D3 Cholecalciferol	320 IU (10 µg)	6,7 mg glucose and 1,2 mg sucrose
Vitamin E as α-tocopherol acetate	8,3 mg	per capsule.
Vitamin B1 Thiamine	1,7 mg	
Vitamin B2 Riboflavin	2,4 mg	
Vitamin B3 Niacinamide	6,8 mg	
Vitamin B5 Pantothenic acid	14,8 mg	
Vitamin B6 Pyridoxine	2,5 mg	
Vitamin B12 Cyanocobalamin	1,5 µg	
Folic acid	0,3 mg	
Vitamin C Ascorbic acid	90,0 mg	
Calcium (as tricalcium phoshate)	41,9 mg	
Iodine (as potassium iodide)	46 µg	
Iron (as ferrous fumarate)	3,6 mg	
Magnesium (as magnesium oxide)	67,7 mg	
Manganese (as manganese sulphate monohydrate)	130 µg	
Molybdenum (as sodium molybdate)	32 µg	
Zinc (as zinc oxide)	4,8 mg	

PHARMACOLOGICAL CLASSIFICATION
D34.12 Complementary Medicine – Health Supplement.
PHARMACOLOGICAL ACTION
REDUVIT PLUS is a multivitamin supplementation. Vitamins and minerals are essential constituents of a balanced diet. Subclinical deficiencies may occur because of stressful situations, environmental factors and/or dietary imbalances. The multivitamins and minerals present in REDUVIT PLUS help by replenishing these nutrients and prevent occurrence of deficiencies.
INDICATIONS
REDUVIT PLUS capsules are indicated as a dietary supplement where a deficiency of the relevant vitamins or minerals exists.
CONTRAINDICATIONS
REDUVIT PLUS capsules are contraindicated in any persons who are hypersensitive to any of the ingredients.
WARNINGS AND SPECIAL PRECAUTIONS
Do not use more than the recommended dosage.
INTERACTIONS
Iron may reduce the effect of certain other drugs such as penicillamine (used as a form of immunosuppression to treat rheumatoid arthritis), levodopa (used to treat Parkinson's disease and dopamine-responsive dystonia), methyldopa (used to treat high blood pressure) and fluoroquinolone such as ciprofloxacin (broad-spectrum antibiotics that play an important role in the treatment of serious bacterial infections).
The effects of vitamin D may be reduced in patients taking barbiturates (central nervous system depressants used for mild sedation to total anaesthesia) and other anticonvulsants (used in the treatment of epileptic seizures).
Calcium should not be given together with phenytoin (antiepileptic) or tetracyclines (antibiotics) as decreased absorption of these drugs will result.
PREGNANCY AND BREASTFEEDING
Safety in pregnancy and breastfeeding has not been established.
DOSAGE AND DIRECTIONS FOR USE
Adults: One (1) capsule daily, unless otherwise recommended by your healthcare professional.
SIDE EFFECTS
Gastrointestinal disorders
Less frequent: Large doses of vitamin C may cause diarrhoea or other gastrointestinal disturbances.
The iron in ferrous fumarate may cause gastric irritation, with either constipation or diarrhoea, and nausea and vomiting.
Renal and urinary disorders
Frequent: Large doses of vitamin B2 may result in a bright yellow discolouration of urine, which may interfere with certain laboratory tests.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Repeated very high doses of vitamin C may lead to the formation of kidney stones in some patients. High doses of vitamin C should be avoided in patients prone to kidney stones.
Acute vitamin A intoxication may occur with very high doses, and is characterised by sedation, headache, irritability, papilloedema (swelling of the eye nerve causing possible blurred vision, headache, eye pain, eye swelling) and generalised peeling of the skin. Symptoms of excessive vitamin D intake are anorexia, muscle weakness, motion sickness, nausea and vomiting, diarrhoea, weight loss, profuse sweating, headache, extreme thirst, production of large volume of urine in a given period and bone pain. If calcium and phosphorus concentrations in the serum and urine are increased excessively, it may lead to hypertension, renal failure and cardiac dysrhythmias. The plasma cholesterol concentration may also be increased. In the event of overdose, medical assistance is required immediately. Treatment is symptomatic and supportive.
IDENTIFICATION
Wine red coloured capsules.
PRESENTATION
30 capsules packed in blister strips and placed in a carton.
STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light. KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.
NAME AND BUSINESS ADDRESS OF THE APPLICANT
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6, 10 Church Street, Durbanville 7551
087 551 3245
DATE OF PUBLICATION OF THIS PACKAGE INSERT
January 2022

30464 01/2022

SKEDULERINGSTATUS: S0

KOMPLEMENTÊRE MEDISYNE – GESONDHEIDSAANVULLING
Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie.

EIENDOMSNAAM EN DOSEERVORM
REDUVIT PLUS kapsule

SAMESTELLING
Elke kapsule bevat:

Vitamien A Retinol	1377 IE (0,5 mg)	Bevat suiker:
Vitamien D3 Cholekalsiferol	320 IE (10 µg)	6,7 mg glukose en 1,2 mg sukrose
Vitamien E as α-tokoferolasetaat	8,3 mg	per kapsule.
Vitamien B1 Tiamien	1,7 mg	
Vitamien B2 Riboflavien	2,4 mg	
Vitamien B3 Niasienamied	6,8 mg	
Vitamien B5 Pantoteensuur	14,8 mg	
Vitamien B6 Piridoksien	2,5 mg	
Vitamien B12 Sianokobalamien	1,5 µg	
Foliensuur	0,3 mg	
Vitamien C Askorbiensuur	90,0 mg	
Kalsium (as trikalsiumfosfaat)	41,9 mg	
Jodium (as kaliumjodied)	46 µg	
Magnesium (as magnesiumoksied)	67,7 mg	
Mangaan (as mangaansulfaatmonohidraat)	130 µg	
Molibdeen (as natriummolibdaatdihidraat)	32 µg	
Sink (as sinkoksied)	4,8 mg	
Yster (as ysterfumaraat)	3,6 mg	

FARMAKOLOGIESE KLASSIFIKASIE
D34.12 Komplementêre Medisyne – Gesondheidsaanvulling.
FARMAKOLOGIESE WERKING
REDUVIT PLUS is 'n multivitamienaanvulling. Vitamiene en minerale is noodsaaklike bestanddele van 'n gebalanseerde dieet. Subkliniese tekorte mag voorkom weens spanning, omgewingsfaktore en/of ongebalanseerde dieet. Die multivitamiene en minerale teenwoordig in REDUVIT PLUS help deur hierdie voedingstowwe aan te vul en die ontstaan van tekorte te voorkom.
INDIKASIES
REDUVIT PLUS kapsules word aangedui as 'n voedingsaanvulling, waar daar 'n tekort aan die betrokke vitamiene of minerale is.
KONTRA-INDIKASIES
REDUVIT PLUS kapsules word teenaangedui by enige persone wat hipersensitief vir enige van die bestanddele is.
WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Moet nie meer as die aanbevole dosis gebruik nie.
INTERAKSIES
Yster mag die effek van sekere ander geneesmiddels, soos penisillamien (gebruik as 'n vorm van immuunonderdrukker om rumatoïede artritis te behandel), levodopa (gebruik om Parkinson se siekte en dopamien-responsiewe distonie te behandel), metieldopa (gebruik om hoë bloeddruk te behandel) en fluoorkinolone soos siprofloksasien (breëspektrumantibiotika wat 'n belangrike rol speel in die behandeling van ernstige bakteriële infeksies) verminder.
Die effekte van vitamien D mag verminder wees by pasiënte wat barbiturate (onderdrukkers van sentrale senuweestelsel vir ligte sedasie tot totale anestesie) en ander antikonvulsante (gebruik in die behandeling van epileptiese toevalle) neem.
Kalsium moet nie saam met fenitoïen (anti-epileptiese middel) of tetrasikliene (antibiotika) geneem word nie, aangesien dit sal veroorsaak dat hierdie middels swakker geabsorbeer word.
SWANGERSKAP EN BORSVOEDING
Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.
DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes: Een (1) kapsule daagliks, behalwe indien dit anders aanbeveel is deur jou professionele gesondheidswerker.
NEWE-EFFEKTE
Gastro-intestinale versteurings
Minder dikwels: Hoë dosisse vitamien C mag diarree of ander gastro-intestinale versteurings veroorsaak.
Die yster in ysterfumaraat mag maagirritasie, met óf hardlywigheid óf diarree, en naarheid en braking, veroorsaak.
Nier- en urienwegversteurings
Dikwels: Hoë dosisse vitamien B2 mag veroorsaak dat die urine heldergeel verkleur, wat kan inmeng met sekere laboratoriumtoetse.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Herhaalde baie hoë dosisse vitamien C mag by sommige pasiënte aanleiding gee tot die vorming van nierstene. Hoë dosisse vitamien C moet vermy word by pasiënte wat geneig is tot nierstene.
Akute vitamien A-vergiftiging mag voorkom met baie hoë dosisse en word gekenmerk deur sedasie, hoofpyn, prikkelbaarheid, papiledeem (swelling van die oogsenuwee, wat moontlike wasige visie, hoofpyn, oogpyn, swelling van die oog, mag veroorsaak) en algemene afskilfering van die vel. Simptome van oormatige vitamien D-inname is anoreksie, spierswakheid, bewegingsiekte, naarheid en braking, diarree, massaverlies, oormatige sweetafskeiding, hoofpyn, uitermatige dors, vorming van 'n groot volume urine in 'n gegewe tydperk en skeletbeenpyn. Indien kalsium- en fosforkonsentrasies in die serum en urine oormatig verhoog, mag dit lei tot hipertensie, nierversaking en kardiale disritmie. Die plasmacholesterolkonsentrasie mag ook verhoog wees. In die geval van 'n oordosering, is mediese bystand onmiddellik nodig. Behandeling is simptomaties en ondersteunend.
IDENTIFIKASIE
Wynrooi kapsules.
AANBIEDING
30 kapsules, in stulpstroke verpak, in 'n buitenste karton.
BEWARINGSINSTRUKSIES
Bêre by of onder 25 °C. Beskerm teen lig. HOU BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMER
Sal met registrasie deur SAHPRA toegeken word.
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
LeBasi Pharmaceuticals (Edms.) Bpk.
San Domenico-gebou, Eenheid 6, Kerkstraat 10, Durbanville 7551
087 551 3245
DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
Januarie 2022

30464 01/2022

SCHEDULING STATUS: S6

PROPRIETARY NAME AND DOSAGE FORM:

OBESAN X tablets

COMPOSITION:
Each tablet contains 35,0 mg phendimetrazine tartrate.
Inactive ingredients: Colloidal silicone dioxide, Ludipress (containing 93 % alpha lactose monohydrate; 3,5 % 2-pyrrolidinone, 1-ethenyl-, homopolymer and 3,5 % polyvinylpyrrolidone, 2-pyrrolidinone, 1-ethenyl-, homopolymer), magnesium stearate and maize starch.
Contains sugar: 250 mg lactose per tablet.

CATEGORY AND CLASS: A 11.3. Anorexigenics.

PHARMACOLOGICAL ACTION: OBESAN X is a sympathomimetic agent which is used as an anorectic in the short-term treatment of moderate to severe obesity. OBESAN X is used to suppress appetite and to make a low-calorie diet more tolerable. These appetite suppressants are of no value without an accompanying stringent dietary regimen.
The central effects of anorexia and wakefulness have proven inseparable. The use of OBESAN X by obese individuals who are well motivated to reduce their food intake may ease the discomfort of adherence to a restricted diet and may be of help in the earlier part of a regimen while new dietary patterns are being established.

INDICATION: Anorexigenic for the treatment of obesity.

CONTRAINDICATIONS: Patients hypersensitive to phendimetrazine tartrate or any other sympathomimetic agent may develop a hypersensitive reaction. This sympathomimetic agent is liable to produce dependency and abuse. It should therefore be used with caution in patients with a history of drug or alcohol abuse and in patients with personality disorders or a history of psychiatric illness.
OBESAN X should be given with caution to patients suffering from anorexia, insomnia, impaired kidney function, cardiovascular disease (especially coronary insufficiency), hypertension, arteriosclerosis, thyrotoxicosis, prostatism, extrapyramidal disorders and narrow angle glaucoma.
OBESAN X should be avoided in children because of the possibility of growth suppression.
The use of OBESAN X should be avoided during pregnancy and breastfeeding.
OBESAN X is contraindicated in patients being treated with monoamine oxidase inhibitors, beta-blockers, ephedrine and other sympathomimetic agents, as a hypersensitive response may result. Caution should be exercised in administering OBESAN X within 14 days of discontinuing other agents with a similar mechanism of action.
Concurrent use of alcohol is not recommended, since this may increase the potential for central nervous system effects, such as dizziness and confusion.
The hypotensive effect of antihypertensive medication may be decreased by concurrent use with OBESAN X.

WARNINGS AND SPECIAL PRECAUTIONS: The use of OBESAN X should be restricted to short periods only (not in excess of six weeks). There is a lack of evidence for efficacy of these agents in the long-term management of obesity.
Urinary excretion of amphetamines is reduced by urinary alkalinizers, which may enhance or prolong their effects. Excretion is increased by urinary acidifiers. Prolonged high doses may need gradual withdrawal as abrupt cessation may produce fatigue and mental depression. Sympathomimetics have dependence-producing properties. Tolerance develops rapidly.

Lactose intolerance: OBESAN X contains lactose monohydrate 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 OBESAN X.
Effects on ability to drive and use machines: OBESAN X may cause dizziness or tiredness, which may affect the ability to drive a vehicle or operate machinery. Patients should therefore take special care before performing tasks that require their attention, until they know how they will react to OBESAN X.

INTERACTIONS: None known.

HUMAN REPRODUCTION: The use of OBESAN X should be avoided during pregnancy and breastfeeding.

DOSAGE AND DIRECTIONS FOR USE: Adults: One or two tablets twice daily, one hour before breakfast and the midday meal. If taken after 4 o'clock in the afternoon (16:00), OBESAN X may interfere with sleep at night.

SIDE EFFECTS: OBESAN X may produce symptoms of overstimulation of the central nervous system, such as psychotic reactions, insomnia, night terrors, nervousness, irritability, euphoria, anxiety, agitation, excitability and restlessness that may be followed by fatigue and depression. Other side effects include dryness of mouth, nausea, vomiting, difficulty in micturition, sweating, altered libido, impotence and tremor. Side effects which are relatively common include headache, anorexia and dizziness. Constipation or diarrhoea with abdominal cramps may occur. Skin rashes have been reported, as well as muscle damage with associated rhabdomyolysis and renal complications. Aplastic anaemia and pancytopenia have occasionally occurred after prolonged use. Systolic and diastolic blood pressure may be increased, or sometimes decreased, especially with high doses, and tachycardia, palpitations, anginal pain or cardiac dysrhythmias may occur. The risk of cardiovascular effects, including dysrhythmias, may be increased by concurrent use of amphetamines and tricyclic antidepressants. Rarely, cardiomyopathy has occurred with chronic use. Diabetic control should be monitored.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: Large doses may give rise to nausea, vomiting, abdominal cramps, fatigue, mental depression, talkativeness, restlessness, rapid breathing, tremor, dysrhythmia, impotence, changes in libido, fever or chilliness, hypotension or hypertension, respiratory failure, disorientation, severe panic state, aggressive behaviour, hallucinations, convulsions and coma.
Symptoms of gross overdosage may be treated by emptying the stomach by lavage and aspiration, if OBESAN X has been ingested within the preceding 3 to 4 hours.
Keep the patient quiet and warm.
If respiration is irregular or cyanosis is present give assisted respiration or inhalation of oxygen.
If hypertension is marked, 5 to 10 mg phentolamine mesilate, or 10 to 20 mg phenoxybenzamine hydrochloride may be given intravenously and may be followed by 2,5 to 5 mg propranolol hydrochloride.
For marked excitement 1 to 1,5 mg chlorpromazine per kg body mass may be given intramuscularly or intravenously. 5 to 10 mg diazepam intravenously may also be of value.
Alternatively, an intermediate acting barbiturate, such as secobarbital sodium or cyclobarbital calcium may be given by mouth, or, if necessary, thiopentone sodium may be administered by intravenous injection.
Provided renal function is adequate, elimination may be assisted by acidification of the urine with ammonium chloride in conjunction with adequate fluid intake. Dialysis may be of value if renal function is impaired.

IDENTIFICATION: White, flat, round tablet with bevelled edges and scored on one side.

PRESENTATION: White HDPE cylindrical securitainer, closed with a white PP cap.
Pack size: 30 tablets.

STORAGE INSTRUCTIONS: Store at or below 25 °C.
Keep in original container until required for use.
KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER: C877 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6
10 Church Street
Durbanville 7551

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
Date of approval: July 1984
Date of revision: January 2022

Patient information leaflet for OBESAN X

SCHEDULING STATUS: S6

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

OBESAN X tablets

Read all of this leaflet carefully before you start taking OBESAN X.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- OBESAN X 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.

1. WHAT OBESAN X CONTAINS
The active ingredient is 35,0 mg phendimetrazine tartrate.
The other ingredients are: colloidal silicone dioxide, Ludipress (containing 93 % alpha lactose monohydrate; 3,5 % 2-pyrrolidinone, 1-ethenyl-, homopolymer and 3,5 % polyvinylpyrrolidone, 2-pyrrolidinone, 1-ethenyl-, homopolymer), magnesium stearate and maize starch.
Contains sugar: 250 mg lactose per tablet.

2. WHAT OBESAN X IS USED FOR
Pharmacotherapeutic group:
OBESAN X is used as an appetite suppressant in the short-term treatment of moderate to severe obesity by suppressing appetite and to make a low-calorie diet more tolerable. These appetite suppressants are of no value without an accompanying stringent dietary regimen.
The central effects of anorexia and wakefulness have proven inseparable.
The use of OBESAN X by obese individuals who are well motivated to reduce their food intake may ease the discomfort of adherence to a restricted diet and may be of help in the earlier part of a regimen while new dietary patterns are being established.
Therapeutic indication:
OBESAN X can be used for the treatment of obesity.

3. BEFORE YOU USE OBESAN X
Do not use OBESAN X:
- If you are hypersensitive (allergic) to phendimetrazine tartrate or any other sympathomimetic agent. This sympathomimetic is liable to produce dependency and abuse. It should therefore be used with caution in patients with a history of drug or alcohol abuse and in patients with personality disorders or a history of psychiatric illness.
- If you suffer from anorexia, insomnia, impaired kidney function, cardiovascular disease (especially coronary insufficiency), hypertension, arteriosclerosis, prostatism, extrapyramidal disorders or narrow angle glaucoma.
- If you are to give OBESAN X to a child. There is a possibility of OBESAN X causing growth suppression in children.
- If you are pregnant or breastfeeding.
- If you are being treated with monoamine oxidase inhibitors, beta-blockers, ephedrine and other sympathomimetic agents, as a hypersensitive response may result. Caution should be taken if OBESAN X is used within 14 days of discontinuing other agents with a similar mechanism of action.
- You should not use alcohol when taking OBESAN X, since this may increase the potential for effects such as dizziness and confusion.
- If you are using antihypertensive medication, because the hypotensive effect of the antihypertensive medication may be decreased if it is used together with OBESAN X.

Take special care with OBESAN X:
The use of OBESAN X should be restricted to short periods only (not more than six weeks).
Pregnancy and breastfeeding: If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking OBESAN X.
Driving and using machinery: OBESAN X may make you feel dizzy or tired. Do not drive a vehicle or perform tasks that require your attention, until you know how you will react to OBESAN X.
Important information about some of the ingredients of OBESAN X:
OBESAN X contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking OBESAN X.
Taking other medicine with OBESAN X: Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO USE OBESAN X
Do not share medicines prescribed for you with any other person.
- Always take OBESAN X tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- The usual dose for adults is one or two tablets twice daily, one hour before breakfast and the midday meal.
- If taken after 4 o'clock in the afternoon (16:00), OBESAN X may interfere with sleep at night.

If you use more OBESAN X tablets than you should:
The following are signs and symptoms of overdosage:
- Large doses may give rise to nausea, vomiting, abdominal cramps, fatigue, mental depression, talkativeness, restlessness, rapid breathing, tremor, arrhythmia, impotence, changes in libido, fever or chilliness, hypotension or hypertension, respiratory failure, disorientation, severe panic state, aggressive behaviour, hallucinations, convulsions and coma.
- Symptoms of gross overdosage may be treated by emptying the stomach by lavage and aspiration, if OBESAN X has been ingested within the preceding 3 to 4 hours. Keep the patient quiet and warm.
- In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison centre.

5. POSSIBLE SIDE EFFECTS
OBESAN X tablets can have side effects:
- Symptoms of overstimulation of the central nervous system, such as psychotic reactions, sleeplessness, night terrors, nervousness, irritability, excitement, anxiety, agitation, excitability and restlessness, that may be followed by tiredness and depression.
- Dryness of mouth, nausea, vomiting, difficulty in urination, sweating, altered libido, impotence and tremor.
- Relatively common side effects: headache, anorexia and dizziness.
- Constipation or diarrhoea with abdominal cramps may occur.
- Skin rashes have been reported.
- Blood disorders have occasionally occurred after prolonged use.
- Blood pressure may be increased, or decreased, especially with high doses, and irregular heartbeat, fast heartbeat and chest pains may occur.
- The risk of effects on the heart, including irregular heartbeats, may be increased by the use of OBESAN X at the same time as amphetamines and tricyclic antidepressants. Rarely, disease of the heart muscle has occurred with long term use.
- Diabetic control should be monitored.
- If you take high doses for a long time, you may need to decrease the dose slowly, because if you stop taking the medicine suddenly, you may feel tired and depressed.
- Your body can become addicted to this medicine.

Not all side effects reported for OBESAN X are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using OBESAN X, please consult your healthcare provider for advice.

6. STORING AND DISPOSING OF OBESAN X
- Store at or below 25 °C.
- Keep in original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use after the expiry date stated on the container.

7. PRESENTATION OF OBESAN X
White HDPE cylindrical securitainer, closed with a white PP cap.
Pack size: 30 tablets.

8. IDENTIFICATION OF OBESAN X
White, flat, round tablet with bevelled edges and scored on one side.

9. REFERENCE NUMBER
C877 (Act 101/1965)

10. NAME AND ADDRESS OF REGISTRATION HOLDER
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6
10 Church Street
Durbanville 7551
087 551 3245

11. DATE OF PUBLICATION
Date of approval: July 1984
Date of revision: January 2022

SKEDULERINGSTATUS: S6

HANDELSNAAM EN DOSEERVORM

OBESAN X tablette

SAMESTELLING:
Elke tablet bevat 35,0 mg fendimetrasientartraat.
Onaktiewe bestanddele: Kolloïdale silikondioksied, Ludipress (bevattende 93 % alfa-laktosemonohidraat; 3,5 % 2-pirrolidinoon, 1-eteniel-, homopolimeer en 3,5 % polivinielpirrolidoon, 2-pirrolidinoon, 1-eteniel-, homopolimeer), magnesiumstearaat en mieliestysel.
Bevat suiker: 250 mg laktose per tablet.

KATEGORIE EN KLAS: A 11.3. Eetlusdempers.

FARMAKOLOGIESE WERKING: OBESAN X is 'n simpatomimetiese middel wat gebruik word as eetlusdemper in die korttermynbehandeling van matige tot ernstige vetsug. OBESAN X word gebruik om die eetlus te onderdruk en sodoende 'n lae-kalorie dieet meer draaglik te maak. Hierdie eetlusdempers is van geen waarde sonder 'n gepaardgaande streng dieetplan nie.
Dit is aangetoon dat die sentrale uitwerking van eetlusdemping en slaaploosheid nie geskei kan word nie. Die gebruik van OBESAN X deur oorgewig individue, wat goed gemotiveerd is om hulle voedselinname te beperk, sal die ongerief van 'n streng dieet vergemaklik terwyl nuwe eetgewoontes aangeleer word.

INDIKASIE: Eetlusdemper vir die behandeling van vetsug.

KONTRA-INDIKASIES: Pasiënte wat hipersensitief vir fendimetrasientartraat of enige ander simpatomimetiese middel is, mag 'n hipersensitiwiteitsreaksie ontwikkel. Hierdie simpatomimetikum kan lei tot afhanklikheid en misbruik. Dit moet dus met omsigtigheid gebruik word by pasiënte met 'n geskiedenis van dwelm- of drankmisbruik, asook pasiënte met persoonlikheidsteurings of 'n geskiedenis van psigiatriese siekte.
OBESAN X moet versigtig toegedien word aan persone wat ly aan anoreksie, slaaploosheid, belemmerde nierfunksie, kardiovaskulêre siektes (veral koronêre ontoereikendheid), hipertensie, slagaarverharding, hipertiroïdisme, prostatisme, ekstrapiramidale steurings en nouhoek-gloukoom.
Die gebruik van OBESAN X moet vermy word by kinders, aangesien dit groei kan onderdruk.
Die gebruik van OBESAN X moet vermy word tydens swangerskap en borsvoeding.
OBESAN X word teenaangedui by pasiënte wat met monoamienoksidase-inhibeerders, beta-blokkers, efedrien en ander simpatomimetiese middels behandel word, aangesien dit 'n hipersensitiwiteitsreaksie mag veroorsaak. Versigtigheid moet aan die dag gelê word met die toediening van OBESAN X binne 14 dae vanaf staking van middels met 'n soortgelyke werking.
Gelyktydige gebruik van alkohol word nie aanbeveel nie, aangesien dit die moontlikheid van sentralesenuweestelseleffekte, soos duiseligheid en verwarring, kan vergroot.
Gelyktydige gebruik van OBESAN X saam met antihipertensiemiddels kan die hipotensiewe effek daarvan verminder.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS: Die gebruik van OBESAN X moet beperk word tot kort tydperke (nie langer as ses weke nie). Daar is min bewyse van die doeltreffendheid van hierdie middel in die langtermynbehandeling van vetsug.
Urinêre uitskeiding van amfetamiene word verminder deur urienalkaliseerders, wat hulle uitwerking kan versterk of verleng. Ekskresie word verhoog deur urienaansuurders. Dit mag nodig wees om die OBESAN X geleidelik te onttrek indien hoë dosisse vir lang tye gebruik is, aangesien 'n plotselinge staking uitputting en geestelike depressie kan veroorsaak. Simpatomimetikums kan afhanklikheid tot gevolg hê. Verdraagsaamheid ontwikkel vinnig.

Laktose-onverdraagsaamheid: OBESAN X bevat laktosemonohidraat wat 'n uitwerking op die bloedsuikerbeheer van pasiënte met diabetes mellitus mag hê. Pasiënte met seldsame oorerflike toestande van galaktose-onverdraagsaamheid, bv. galaktosemie, die Laplander-laktasetekort of glukose-galaktosewanabsorpsie moenie OBESAN X neem nie.
Effek op die vermoë om te bestuur en masjiene te gebruik: OBESAN X kan duiseligheid of moegheid veroorsaak, wat die vermoë om te bestuur en 'n voertuig te bestuur of masjinerie te hanteer kan beïnvloed. Pasiënte moet dus baie versigtig wees wanneer hulle take uitvoer wat konsentrasie verg, totdat hulle weet hoe hulle op OBESAN X sal reageer.

INTERAKSIES: Geen bekend nie.

MENSLIKE VOORTPLANTING: Die gebruik van OBESAN X moet vermy word tydens swangerskap en borsvoeding.

DOSIS EN GEBRUIKSAANWYSINGS: Volwassenes: Een of twee tablette, twee keer per dag, een uur voor ontbyt en middagete. Indien dit ná 4 uur in die middag (16:00) geneem word, kan OBESAN X slaaploosheid veroorsaak.

NEWE-EFFEKTE: OBESAN X mag simptome van oorstimulasie van die sentrale senuweestelsel veroorsaak, soos psigotiese reaksies, slaaploosheid, nagvrese, senuweeagtigheid, prikkelbaarheid, euforie, angstigheid, agitasie, opgewondenheid en rusteloosheid, wat gevolg kan word deur uitputting en neerslagtigheid. Ander newe-effekte sluit droë mond, naarheid, vomering, moeilike urinering, sweet, gewysigde libido, impotensie en bewing in. Newe-effekte wat betreklik dikwels voorkom sluit hoofpyn, aptytverlies en lighoofdigheid in. Hardlywigheid of diarree met gepaardgaande buikkrampe mag voorkom. Veluitslag is al gerapporteer, sowel as spierskade met meegaande rabdomiolise en nier-komplikasies. Aplastiese anemie en pansitopenie het soms voorgekom na langdurige gebruik. Sistoliese en diastoliese bloeddruk mag verhoog word, of soms verlaag word, veral met hoë dosisse. Tagikardie, hartkloppings, angina of kardiale disritmie mag voorkom. Die risiko van kardiovaskulêre effekte, insluitende disritmie, mag verhoog word met die gelyktydige gebruik van amfetamiene en trisikliese antidepressante. Kardiomiopatie (hartspiersiekte) het selde voorgekom met chroniese gebruik. Kontrole van diabetes moet gemonitor word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN: Groot dosisse mag naarheid, braking, buikkrampe, moegheid, terneergedruktheid, spraaksaamheid, rusteloosheid, vinnige asemhaling, tremor, disritmie, impotensie, verandering in libido, koors of kouekoors, hipotensie of hipertensie, respiratoriese versaking, disoriëntasie, erge toestand van paniek, aggressiewe gedrag, hallusinasies, konvulsies en koma veroorsaak.
Simptome van groot oordoserings kan behandel word deur maagspoeling en aspirasie indien OBESAN X in die voorafgaande 3 tot 4 uur ingeneem is.
Hou die pasiënt stil en warm.
Indien asemhaling ongereeld is of sianose voorkom, ondersteun respirasie of gee suurstof vir inaseming. Indien hipertensie beduidend is, kan 5 tot 10 mg fentolamienmesilaat of 10 tot 20 mg fenoksibensamienhidrochloried binne-aars toegedien word en mag opgevolg word met 2,5 tot 5 mg propranololhidrochloried.
Vir merkbare opgewondenheid kan 1 tot 1,5 mg chloorpromasien per kg liggaamsmassa binnespiers of binne-aars toegedien word. Toediening van 5 tot 10 mg diasepaam binne-aars kan ook help.
Alternatiewelik mag 'n intermediêr-werkende barbituraat soos natriumsekobarbitaal of kalsiumsiklobarbitaal mondeliks toegedien word, of indien nodig, mag natriumtiopentoon binne-aars ingespuit word.
Op voorwaarde dat nierfunksie voldoende is, mag uitskeiding aangehelp word deur die aansuur van urine met ammoniumchloried met gepaardgaande voldoende vloeistofinname. Dialise mag van waarde wees indien nierfunksie belemmer is.

IDENTIFIKASIE: Wit, plat, ronde tablet met afgeskuinste kante en 'n keep aan die een kant.

AANBIEDING: Wit HDPE silindriese sekuriteitshouer, toegemaak met 'n wit PP deksel.
Verpakkingsgrootte: 30 tablette.

BERGINGSAANWYSINGS: Bêre by of onder 25 °C.
Bêre in die oorspronklike houer tot nodig vir gebruik.
HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER: C877 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
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PUBLIKASIEDATUM VAN DIE PROFESSIONELE INLIGTING
Datum van goedkeuring: Julie 1984
Datum van hersiening: Januarie 2022

Pasiëntinligtingsblad vir OBESAN X

SKEDULERINGSTATUS: S6

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM

OBESAN X tablette

Lees hierdie hele inligtingsblad noukeurig deur, voordat u begin om OBESAN X te neem.
- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Indien u enige verdere vrae het, vra asseblief u dokter of apteker.
- OBESAN X is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al het hulle dieselfde simptome as u.

1. WAT OBESAN X BEVAT
Die aktiewe bestanddeel is 35,0 mg fendimetrasientartraat.
Die ander bestanddele is: kolloïdale silikondioksied, Ludipress (bevattende 93 % alfa-laktosemonohidraat; 3,5 % 2-pirrolidinoon, 1-eteniel-, homopolimeer en 3,5 % polivinielpirrolidoon, 2-pirrolidinoon, 1-eteniel-, homopolimeer), magnesiumstearaat en mieliestysel.
Bevat suiker: 250 mg laktose per tablet.

2. WAARVOOR OBESAN X GEBRUIK WORD
Farmakoterapeutiese groep:
OBESAN X word gebruik vir die korttermynbehandeling van matige tot erge vetsug deur die eetlus te onderdruk en sodoende 'n lae-kalorie dieet meer draaglik te maak. Hierdie eetlusdempers is van geen waarde sonder 'n gepaardgaande streng dieetplan nie.
Die sentrale uitwerking van eetlusdemping en slaaploosheid blyk onskeibaar te wees.
Die gebruik van OBESAN X deur oorgewig individue, wat goed gemotiveerd is om hulle voedselinname in te perk, sal die ongerief van 'n streng dieet vergemaklik terwyl nuwe eetgewoontes aangeleer word.
Terapeutiese indikasie:
OBESAN X kan vir die behandeling van vetsug (obesiteit) gebruik word.

3. VOORDAT U OBESAN X GEBRUIK
Moenie OBESAN X gebruik nie:
- Indien u hipersensitief (allergies) is vir fendimetrasientartraat of enige ander simpatomimetiese middel. Hierdie simpatomimetiese middel kan afhanklikheid veroorsaak en lei tot misbruik. Dit moet dus met omsigtigheid gebruik word by pasiënte met 'n geskiedenis van dwelm- of drankmisbruik, asook by pasiënte met persoonlikheidsteurings of 'n geskiedenis van psigiatriese siekte.
- Indien u ly aan anoreksie, slaaploosheid, belemmerde nierfunksie, kardiovaskulêre siektes (veral koronêre ontoereikendheid), hoë bloeddruk, slagaarverharding, prostatisme, ekstrapiramidale steurings en nouhoek-gloukoom.
- Indien u OBESAN X vir 'n kind wil gee. Daar is 'n moontlikheid dat OBESAN X groei by kinders kan onderdruk.
- Indien u swanger is of u baba borsvoed.
- Indien u behandel word met monoamienoksidase-inhibeerders, beta-blokkers, efedrien en ander simpatomimetiese middels, aangesien dit tot 'n hipersensitiwiteitsreaksie mag aanleiding gee. Wees versigtig indien OBESAN X binne 14 dae na staking van ander middels met 'n soortgelyke werking gebruik word.
- U moenie alkohol gebruik wanneer u OBESAN X neem nie, aangesien dit die moontlikheid van effekte soos duiseligheid en verwarring kan vergroot.
- Indien u medikasie vir hoë bloeddruk gebruik, omdat die bloeddrukverlagende effek van antihipertensiemiddels deur gelyktydige gebruik van OBESAN X verminder kan word.

Wees versigtig met OBESAN X:
Die gebruik van OBESAN X moet beperk word tot slegs kort periodes (nie meer as ses weke nie).
Swangerskap en borsvoeding: Indien u swanger is of u baba borsvoed, raadpleeg asseblief u gesondheidsorgverskaffer voordat u OBESAN X neem.
Bestuur en die gebruik van masjinerie: OBESAN X kan u duiselig of moeg laat voel. Moenie 'n voertuig bestuur of take verrig wat konsentrasie verg nie, totdat u weet hoe u op OBESAN X sal reageer.
Belangrike inligting oor sommige van die bestanddele van OBESAN X:
OBESAN X bevat laktose wat 'n uitwerking op u bloedglukosebeheer kan hê indien u aan diabetes mellitus ly. Indien u dokter vir u gesê het dat u onverdraagsaam vir sekere suikers is, behoort u u dokter te kontak voordat OBESAN X geneem word.
Die neem van ander medisyne saam met OBESAN X: Sê altyd vir u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisynes in.)

4. HOE OM OBESAN X TE GEBRUIK
Moenie medisynes wat vir u voorgeskryf is met iemand anders deel nie.
- Neem OBESAN X tablette altyd presies soos wat u dokter vir u voorgeskryf het. Kontroleer gerus met u dokter of apteker indien u onseker is.
- Die gewone dosis vir volwassenes is een of twee tablette, twee keer per dag, een uur voor ontbyt en die middagmaal.
- Indien dit ná 4 uur in die middag (16:00) geneem word, kan OBESAN X slaaploosheid veroorsaak.

Indien u meer OBESAN X tablette geneem het as wat u behoort:
Die volgende is tekens en simptome van oordosering:
- Groot dosisse mag naarheid, braking, buikkrampe, moegheid, terneergedruktheid, spraaksaamheid, rusteloosheid, vinnige asemhaling, bewing, onegalige hartklop, impotensie, verandering in libido, koors of kouekoors, lae of hoë bloeddruk, asemhalingversaking, disoriëntasie, erge paniektoestand, aggressiewe gedrag, hallusinasies, konvulsies en koma veroorsaak.
- Simptome van groot oordoserings kan behandel word deur maagspoeling en aspirasie indien OBESAN X in die voorafgaande 3 tot 4 uur ingeneem is. Die pasiënt moet stil en warm gehou word.

In die geval van oordosering, raadpleeg u dokter of apteker onmiddellik. Indien nie een van hulle beskikbaar is nie, verkry hulp by die naaste hospitaal of gifsentrum.

5. MOONTLIKE NEWE-EFFEKTE
OBESAN X tablette kan newe-effekte hê:
- Simptome van oorstimulasie van die sentrale senuweestelsel, soos psigotiese reaksies, slaaploosheid, nagvrese, senuweeagtigheid, prikkelbaarheid, welsynsgevoel, angstigheid, prikkelbaarheid, opgewondenheid en rusteloosheid, wat gevolg kan word deur uitputting en neerslagtigheid.
- Droë mond, naarheid, braking, moeilike urinering, sweet, gewysigde libido, impotensie en bewing.
- Relatief algemene newe-effekte: hoofpyn, aptytverlies en lighoofdigheid.
- Hardlywigheid of diarree met buikkrampe kan voorkom.
- Veluitslae is al gerapporteer.
- Bloedafwykings het per geleentheid voorgekom na langdurige gebruik.
- Bloeddruk kan verhoog of verlaag wees, veral met hoë dosisse, en onreëlmatige hartklop, vinnige hartklop en borskaspyn kan voorkom.
- Die risiko van uitwerking op die hart, insluitende onreëlmatige hartklop, kan groter wees indien OBESAN X terselfdertyd as amfetamiene en trisikliese antidepressante gebruik word. Siekte van die hartspier het uiters selde met langtermyngebruik voorgekom.
- Diabetiese beheer moet dopgehou word.
- Indien u hoë dosisse vir 'n lang tyd geneem het, mag dit nodig wees dat u die dosis stadig verlaag, want u mag moeg en terneergedruk voel indien u skielik ophou om hierdie medisyne te neem.
- U liggaam kan verslaaf raak aan hierdie medisyne.

Nie alle newe-effekte wat vir OBESAN X gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheid agteruitgaan of indien u ongewenste effekte ervaar terwyl u OBESAN X gebruik, konsulteer asseblief u gesondheidsorgverskaffer.

6. BERGING EN WEGDOENING VAN OBESAN X
- Bêre by of onder 25 °C.
- Bêre in die oorspronklike houer tot nodig vir gebruik.
- STOOR ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.
- Moenie ná die vervaldatum wat op die houer voorkom gebruik nie.

7. AANBIEDING VAN OBESAN X
Wit HDPE silindriese sekuriteitshouer, toegemaak met 'n wit PP deksel.
Verpakkingsgrootte: 30 tablette.

8. IDENTIFIKASIE VAN OBESAN X
Wit, plat, ronde tablet met afgeskuinste kante en 'n keep aan die een kant.

9. VERWYSINGSNOMMER
C877 (Wet 101/1965)

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
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11. PUBLIKASIEDATUM
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