SENTRY D VOUBILJET

SKEDULERINGSTATUS S0

EIENDOMSNAAM (EN DOSEERVORM)
Sentry D (Orale oplosbare films)

SAMESTELLING
Elke orale oplosbare film bevat:
Vitamien D 1000 I.U.
Die onaktiewe bestanddele is: Karamel vloeistof, sitroensuur, crospovidoon XL 10, dikalsiumfosfaat, gliserieloleaat, hidroksipropielmetielsellulose, mannitol, mieliestysel, mentol, lemoen geursel, polisorbaat 80, gesuiwerde water, sakkarien natrium en sukralose.

FARMAKOLOGIESE KLASSIFIKASIE
D. 22.2 Vitamiene, ander (Gesondheidsaanvulling)

FARMAKOLOGIESE AKSIE
Farmakodinamiese eienskappe
Vitamien D stimuleer intestinale absorpsie van kalsium, asook van kalsium in die osteoïed, en vrystelling van kalsium vanuit beenweefsel. Die aktiewe en passiewe vervoer van fosfaat word ook gestimuleer. Uitskeiding van kalsium en fosfaat word in die niere verhoed deur tubulêre resorpsie te bevorder.

Farmakokinetiese eienskappe
Cholekalsiferol word vanuit die gastroïntestinale stelsel geabsorbeer in die teenwoordigheid van gal, in die sirkulasie in en is onderhewig aan enterohepatiese sirkulasie. Dit word in die lewer gehidroksileer om 25-hidroksicholekalsiferol te vorm, en ondergaan dan verdere hidroksilasie in die niere om die aktiewe metaboliet, 1,25 dihidroksicholekalsiferol (calcitriol) te vorm. Vitamien D metaboliete bind aan spesifieke plasmaproteïene, α-globulien, en word hoofsaaklik in die gal en ontlasting uitgeskei.

INDIKASIES
Sentry D dra by tot die instandhouding van sterk bene en tande, en die normale funksie van die immuunstelsel.

KONTRA INDIKASIES
Indien u ly aan hipervitaminose D, nefrolitiase of ernstige nierinkorting.
Siektes wat lei tot hiperkalsemie en/of hiperkalsurie.
Pasiënte met 'n bekende hipersensitiwiteit vir enige van die bestanddele in die produk.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Geen ander aanvulling wat vitamien D bevat moet geneem word wanneer u **Sentry D** gebruik nie, tensy onder die toesig van u dokter.
Vitamien D moet gebruik word met omsig by pasiënte wat kardiale glikosiede ontvang as behandeling vir hartsiektes (sien **Interaksies**).
Indien u galsuur sekwestrante of orlistat vir gewigsverlies gebruik, konsulteer u dokter voordat u **Sentry D** neem (sien **Interaksies**).
Sentry D orale films word nie aanbeveel tydens swangerskap of laktasie nie, tensy die kliniese toestand van die vrou behandeling benodig (sien **Swangerskap en Laktasie**).

Uitwerking op die vermoë om te bestuur en masjinerie te hanteer
Sentry D behoort geen of 'n weglaatbare effek op die vermoë om te bestuur of masjinerie te gebruik te hê.

INTERAKSIES
Konsulteer u dokter voordat u **Sentry D** neem indien u enige van die volgende medisynes neem:
Orlistat, mineraal olie, galsuur sekwestrante soos cholestiramien, digoksien, aluminiumhidroksied, magnesiumhidroksied, magnesiumsitraat en diuretika soos chloortalidoon, hidrochloortiasied en chloortiasied.
Die neem van **Sentry D** met hierdie medikasies moet met ten minste 2 ure geskei word.
Vermy of verminder alkohol inname tydens **Sentry D** behandeling aangesien alkohol vitamien D absorpsie kan verminder.

SWANGERSKAP EN LAKTASIE
Sentry D word nie aanbeveel tydens swangerskap nie, tensy onder toesig van 'n dokter. Cholekalsiferol en die metaboliete daarvan word in borsmelk uitgeskei en word dus nie aanbeveel in borsvoedende moeders nie.

DOSERING EN GEBRUIKSAANWYSINGS
Volwassenes: Los een film in die mond op, een keer per dag. **Sentry D** moet geneem word met die hoofmaaltyd van die dag.
Sentry D word nie aanbeveel vir kinders onder die ouderdom van 12 jaar nie.

NEWE-EFFEKTE
Immuunsisteem versteurings:
Seldsaam: swelling van die gesig, keel en tong.
Senuweestelsel versteurings:
Seldsaam: ernstige duiseligheid, hoofpyn, swakheid, gebrek aan energie, moegheid.
Kardiale versteurings:
Seldsaam: veranderinge in hartritme insluitend onreëlmatige of vinnige hartkloppings.
Respiratoriese, torakale en mediastinale versteurings:
Seldsaam: moeilike asemhaling.
Gastroïntestinale versteurings:
Seldsaam: droë mond, braking.
Vel en subkutaneuse weefsel versteurings:
Seldsaam: allergiese reaksies soos uitslag of pruritis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Die ernstigste gevolg van akute of kroniese oordosering is hiperkalsemie weens vitamien D toksisiteit. Simptome kan naarheid, braking, swakheid, apatie, anoreksie, poliurie, konstipasie en dorsheid insluit. Kroniese oordosering kan lei tot orgaan en vaskulêre kalsifikasie weens hiperkalsemie. Alle inname van vitamien D moet gestaak word. Behandeling van 'n oordosis moet simptomaties en ondersteunend wees.

IDENTIFIKASIE
Sentry D is 'n dun film, en ligbruin kleur

AANBIEDING
Elke karton bevat 30 sakkies. Elke sakkie bevat een orale oplosbarefilm.

BERGINGSINSTRUKSIES
Berg by of benede 25 ˚C in 'n koel, droë plek.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER
Moet toegeken word

VRYWARING
Hierdie medisyne is nie geëvalueer deur die Medisyne Beheerraad nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, te behandel, genees of te voorkom nie.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
Lamar International (Pty) Ltd
Pasita Straat 13
Rosen Heights, Rosen Park
Bellville
Kaapstad
7530

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
Moet toegeken word

SENTRY D PACKAGE INSERT

SCHEDULING STATUS S0

PROPRIETARY NAME (AND DOSAGE FORM)
Sentry D (Orodispersible film)

COMPOSITION
Each orodispersable film contains:
Vitamin D 1000 I.U.
The other ingredients are: Caramel liquid, citric acid, crospovidone XL 10, dicalcium phosphate, glyceryl oleate, hydroxypropyl methylcellulose, mannitol, maize starch, menthol, orange flavour, polysorbate 80, purified water, saccharine sodium and sucralose.

PHARMACOLOGICAL CLASSIFICATION
D. 22.2 Vitamins, other (Health Supplement)

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Vitamin D stimulates intestinal absorption of calcium, incorporation of calcium into the osteoid, and release of calcium from bone tissue. The active and passive transport of phosphate is stimulated as well. Excretion of calcium and phosphate is inhibited in the kidney by promoting tubular resorption.

Pharmacokinetic properties
Cholecalciferol is absorbed from the gastro-intestinal tract, in the presence of bile, into the circulation and is subject to entero-hepatic circulation. It is hydroxylated in the liver to form 25-hydroxycholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1,25 dihydroxycholecalciferol (calcitriol).Vitamin D metabolites are bound to specific plasma proteins, α-globin and are excreted mainly in the bile and faeces.

INDICATIONS
Sentry D contributes to the maintenance of strong bones and teeth, and the normal function of the immune system.

CONTRAINDICATIONS
If you suffer from hypervitaminosis D, nephrolithiasis or severe renal impairment.
Diseases resulting in hypercalcaemia and/or hypercalciuria.
Patients with known hypersensitivity to any of the ingredients in this product.

WARNINGS AND SPECIAL PRECAUTIONS
No other supplement containing vitamin D should be taken while taking **Sentry D** except under supervision from your doctor.
Vitamin D should be used with caution in patients receiving cardiac glycosides as treatment for cardiovascular disease (see **Interactions**).
If you are taking bile acid sequestrants or orlistat for weight loss, consult your doctor before using **Sentry D** (see **Interactions**).
Sentry D oral films are not recommended during pregnancy or lactation unless the clinical condition of the woman requires treatment (see **Pregnancy and Lactation**).

Effects on ability to drive and handle machinery
Sentry D should have no or negligible influence on the ability to drive or use machinery.

INTERACTIONS
Consult your doctor before taking **Sentry D** if you are taking any of the following medicines:
Orlistat, mineral oil, bile acid sequestrants such as cholestyramine, digoxin, aluminium hydroxide, magnesium hydroxide, magnesium citrate and diuretics such as chlorthalidone, hydrochlorothiazide and chlorothiazide.
Taking **Sentry D** with these medications should be separated by at least 2 hours.
Avoid or limit alcohol consumption while taking **Sentry D** as alcohol can decrease vitamin D absorption.

PREGNANCY AND LACTATION
Sentry D is not recommended during pregnancy unless under supervision of a doctor.
Cholecalciferol and its metabolites are excreted in breast milk and is therefore not recommended for breastfeeding mothers.

DOSAGE AND DIRECTIONS FOR USE
Adults: Dissolve one film in the mouth once daily. **Sentry D** should be taken with the main meal of the day.
Sentry D is not recommended for children under 12 years.

SIDE-EFFECTS
Immune system disorders:
Rare: swelling of the face, throat and tongue
Nervous system disorders:
Rare: severe dizziness, headache, weakness, lack of energy, fatigue
Cardiac disorders:
Rare: changes in hearth rhythm, including irregular or racing heartbeat
Respiratory, thoracic and mediastinal disorders:
Rare: trouble breathing
Gastro-intestinal disorders:
Rare: dry mouth, vomiting
Skin and subcutaneous tissue disorders:
Rare: allergic reactions such as rash or itching

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT
The most serious consequence of acute or chronic overdose is hypercalcaemia due to vitamin D toxicity. Symptoms may include nausea, vomiting, weakness, apathy, anorexia, polyuria, constipation and thirst. Chronic overdoses can lead to organ and vascular calcification resulting from hypercalcaemia. All intake of vitamin D should be stopped. Treatment of an overdose should be symptomatic and supportive.

IDENTIFICATION
Sentry D is a thin film with a light brown colour

PRESENTATION
Each carton contains 30 sachets. Each sachet contains one orodispersible film.

STORAGE INSTRUCTIONS
Store at or below 25 ˚C in a cool, dry place.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER
To be allocated

DISCLAIMER
This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Lamar International (Pty) Ltd
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DATE OF PUBLICATION OFTHE PACKAGE INSERT
To be allocated