

CLIENT: Forrester Pharma
PRODUCT: Sentry C 20 Effervescent Tablets
INSERT SIZE: 170 x 230 mm
DATE: 18 July 2019
RESOURCE CODE: FP0045/19A
PRINT: 2 colours Black + Pantone 021 C

SCHEDULING STATUS

S0

PROPRIETARY NAME (AND DOSAGE FORM)

Sentry C (effervescent tablet)

COMPOSITION

Each effervescent tablet contains:

Vitamin C (Ascorbic acid) 1 000 mg

The other ingredients are citric acid, dextrose, lemon flavourant, maltodextrin, polyethylene glycol, riboflavine-5-phosphate, sodium hydrogen carbonate, sorbitol and sucralose.

Contains sugar (174 mg dextrose & 160 mg sorbitol per tablet).

Contains sweetener (30 mg sucralose per tablet).

CATEGORY AND CLASS

D. 34.11 Vitamins

Complementary Medicine: Health Supplement

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

The active ingredient provides vitamin C which is involved in metabolic processes such as lipid and protein synthesis, oxidation-reduction reactions, cellular respiration and carbohydrate breakdown and synthesis.

Pharmacokinetic properties

Vitamin C is freely absorbed from the digestive tract and is extensively distributed in the bodily tissues. Blood plasma levels of ascorbic acid are elevated as the dose ingested is increased until a level state is reached and the surplus is eliminated unchanged at a high rate in the urine.

INDICATIONS

Sentry C is a vitamin C supplement which acts as an antioxidant aiding in the maintenance of good health and wound healing.

Sentry C supports the normal function of the immune system, also during and after intense physical stress.

Sentry C helps to metabolise fats and proteins as well as assisting in the development and maintenance of cartilage, bones, teeth and gums and connective tissue formation.

CONTRAINDICATIONS

If you suffer from oxalate kidney stones and certain illnesses in which too much iron is retained by the body (thalassaemia, haemochromatosis, sideroblastic anaemia), consult your doctor before taking **Sentry C**.

Vitamin C should not be taken in higher doses in the case of glucose-6-phosphate-dehydrogenase deficiency of the red blood cells (e.g. favism).

Patients with known hypersensitivity to any of the ingredients in this product.

WARNINGS AND SPECIAL PRECAUTIONS

High doses of vitamin C can lead to the formation of calcium-oxalate kidney stones, which can occur even at doses of 2-3 g per day in the case of existing restriction of the kidney function.

Patients being treated with warfarin or other anticoagulants should avoid taking high doses of vitamin C (see Interactions).

Vitamin C is an antioxidant and antioxidants may reduce the activity of chemotherapy. Consult your doctor before taking **Sentry C**.

Effects on ability to drive and handle machinery

Sentry C should have no or negligible influence on the ability to drive or use machinery.

INTERACTIONS

Taking vitamin C leads to the increased absorption of iron and aluminium in the intestinal tract. This can impact patients with kidney failure.

The efficacy of warfarin and other anticoagulant medicine may be reduced by taking high doses of vitamin C.

Vitamin C is an antioxidant and may reduce the efficacy of chemotherapy.

HUMAN REPRODUCTION

The safety of taking **Sentry C** during pregnancy and lactation has not yet been established.

DOSAGE AND DIRECTIONS FOR USE

Adults: Dissolve tablet in a glass of water before use. Take one tablet once daily or as recommended by your healthcare provider.

SIDE-EFFECTS

Nervous system disorders: flushing, headache, drowsiness and fatigue.

Gastrointestinal disorders: abdominal cramps, diarrhoea, nausea and vomiting, indigestion and inflammation of the oesophagus.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Overdosage of the medication can lead to diarrhoea, accompanied by stomach ache. If this occurs, treatment with vitamin C should be stopped. In the event of kidney pain or difficulty in urination following a high dose of **Sentry C**, consult your doctor immediately.

Treatment of an overdose should be symptomatic and supportive.

IDENTIFICATION

Citrus-flavoured, round, flat tablet with a mosaic surface, with a diameter of 25 mm.

PRESENTATION

White polypropylene cylindrical tube with a white LDPE cap with silica gel desiccant, containing 20 effervescent tablets

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 unregistered product has not been evaluated by the SAHPRA for quality, safety or intended use.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PACKAGE INSERT

May 2018



FP0045/19A

SKEDULERINGSSTATUS

SO

EIENDOMSNAAM (EN DOSEERVORM)

Sentry C (bruistablet)

SAMESTELLING

Elke bruistablet bevat:

Vitamin C (Askorbiensuur) 1 000 mg

Die onaktiewe bestanddele is sitroensuur, dekstrose, suurlemoen geurmiddel, maltodekstrien, poliëtiëenglikol, riboflavin-5-fosfaat, natriumwaterstofkarbonaat, sorbitol en sukralose.

Bevat suiker (174 mg dekstrose & 160 mg sorbitol per tablet).

Bevat versoeter (30 mg sukralose per tablet).

KATEGORIE EN KLAS

D. 34.11 Vitamiene

Komplementêre Medisyne: Gesondheidsaanvulling

FARMAKOLOGIESE AKSIE

Farmakodinamiese eienskappe

Die aktiewe bestanddeel verskaf vitamien C wat betrokke is by metaboliese prosesse soos lipied- en proteïensintese, oksidasie-reduksie reaksies, selrespirasie, asook koolhidraatafbraak en -sintese.

Farmakokinetiese eienskappe

Vitamien C word vrylik geabsorbeer uit die spysverteringskanaal en word op groot skaal versprei in die liggaamsweefsel. Bloedplasmavlakke van askorbiensuur neem toe as die dosis wat ingeneem word verhoog, totdat 'n plato bereik word, en die oorskot word teen 'n hoë tempo onveranderd in die urine uitgeskei.

INDIKASIES

Sentry C is 'n vitamien C-aanvulling wat dien as 'n antioksidant wat ondersteunend is in die handhawing van goeie gesondheid en wondgenesing.

Sentry C ondersteun die normale funksionering van die immuunstelsel, ook tydens en na intensiewe fisiese stress.

Sentry C help om vette en proteïene te metaboliseer en ondersteun ook die ontwikkeling en instandhouding van kraakbeen, bene, tande en tandvleis, sowel as bindweefsel vorming.

KONTRA-INDIKASIES

Indien u aan oksalaat nierstene, en sekere siektes waar die liggaam te veel yster behou ly, (talassemie, hemochromatose, sideroblastiese bloedarmoede), raadpleeg u dokter voordat u **Sentry C** gebruik.

Vitamien C moet nie in hoë dosisse geneem word in die geval van glukose-6-fosfaat- dehidrogenase tekort van die rooibloedselle nie (bv. favisme).

Pasiënte met 'n bekende hipersensitiewiteit vir enige van die bestanddele in die produk.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

Hoë dosisse vitamien C kan lei tot die vorming van kalsium-oksalaat nierstene, wat selfs teen dosisse van 2-3 g per dag in die geval van bestaande inkorting van die nierfunksie kan voorkom.

Pasiënte wat met warfarin of ander antikoagulant behandel word, moet dit vermy om hoë dosisse vitamien C te neem (sien Interaksies).

Vitamien C is 'n antioksidant en antioksidante kan die aktiwiteit van chemoterapie verminder. Raadpleeg u dokter voordat u **Sentry C** gebruik.

Uitwerking op die vermoë om te bestuur en masjinerie te hanteer

Sentry C behoort geen of 'n weglaatbare effek op die vermoë om te bestuur of masjinerie te gebruik te hê.

INTERAKSIES

Die gebruik van vitamien C kan lei tot die verhoogde absorpsie van yster en aluminium in die dermkanaal. Dit kan 'n impak hê op pasiënte met nierversaking.

Die doeltreffendheid van warfarin en ander antikoagulant medisyne kan verminder word deur die gebruik van hoë dosisse vitamien C.

Vitamien C is 'n antioksidant wat die werking van chemoterapie kan verminder.

MENSLIKE VOORTPLANTING

Die veiligheid van die gebruik van **Sentry C** tydens swangerskap en borsvoeding is nog nie vasgestel nie.

DOSERING EN GEBRUIKSAANWYSINGS

Volwassenes: Los een tablet in 'n glas water op voor gebruik. Neem een tablet een keer per dag of soos wat deur jou gesondheidsorgverskaffer aanbeveel word.

NEWE-EFFEKTE

Senuweestelselversteurings: gloede, hoofpyn, lomerigheid en moegheid.
Gastroïntestinale versteurings: maagkrampe, diarree, naarheid en braking, slegte spysvertering en inflammasie van die esofagus.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Oordosering van die medikasie kan lei tot diarree, met gepaardgaande maagpyn. Indien dit gebeur, moet behandeling met vitamien C gestop word. In die geval van nierpyn of moeilike urinerig ná 'n hoë dosis van **Sentry C**, raadpleeg jou dokter onmiddellik.

Behandeling van 'n oordosis moet simptome en ondersteunend wees.

IDENTIFIKASIE

Sitrus-geurde, ronde, plat tablet met 'n mosaïekoppervlak, met 'n deursnee van 25 mm.

AANBIEDING

'n Wit polipropileen silindriese buis met 'n wit LDPE doppie, met silikagel-droogmiddel, wat 20 bruistablette bevat.

BERGINGSINSTRUKSIES

Berg by of benede 25 °C in 'n koel, droë plek.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIE-NOMMER

Moet toegeken word.

VRYWARING

Hierdie ongeregisteerde produk is nie deur die SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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DATUM VAN PUBLIKASIE VAN DIE VOUBILJET

Mei 2018



FP0045/19A