

INSADOL- corn sterilized quantitative extract (beta sitosterol) tablet
I World Pharmaceutical Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Corn sterilized quantitative extract (beta sitosterol)

Periodontal disease [Dental caries disease, gingivitis, periodontitis (periodontal periodontitis)]

Keep out of reach of children

- adult: two tablets once, three times a day before meal
- as a maintenance dose, one tablet once, three times a day before meal

Do not take this medicine if

- people who are hypersensitive to the drugs and ingredients contained in this medicine

Consult a doctor, dentist, or pharmacist before taking this medicine

■ Patients who are overreacting to substrates of azoic pigment, acetyl salicylic acid or other prostaglandin syncase inhibitors should be careful about the use of this drug ■ Be careful because this drug may interfere with the absorption of cholesterol medicines.

■ Pregnancy and lactation (for pregnant women or wives who are likely to be pregnant, only if the therapeutic benefit exceeds the risk) ■ Since this drug contains yellow 4 (tartrazine), consult a doctor, dentist, or pharmacist before taking it (for that item only)

Immediately stop taking this medicine and consult a doctor or pharmacist if: ■ the drug is administered to patients with asthma or chronic stomatosis or is overreacting to non-steroidal anti-inflammatory drugs, it may cause anaphylaxis or respiratory system to overreact

magnesium stearate, microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, povidone K30

For oral use only

INSADOL

Drug Facts

Active Ingredients (in one tablet)

Corn sterilized quantitative extract 35.0mg
(beta sitosterol)

Purpose
oral care

Uses

Periodontal disease [Dental caries disease, gingivitis, periodontitis
(periodontal periodontitis)]

Warnings

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Directions

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■ as a maintenance dose, one tablet once, three times a day before meal

Other Information

■ Store at room temperature

Inactive Ingredient

magnesium stearate, microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, povidone K30

Questions or comments?

Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405

Distributed By: P&K FRONTIER MARKETING CORP.

329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA

Made in South Korea

INSADOL

corn sterilized quantitative extract (beta sitosterol) tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73442-0002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.BETA.-SITOSTEROL (UNII: S347WMO6M4) (.BETA.-SITOSTEROL - UNII:S347WMO6M4)	.BETA.-SITOSTEROL	35 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	ISD
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73442-0002-1	100 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/08/2019	

Labeler - I World Pharmaceutical Co., Ltd. (688222857)

Registrant - I World Pharmaceutical Co., Ltd. (688222857)

Establishment

Name	Address	ID/FEI	Business Operations
I World Pharmaceutical Co., Ltd		688222857	manufacture(73442-0002)

Revised: 11/2019

I World Pharmaceutical Co., Ltd.