

INSADOL- corn sterilized quantitative extract (beta sitosterol) tablet
LYDIA 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 synthase 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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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:72988-0016 |
| 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:72988-0016-1 | 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 - LYDIA Co., Ltd (695735569)

Registrant - LYDIA Co., Ltd (695735569)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|-------------------------|
| I World Pharmaceutical Co., Ltd | | 688222857 | manufacture(72988-0016) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|---------------------|
| LYDIA Co., Ltd | | 695735569 | label(72988-0016) |

Revised: 10/2019

LYDIA Co., Ltd