ETON Q- zea mays whole tablet Chong Kun Dang Pharm. Corp.

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.

ACTIVE INGREDIENT

Active ingredient (In each tablet)

INACTIVE INGREDIENTS

Microcrystalline Cellulose, Corn Starch, Colloidal Silicon Dioxide, Povidone (K-30), Kaolin, Magnesium Stearate

PURPOSE

Treatment for gingivitis and mild/moderate periodontitis

WARNINGS

Do not use

■ If you are hypersensitive to Zea Mays L. or any of the inactive ingredients in this drug ■ Ask a doctor of pharmacist before use if you are applicable to following conditions: 1) Azo pigments; Use with caution in patients with hypersensitivity to acetylsalicylic acid or other prostaglandin synthase inhibitors.do. 2) Be careful as this drug may interfere with the absorption of cholesterol drugs. 3) Pregnant or likely to be pregnant. Women who are pregnant or are breast-feeding (the safety of administration during pregnancy has not been established, so pregnant or breast-feeding women who may be pregnant). For women, it is administered only when it is judged that the therapeutic benefit outweighs the risk.) 4) This drug contains Yellow No. 4(Atrazine), Yellow No. 5(Sunset Yellow FCF). Please, consult your doctor, dentist, or pharmacist before taking if you are hypersensitive or allergic any of the ingredients in this drug \blacksquare In the following cases, stop taking this drug immediately and consult a doctor, dentist or pharmacist. Whenever possible, carry this information with you. 1) May cause mild laxative effects. 2) If this drug is administered to a patient with asthma, chronic urticaria, or hypersensitivity to nonsteroidal anti-inflammatory drugs, it may cause hypersensitivity to the skin or respiratory system. 3) As a result of a clinical trial conducted on patients with periodontal disease to evaluate the efficacy and safety of this drug in Korea, taking this drug (3 times a day for 4 weeks, 2 tablets at a time, 4 weeks to 12 weeks) The adverse reactions reported in 72 patients who took this drug 3 times a day, 1 tablet at a time, for a total of 12 weeks) were as follows, regardless of the causal relationship. Nasopharyngitis (2 cases), dental abscess (pus), abdominal pain (belly pain), tooth fracture, AST increase, ALT increase, glaucoma, hyperlipidemia, pain in limbs, tooth

extraction (extraction) (1 case each). 4) If there is no improvement in symptoms even after taking it for more than 1 month. Other precautions when taking this drug. 1) Be sure to follow the prescribed usage and dosage. 2) Do not take this drug continuously for a long time.

KEEP OUT OF REACH OF CHILDREN

NA

Uses

- Adjuvant treatment for gingivitis
- Mild/moderate periodontitis after periodontal treatment

Directions

■ Administration

Adults: take orally. In initial, take 2 tablets three times per day before meals (on empty stomach). For maintenance, take 1 tablet three times a day in empty before meals (on empty stomach). Appropriately increase or decrease amount of administration according to your age and symptoms.

Other Information

Storage at room temperature between 1~30°C (33.8~86.0 °F)
 Do not use if carton is opened ■ Do not use if foil inner seal is broken or missing ■ Keep out of reach of children ■ Store at a cool and dry place, away from direct sunlight and high temperature ■ Taking drugs out of their original containers and storing them in other containers may cause misuse or deterioration of drugs, therefore, put them in the original containers and keep them tightly closed.

QUESTIONS

■ Call +82-080-6776-080 ■ Website: http://www.ckdpharm.com

PACKAGE LABEL







| Drug Facts | | | |
|--|--|--|--|
| Active ingredient(in each sublet) ZEMAYS WHOLE (frated Extra of Zha Mays L. Ursaponifatio Fraction) ——————————————————————————————————— | Auguse Treament for ging vite and mid/moderate periodontitis | | |
| Uses • Adjuant treatment for ginglikis • Mild incolorate periodontilis after periodontal treatment | | | |
| Wherings Fig. was proceeded to 20 kg/s, a a graften solel register to the day of loss about the south year. Fig. was proceeded to 20 kg/s, a a graften solel register to the day of loss about the south year. Fig. was proceeded to 20 kg/s, a a graften solel register to the day of loss about the solel was the white the solel register to the three days and the solel register to the | aception of children's drugs. If Program to Rely to the program. Where who are promise programs are programs of the works in a children's desired by the track if Where processes, can be for formed with you. If Wag cases in Blasses and it was programs of the second of the programs of the control blasses in the gramma of the programs of the programs of the control blasses and entirely the busy through the control blasses in the second of the control of the programs of the programs of the control blasses and entirely the busy through the Cases of, and all assess (and, all others of the control of the programs of the programs of the programs of the control of the programs of the programs of the programs of the control of the programs of the programs of the programs of the control of the programs of the programs of the programs of the control of control of cont | | |
| Denotices **Alexandars **Ale | | | |
| One foreign. Other foreign. | | | |
| Questions • Cut 42-09-977-98 • Vibitats imp://www.dopham.com | | | |
| hactive ingredients : Monogotaline Coluisse, Com Starch, Coloida Silcon Dioide, Povidone (K-90), Kacim, Magnesium Starch | 10 | | |
| Factive ingredient Sections (as the structure of the stru | | | |







ETON Q

zea mays whole tablet

| Product Information | | | | |
|---------------------|----------------|--|--|--|
| Product Type | HUMAN OTC DRUG | | | |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82024-010

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ZEA MAYS WHOLE (UNII: 1G5HNE09V8) (ZEA MAYS WHOLE - UNII:1G5HNE09V8) ZEA MAYS WHOLE 35.0 mg

Inactive Ingredients Ingredient Name Strength MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) STARCH, CORN (UNII: 08232NY3SJ) SILICON DIOXIDE (UNII: ETJ7Z6XBU4) Povidone (UNII: FZ989GH94E) Kaolin (UNII: 24H4NWX5CO) Magnesium Stearate (UNII: 70097M6I30)

| Product Characteristics | | | | |
|-------------------------|--------|--------------|----------|--|
| Color | orange | Score | no score | |
| Shape | ROUND | Size | 10mm | |
| Flavor | | Imprint Code | CKD | |
| Contains | | | | |
| | | | | |

| Packaging | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:82024-010- 01 | 270 in 1 CARTON; Type 0: Not a Combination Product | 07/01/2021 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 07/01/2021 | |
| | | 07/01/2021 | |

Labeler - Chong Kun Dang Pharm. Corp. (694720364)

Registrant - Chong Kun Dang Pharm. Corp. (694720364)

| Establishment | | | | |
|--------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| DongSung Pharm Co., Ltd. | | 687856557 | manufacture(82024-010) | |

Revised: 7/2021 Chong Kun Dang Pharm. Corp.