ZELCOM- flubendazol tablet OASIS TRADING

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.

Flubendazol

Flubendazol is an anthelmintic (an-thel-MIN-tik) or anti-worm medication. It prevents newly hatched insect larvae (worms) from growing or multiplying in your body

Keep out of reach of children

- adult and children 2 years of age and older: 1 tablet
- children under 1 years of age: ask a doctor

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

cellulose, corn starch, magnesium stearate, sodium starch

For oral use only

ZELCOM

| Active Ingredients (in one tablet) Flubendazol 500mg | Purpose Andelmintics |
|--|-------------------------|
| Uses Flubendazol is an anthelmintic (an-thel-MIN-tik) medication. It prevents newly hatched insect lar growing or multiplying in your body | or anti-worm |
| Warnings If pregnant or breast-feeding, ask a health pro Keep out of reach of children. In case of overd help or contact a Poison Control Center right as | ose, get medical |
| Directions ■ adult and children 2 years of age and older: 1 ■ children under 1 years of age: ask a doctor | |
| Other Information ■ Store at room temperature | |
| Inactive Ingredient cellulose, corn starch, magnesium stearate, sodi | um starch |
| Questions or comments? Call weekdays from 9 a.m to 5 p.m EST at (201) Distributed By: P&K FRONTIER MARKETING C 329 BROAD AVENUE # 2F, PALISADES PARK, NJ | ORP. |

ZELCOM flubendazol tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72689-0009 Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name **Basis of Strength**

FLUBENDAZOLE 500 mg

FLUBENDAZOLE (UNII: R8 M46911LR) (FLUBENDAZOLE - UNII:R8 M46911LR)

Strength

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
| | |

MAGNESIUM STEARATE (UNII: 70097M6I30)

Product Characteristics

| Color | pink | Score | no score |
|----------|------|--------------|----------|
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | ZELCOM |
| Contains | | | |

Packaging

| ш | | ~ ~ | | | |
|-----|---|-----------|---------------------|-----------------------------|---------------------------|
| ı | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| - 1 | | | | | |

1 NDC:72689-0009-1 1 in 1 BLISTER PACK; Type 0: Not a Combination Product 11/16/2018

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
|-----------------------|--|----------------------|--------------------|--|
| unapproved drug other | | 11/15/2018 | | |
| | | | | |

Labeler - OASIS TRADING (689991468)

Registrant - OASIS TRADING (689991468)

| Establishment | | | |
|---------------|---------|-----------|-------------------------|
| Name | Address | ID/FEI | Business Operations |
| OASIS TRADING | | 689991468 | manufacture(72689-0009) |

Revised: 11/2018 OASIS TRADING