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|---|---|---|
| **Brand Name** : **AGOBEN SUSPENSION**<br>**Generic Name** : Mebendazole Oral Suspension USP | | 2021 |
| | | |
| **Module 1**<br>**1.5** | Administrative Information and Product Information<br>Product Information | **Confidential** |

## 1.5 PRODUCT INFORMATION

### 1.5.1 Prescribing information (Summary of products characteristics)

# SUMMARY PRODUCT CHARACTERISTICS

## 1. Name of drug product:

**AGOBEN SUSPENTION** (Mebendazole Oral Suspension USP)

## 2. Qualitative and Quantitative Composition:

Each 5 ml contains: Mebendazole USP 100 mg

## 3. Pharmaceutical form:

Light orange coloured uniform suspension on shaking.

## 4. Clinical particulars:

### 4.1 Therapeutic Indications:

**Mebendazole** (**MBZ**) is a medication used to treat a number of parasitic worm infestations. This includes ascariasis, pinworm disease, hookworm infections, guinea worm infections, hydatid disease, and giardia, among others. It is taken by mouth.

Mebendazole is usually well tolerated. Common side effects include headache, vomiting, and ringing in the ears. If used at large doses it may cause bone marrow suppression. It is unclear if it is safe in pregnancy. Mebendazole is a broad-spectrum antihelminthic agent of the benzimidazole type.

Mebendazole came into use in 1971, after it was developed by Janssen Pharmaceutica in Belgium. It is on the World Health Organization's List of Essential Medicines. Mebendazole is available as a generic medication.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

## 4.2 Posology and Method of Administration:

Adults and children over 2 years:

Enterobiasis:

1 x 5 ml (1 dosing cup).

It is highly recommended that a second dose is taken after 2 weeks, if reinfection is suspected.

Ascariasis, trichuriasis, ancylostomiasis, necatoriasis and mixed infections:

1 x 5 ml (1 dosing cup) bd for three days.

Children under 2 years:

Mebendazole has not been extensively studied in children below the age of 2 years.

Currently available data are described in section 4.4, 4.8 and 5.2, but no recommendations on a posology can be made.

Because of the lack of sufficient safety data, Mebendazole should not be used in children below the age of 1 year.

Method of administration.

Oral Use

mebendazole oral suspension should be considered for patients such as young children who are unable to swallow the tablet.

Method of administration: Oral.

## 4.3 Contraindications:

Mebendazole is contraindicated in pregnancy and in patients who have shown hypersensitivity to the product or any components.

## 4.4 Special Warnings and Precautions for Use:

Follow all directions on your medicine label and package. Tell each of your healthcare providers about all your medical conditions, allergies, and all medicines you use.

## 4.5 Pregnancy and Lactation:

This drug should be used during pregnancy only if the benefit outweighs the risk.
-According to some authorities: Use is contraindicated.

AU TGA pregnancy category: B3
US FDA pregnancy category: Not assigned.

Risk summary: Insufficient data available on use of this drug in pregnant women to inform a drug-related risk.

### 4.6 Overdose:

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose symptoms may include upper stomach pain, loss of appetite, dark urine, or jaundice (yellowing of the skin or eyes).

## 5. Pharmacological properties:

### 5.1 Pharmacodynamic properties:

### 5.2 Pharmacokinetic Properties:

## 6. Pharmaceutical particulars:

### 6.1 List of Excipients:

| | |
|---|---|
| Sucrose | BP |
| Methyl Paraben sodium | BP |
| Propyl Paraben sodium | BP |
| Sodium Benzoate | BP |
| Carboxy methyl cellulose sodium | BP |
| Glycerine | BP |
| Colour sunset yellow supra | INH |
| Essence Pineapple No. 1 | INH |
| Citric Acid monohydrates | BP |

### 6.2 Incompatibilities:
None Reported

### 6.3 Shelf-Life:
36 months from the date of manufacture.

### 6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light.

### 6.5 Nature and Contents of Container:

30 ML suspension in one bottle. Such bottle packed in export worthy shipper.

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**6.6 Special precautions for disposal:**
None reported.

## 7. Registrant:
**AGOG PHARMA LTD.**
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

## 8. Manufacturer:
**AGOG PHARMA LTD.**
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
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India.

## 9. Date of revision of the text :