



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-09515

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauripada, 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

Brand Name : AGOBEX TABLETS		2021
Generic Name : Mebendazole Tablets		
Module 1	Administrative Information and Product Information	Confidential
1.5	Product Information	

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Mebendazole Tablets

1.1 (Trade) name of product

AGOBEX TABLETS

1.2 Strength

Each uncoated tablet contains:
Mebendazole 100mg

1.3 Pharmaceutical Dosage Form

uncoated tablets



AGQ Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-09515

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurainpada, Vasai (E), Dist. Thane - 401 208, INDIA.

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Each uncoated tablet contains:
Mebendazole 100mg

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Overages	Qty. / Tab.
Mebendazole	USP	100mg	2%	102.00 mg
<u>Granulation</u>				
Di basic Calcium phosphate	BP	-	-	28.000 mg
Maize Starch	BP	-	-	35.613mg
Colour sunset yellow supra	Inhouse	-	-	0.300mg
Colloidal Silicon Dioxide	BP	-	-	2.300mg
Sodium Starch Glycolate	BP	-	-	3.000mg
Methyl Paraben Sodium	BP	-	-	0.200mg
Propyl Paraben Sodium	BP	-	-	0.050mg
Maize Starch	BP	-	-	11.000mg
<u>Lubrication</u>				
Talcum	BP	-	-	3.000mg
Magnesium Stearate	BP	-	-	1.000mg
Maize Starch	BP	-	-	2.000mg
Sodium Starch Glycolate	BP	-	-	3.000mg
Colloidal Silicon Dioxide	BP	-	-	2.000mg
Essence orange Powder	Inhouse	-	-	1.500mg

BP 2019 = British Pharmacopoeia 2019.
USP 42 = United States Pharmacopoeia 42.



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-09515

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauripada, 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

3. PHARMACEUTICAL DOSAGE FORM

Uncoated tablets

Orange coloured, Round, Flat, uncoated tablets having 'AGOG'
On one side and break line on other side.



Agog Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-09515

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

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Mebendazole tablets are indicated for the treatment of enterobius

4.2 Method of Administration

For other types of common worm infection, take mebendazole by mouth for 3 days usually twice a day in the morning and in the evening.

4.3 Contraindications

Transient abdominal pain and diarrhea usually seen in patients being treated for heavy infections.

4.4 Special Warnings and Precautions for Use

Mebendazole is teratogenic & embryotoxic in pregnant rats at doses as low as 100 mg/kg Hence use of the same is not recommended in pregnant women

4.5 Use in Pregnancy and Lactation

Not recommended for pregnant women.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Mebendazole	USP	102.00 mg
-------------	-----	-----------

Granulation

Di basic Calcium phosphate	BP	28.000 mg
Maize Starch	BP	35.613mg
Colour sunset yellow supra	Inhouse	0.300mg
Colloidal Silicon Dioxide	BP	2.300mg
Sodium Starch Glycolate	BP	3.000mg
Methyl Paraben Sodium	BP	0.200mg
Propyl Paraben Sodium	BP	0.050mg
Maize Starch	BP	11.000mg

Lubrication

Talcum	BP	3.000mg
Magnesium Stearate	BP	1.000mg
Maize Starch	BP	2.000mg
Sodium Starch Glycolate	BP	3.000mg
Colloidal Silicon Dioxide	BP	2.000mg
Essence orange Powder	Inhouse	1.500mg

6.2 Incompatibilities

None reported



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-09515

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauripada, 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

6.3 Shelf-Life


36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 30°C.
Protect from light.


6.5 Nature and Contents of Container

Jar pack of 1000 tablets


ANIL K. PANDEY
DIRECTOR

Date :
Director of the manufacturer
(Signature, Full name, Stamp)




ANIL K. PANDEY
DIRECTOR

Date :
Director of applicant company
(Signature, Full name, Stamp)

