

DEFENDAZOLE- fenbendazole suspension
Norbrook Laboratories Limited

INDICATIONS:

Beef and Dairy Cattle – 2.3 mg/lb (5 mg/kg) body weight for the treatment and control of: **Lungworms**: Adult *Dictyocaulus viviparus*; **Stomach worms**: Adult brown stomach worms (*Ostertagia ostertagi*), Adult and fourth stage larvae barberpole worms (*Haemonchus contortus* & *H. placei*), and Adult and fourth stage larvae small stomach worms (*Trichostrongylus axei*); **Intestinal worms** (Adult and fourth stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helveticus*), small intestinal worms (*Cooperia punctata* & *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

Goats – 2.3 mg/lb (5 mg/kg) body weight for the treatment and control of: **Stomach worms** (adults): *Haemonchus contortus* and *Teladorsagia circumcincta*.

DIRECTIONS:

Administer orally. The recommended dose of 2.3 mg/lb (5 mg/kg) of body weight is achieved when 2.3 mL of the drug are given for each 100 lb body weight.

EXAMPLES:

Cattle:

<u>Body Weight</u>	<u>Amount</u>
100 lb	2.3 mL
200 lb	4.6 mL
300 lb	6.9 mL
400 lb	9.2 mL
500 lb	11.5 mL
1000 lb	23.0 mL
1500 lb	34.5 mL

Goats :

<u>Body Weight</u>	<u>Amount</u>
25 lb	0.6 mL
50 lb	1.2 mL
75 lb	1.7 mL
100 lb	2.3 mL
125 lb	2.9 mL

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

WARNINGS:

NOT FOR USE IN HUMANS.

KEEP OUT OF REACH OF CHILDREN.

The Safety Data Sheet (SDS) contains more detailed occupational safety information.

Contact Information:

For customer service, adverse effects reporting, and/or a copy of the SDS, call 1-866-591-5777.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS, or <http://www.fda.gov/reportanimalae>

OTHER WARNINGS:

Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.

Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.

Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).

A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

Restricted drug (California) - use only as directed.

Store at temperatures between 59 °F (15 °C) and 86 °F (30 °C).

Excursions are permitted up to 104 °F (40 °C) however such exposure should be minimized. Brief exposure to temperatures down to 36 °F (2 °C) may be tolerated.

Protect from freezing. Shake well before use.

Withdrawal Periods and Residue Warnings:

Milk taken from cows during treatment and for 48 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use

in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

Goats must not be slaughtered for human consumption within 6 days following last treatment with this drug product. Because a milk discard time has not been established, do not use in lactating goats.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Made in the UK

Norbrook Laboratories Limited
Newry, Co. Down, BT35 6QQ,
Northern Ireland.

Approved by FDA under ANADA # 200-831

Defendazole™ is a trademark of Norbrook Laboratories Limited

Principal Display Panel - 100 mg/mL Carton Label

NDC 55529-165-08

Defendazole™
(fenbendazole)

Dewormer
for **Beef & Dairy Cattle**
and **Goats**

Suspension 10%
(100 mg/mL)

5 Liter
(169 fl oz.)

Norbrook®



Principal Display Panel - 100 mg/mL Jug Label

NDC 55529-165-08

Defendazole™ (fenbendazole)

Dewormer for Beef & Dairy Cattle and Goats

Suspension 10%
(100 mg/mL)

5 Liter
(169 fl oz.)

Norbrook®



INDICATIONS:

Beef and Dairy Cattle - 2.3 mg/lb (5 mg/kg) body weight by the mouth and control of:
Lungworms: Adult *Oxyuris equi* and *Strongylus edentatus*; Stomach worms: Adult brown stomach worms (*Oesophagostomum dentatum*, *Adult and fourth stage larvae of hookworms* (*Ancylostoma caninum* & *H. punctatum*), *Adult and fourth stage larvae of small stomach worms* (*Trichostrongylus axei*); **Intestinal worms:** *Adult and fourth stage larvae of hookworms* (*Haemonchus contortus* and *teladorspatula circumflexa*), *Adult and fourth stage larvae of roundworms* (*Ascaris suum*), *Adult and fourth stage larvae of hookworms* (*Trichostrongylus axei*), *Adult and fourth stage larvae of roundworms* (*Oesophagostomum dentatum*), *Adult and fourth stage larvae of hookworms* (*Ancylostoma caninum* & *H. punctatum*), *Adult and fourth stage larvae of small stomach worms* (*Trichostrongylus axei*); **Stomach worms (adults):** *Haemonchus contortus* and *Teladorspatula circumflexa*.

Goats - 2.3 mg/lb (5 mg/kg) body weight for the treatment and control of:

Stomach worms (adults): *Haemonchus contortus* and *Teladorspatula circumflexa*.

DIRECTIONS:

Administer orally. The recommended dose of 2.3 mg/lb (5 mg/kg) of body weight is achieved when 2.3 mL of the drug are given for each 100 lb body weight.

EXAMPLES:

Cattle:

Body Weight	Amount
100 lb	2.3 mL
200 lb	4.6 mL
300 lb	6.9 mL
400 lb	9.2 mL
500 lb	11.5 mL
1000 lb	23.0 mL
1500 lb	34.5 mL

Goats:

Body Weight	Amount
24 lb	0.6 mL
50 lb	1.2 mL
75 lb	1.7 mL
100 lb	2.3 mL
125 lb	2.9 mL

Do not underdose. Ensure each animal receives the correct dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

WARNINGS: NOT FOR USE IN HUMANS. KEEP OUT OF REACH OF CHILDREN. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

Contact Information: For customer service, adverse effects reporting, and/or a copy of the SDS, call 1-866-591-5777. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-404-VETS, or <http://www.fda.gov/vetadverse>. Made in the UK

OTHER WARNINGS: Parasite resistance may develop to any dewormer, and has been reported for most dewormers (de-wormers). Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.

Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is effective.

appropriate for the herd, prior to the use of any dewormer. Monitoring the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).

A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction test may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

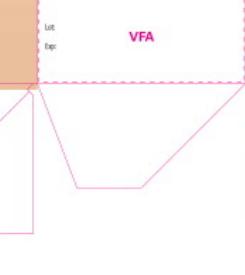
A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction test may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

Restricted drug (California) – use only as directed. Store at temperatures between 59°F (15°C) and 86°F (30°C). Exposures are permitted up to 104°F (40°C) however such exposure should be minimized. Brief exposure to temperatures down to 36°F (2°C) may be tolerated.

Protect from freezing. Shake well before use.

Approved by FDA under ANADA # 200-831

Defendazole™ is a trademark of Norbrook Laboratories Limited



NDC 55529-165-08

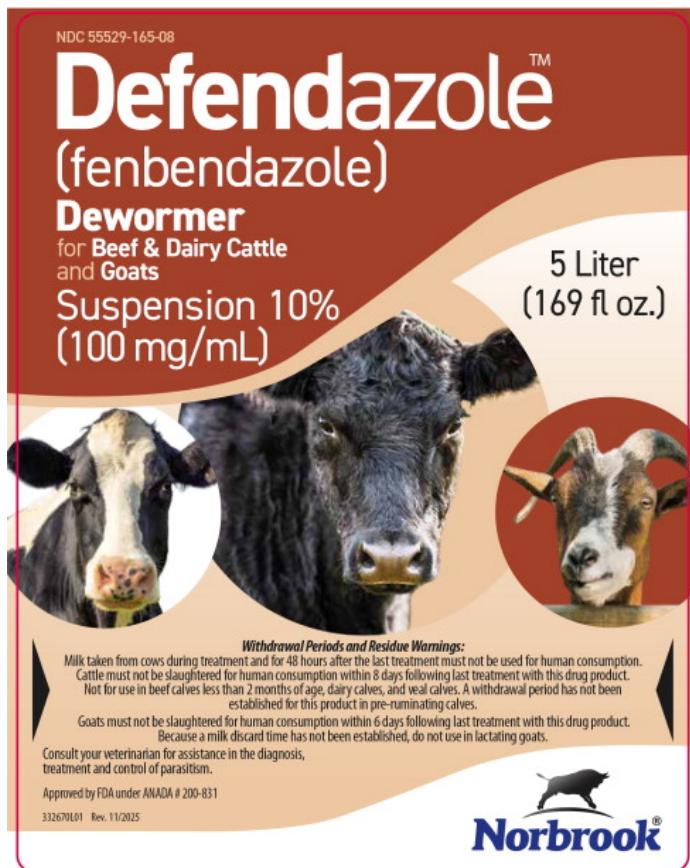
Defendazole™ (fenbendazole)

Dewormer for Beef & Dairy Cattle and Goats

Suspension 10%
(100 mg/mL)

5 Liter
(169 fl oz.)

5 Liter
(169 fl oz.)</p



DEFENDAZOLE

fenbendazole suspension

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDL:55529-165
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FENBENDAZOLE (UNII: 621BVT9M36) (FENBENDAZOLE - UNII:621BVT9M36)	FENBENDAZOLE	100 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55529-165-06	1 in 1 CARTON		
1		1000 mL in 1 JUG		
2	NDC:55529-165-08	1 in 1 CARTON		
2		5000 mL in 1 JUG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200831	01/19/2026	

Labeler - Norbrook Laboratories Limited (214580029)

Revised: 1/2026

Norbrook Laboratories Limited