

**Product name:** FASINEX<sup>®</sup> 240 Oral Flukicide for Cattle

**Date of update:** 20 November 2003      **Page:** 1 of 9

**Today's date:** 2 June, 2005

**Type of label:** Composite: Primary label and leaflet

**Pack sizes:** 0.8, 2.2, 5, 10, 13, 15, 20 L      **Version:** 13

**File:** FASINEX 240 JB1Jan04.doc

**Reason:** New promotional pack. Update addresses (JB)

Text above this line is not included in the actual label.

---

**Primary label (front panel – 0.8L / 2.2L / 5L / 10L / 13L / 15L / 20L)**

---

**POISON  
KEEP OUT OF REACH OF CHILDREN  
READ SAFETY DIRECTIONS BEFORE OPENING OR USING  
FOR ANIMAL TREATMENT ONLY**

## **FASINEX<sup>®</sup> 240 Oral Flukicide for Cattle**

Active Constituent: 240 g/L TRICLABENDAZOLE

For the treatment of triclabendazole-susceptible Early Immature, Immature and Mature liver fluke  
(*Fasciola hepatica*) in cattle.

0.8 L / 2.2 L / 5 L / 10 L / 13 L / 15 L / 20 L

SHAKE WELL BEFORE USE

Product name: FASINEX® 240 Oral Flukicide for Cattle  
 Date of update: 20 November 2003 Page: 2 of 9  
 Today's date: 2 June, 2005 Type of label: Composite: Primary label and leaflet  
 Pack sizes: 0.8, 2.2, 5, 10, 13, 15, 20 L Version: 13  
 File: FASINEX 240 JB1Jan04.doc Reason: New promotional pack. Update addresses (JB)  
 Text above this line is not included in the actual label.

**Primary label (back panel - 0.8 L / 2.2 L / 5 L)**

**FASINEX® 240 Oral Flukicide for Cattle**

**READ INSTRUCTION LEAFLET BEFORE USING THIS PRODUCT**

**DIRECTIONS FOR USE  
 SHAKE WELL BEFORE USE**

**Restraints: DO NOT USE in lactating cows where milk or milk products may be used for human consumption.**

**ORAL DOSE RATE: CATTLE 2.5 mL per 50 kg BW**

Cattle weight	Oral dose (mL)	No. treated per			Critical comments
		0.8 L pack	2.2 L pack	5 L pack	
Up to 100 kg	0.5 mL/10 kg bodyweight				1. FASINEX 240 may be administered at the same time as animals are treated for lice. 2. FASINEX 240 may be administered to calves, pregnant cows or weak or debilitated animals. 3. Wash out equipment with water after use. 4. FASINEX 240 is palatable to cows. 5. Cattle in excess of 650 kg are to be dosed at the rate of 2.5 mL per 50 kg bodyweight. A representative sample of animals should be weighed before treatment either with scales or a weighband. Dose rate to be based on heaviest cattle in each group (bulls, cows, steers, calves, etc.). DO NOT underdose. Where there is a larger variation in size within the group, draft into two or more lines based on bodyweight, to avoid excessive overdosing.
101-150 kg	7.5	106	293	666	
151-200 kg	10	80	220	500	
201-250 kg	12.5	64	176	400	
251-300 kg	15	53	146	333	
301-400 kg	20	40	110	250	
401-500 kg	25	32	88	200	
501-600 kg	30	26	73	166	
601-650 kg	32.5	24	67	153	
Over 650 kg	2.5 mL/50 kg bodyweight				

**Precaution:** In areas where Black Disease is known to occur, adequate vaccination procedures are advised.

**WITHHOLDING PERIODS:**

**MEAT – DO NOT USE less than 21 days before slaughter for human consumption.**

**MILK - DO NOT USE in lactating cows where milk or milk products may be used for human consumption.**

**DO NOT USE less than 21 days before calving in cows where milk and milk products from treated cattle may be used for human consumption. Where FASINEX 240 is accidentally given within this period or should any cows calve earlier than 21 days after treatment, milk will contain residues. This milk must not be used for human consumption, or supplied for processing for at least 21 days following treatment. Calves fed this milk should not be slaughtered for human consumption within 10 days. Lambs or kids fed this milk should not be slaughtered for human consumption within 7 days.**

**Export Slaughter Interval: 56 days**

**Product name:** FASINEX® 240 Oral Flukicide for Cattle  
**Date of update:** 20 November 2003      **Page:** 3 of 9  
**Today's date:** 2 June, 2005      **Type of label:** Composite: Primary label and leaflet  
**Pack sizes:** 0.8, 2.2, 5, 10, 13, 15, 20 L      **Version:** 13  
**File:** FASINEX 240 JB1Jan04.doc      **Reason:** New promotional pack. Update addresses (JB)  
Text above this line is not included in the actual label.

---

## SAFETY DIRECTIONS

**Harmful if absorbed by skin contact or swallowed. Avoid contact with skin. Wash hands after use.**

## FIRST AID

**If poisoning occurs contact a doctor or Poisons Information Centre (Ph: 131126).**

**Material Safety Data Sheet:** If additional hazard information is required refer to the Material Safety Data Sheet. For a copy phone 1800 633 768.

## Protection of Livestock, Wildlife and Others

Dangerous to fish. DO NOT contaminate dams, rivers or streams with the drench or used container.

**Disposal:** Triple rinse containers before disposal and dispose of rinsate in a disposal pit away from desirable plants and their roots, and watercourses. On-site disposal of undiluted chemicals is unacceptable.

Destroy empty containers by breaking, crushing, puncturing or shredding them where applicable. Dispose of the containers at a local authority landfill that does not burn its refuse. If there is no local authority landfill readily available in your area, bury the containers at a depth of 500 mm or more at a licensed/approved disposal site. In some States wastes can only be buried at a licensed landfill. DO NOT burn empty containers or product.

**Storage:** Store below 30°C (Room Temperature) in original container, tightly closed, in a cool dry place. Protect from frost.

Batch Number	
Expiry Date	

APVMA Approval No. 51262/ [0L800/1203](#)

APVMA Approval No. 51262/ [2L200/1203](#)

APVMA Approval No. 51262/ [5L/1203](#)

® Registered trademark of Novartis AG, Basel, Switzerland

NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY LIMITED, ACN 076 745 198  
54 Waterloo Road, NORTH RYDE NSW 2113.

☎ NOVARTIS CUSTOMER ASSISTANCE 1800 633 768 TOLL FREE from anywhere in Australia 8:30 am to 5:30 pm E.S.T. Monday to Friday.

Product name: FASINEX® 240 Oral Flukicide for Cattle  
 Date of update: 20 November 2003 Page: 4 of 9  
 Today's date: 2 June, 2005 Type of label: Composite: Primary label and leaflet  
 Pack sizes: 0.8, 2.2, 5, 10, 13, 15, 20 L Version: 13  
 File: FASINEX 240 JB1Jan04.doc Reason: New promotional pack. Update addresses (JB)  
 Text above this line is not included in the actual label.

**Primary label (back panel - 10 L / 13 L / 15 L / 20 L )**

**FASINEX® 240 Oral Flukicide for Cattle**

**DIRECTIONS FOR USE  
 SHAKE WELL BEFORE USE**

**Restraints: DO NOT USE in lactating cows where milk or milk products may be used for human consumption.**

**ORAL DOSE RATE: CATTLE 2.5 mL per 50 kg BW**

Cattle weight	Oral dose (mL)	No. treated per pack				Critical comments
		10 L	13 L	15 L	20 L	
Up to 100 kg	0.5 mL/10 kg bodyweight					1. FASINEX 240 may be administered at the same time as animals are treated for lice. 2. FASINEX 240 may be administered to calves, pregnant cows or weak or debilitated animals. 3. Wash out equipment with water after use. 4. FASINEX 240 is palatable to cows. 5. Cattle in excess of 650 kg are to be dosed at the rate of 2.5 mL per 50 kg bodyweight. A representative sample of animals should be weighed before treatment either with scales or a weighband. Dose rate to be based on heaviest cattle in each group (bulls, cows, steers, calves, etc.). DO NOT underdose. Where there is a large variation in size within the group, draft into two or more lines based on bodyweight, to avoid excessive overdosing.
101-150 kg	7.5	1333	1733	2000	2666	
151-200 kg	10	1000	1300	1500	2000	
201-250 kg	12.5	800	1040	1200	1600	
251-300 kg	15	666	866	1000	1333	
301-400 kg	20	500	650	750	1000	
401-500 kg	25	400	520	600	800	
501-600 kg	30	333	433	500	666	
601-650 kg	32.5	307	400	461	615	
Over 650 kg	2.5 mL/50 kg bodyweight					

**Precaution:** In areas where Black Disease is known to occur, adequate vaccination procedures are advised.

**General Instructions:**

**SHAKE WELL BEFORE USE**

FASINEX 240 Oral Flukicide for Cattle is a ready to use, free flowing aqueous suspension for the treatment and control of acute and chronic fascioliasis of cattle.

FASINEX 240 contains triclabendazole, a member of the *benzimidazole* family of drenches. It is effective against triclabendazole sensitive strains of *Fasciola hepatica* (liver fluke).

Resistance may develop to any drench.

FASINEX 240 when used at the recommended rate of 12 mg triclabendazole/kg bodyweight for cattle, i.e. 2.5 mL FASINEX 240 per 50 kg bodyweight, is highly effective against susceptible early immature fluke as well as immature and adult fluke, and has a high safety margin.

Ask your local veterinary practitioner or animal health adviser for recommended parasite management practices for your area to reduce development of resistance. It is advisable that a drench resistance test be conducted before any drench is used.

Product name: FASINEX® 240 Oral Flukicide for Cattle  
Date of update: 20 November 2003 Page: 5 of 9  
Today's date: 2 June, 2005 Type of label: Composite: Primary label and leaflet  
Pack sizes: 0.8, 2.2, 5, 10, 13, 15, 20 L Version: 13  
File: FASINEX 240 JB1Jan04.doc Reason: New promotional pack. Update addresses (JB)  
Text above this line is not included in the actual label.

---

**WITHHOLDING PERIODS:**

**MEAT – DO NOT USE less than 21 days before slaughter for human consumption.**

**MILK - DO NOT USE in lactating cows where milk or milk products may be used for human consumption.**

**DO NOT USE less than 21 days before calving in cows where milk and milk products from treated cattle may be used for human consumption. Where FASINEX 240 is accidentally given within this period or should any cows calve earlier than 21 days after treatment, milk will contain residues. This milk must not be used for human consumption, or supplied for processing for at least 21 days following treatment. Calves fed this milk should not be slaughtered for human consumption within 10 days. Lambs or kids fed this milk should not be slaughtered for human consumption within 7 days.**

**Export Slaughter Interval: 56 days**

**SAFETY DIRECTIONS**

**Harmful if absorbed by skin contact or swallowed. Avoid contact with skin. Wash hands after use.**

**FIRST AID**

**If poisoning occurs contact a doctor or Poisons Information Centre (Ph: 131126).**

**Material Safety Data Sheet:** If additional hazard information is required refer to the Material Safety Data Sheet. For a copy phone 1800 633 768.

**Protection of Livestock, Wildlife and Others**

**Dangerous to fish. DO NOT contaminate dams, rivers or streams with the drench or used container.**

**Disposal:** Triple rinse containers before disposal and dispose of rinsate in a disposal pit away from desirable plants and their roots, and watercourses. On-site disposal of undiluted chemicals is unacceptable.

Destroy empty containers by breaking, crushing, puncturing or shredding them where applicable. Dispose of the containers at a local authority landfill that does not burn its refuse. If there is no local authority landfill readily available in your area, bury the containers at a depth of 500 mm or more at a licensed/approved disposal site. In some States wastes can only be buried at a licensed landfill. DO NOT burn empty containers or product.

**Storage:** Store below 30°C (Room Temperature) in original container, tightly closed, in a cool dry place. Protect from frost.

Batch Number	
Expiry Date	

APVMA Approval No. 51262/[10L/1203](#)

APVMA Approval No. 51262/[13L/1203](#)

APVMA Approval No. 51262/[15L/1203](#)

APVMA Approval No. 51262/[20L/1203](#)

® Registered trademark of Novartis AG, Basel, Switzerland

NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY LIMITED, ACN 076 745 198  
54 Waterloo Road NORTH RYDE NSW 2113

**Product name:** FASINEX<sup>®</sup> 240 Oral Flukicide for Cattle

**Date of update:** 20 November 2003      **Page:** 6 of 9

**Today's date:** 2 June, 2005

**Type of label:** Composite: Primary label and leaflet


**Pack sizes:** 0.8, 2.2, 5, 10, 13, 15, 20 L      **Version:** 13

**File:** FASINEX 240 JB1Jan04.doc

**Reason:** New promotional pack. Update addresses (JB)

Text above this line is not included in the actual label.

---

 NOVARTIS CUSTOMER ASSISTANCE 1800 633 768 TOLL FREE from anywhere in Australia 8:30 am to 5:30 pm E.S.T. Monday to Friday.

Product name: FASINEX<sup>®</sup> 240 Oral Flukicide for Cattle  
Date of update: 20 November 2003      Page: 7 of 9  
Today's date: 2 June, 2005      Type of label: Composite: Primary label and leaflet  
Pack sizes: 0.8, 2.2, 5, 10, 13, 15, 20 L      Version: 13  
File: FASINEX 240 JB1Jan04.doc      Reason: New promotional pack. Update addresses (JB)  
Text above this line is not included in the actual label.

---

**Leaflet (0.8 L, 2.2 L and 5 L sizes only - 10L, 13 L, 15 L and 20 L packs do not have a leaflet)**

**POISON  
KEEP OUT OF REACH OF CHILDREN  
READ SAFETY DIRECTIONS BEFORE OPENING OR USING  
FOR ANIMAL TREATMENT ONLY**

## **FASINEX<sup>®</sup> 240 Oral Flukicide for Cattle**

Active Constituent: 240 g/L TRICLABENDAZOLE

Complete directions for use inside - read before using

**For the treatment of triclabendazole-susceptible Early Immature, Immature and Mature liver fluke (*Fasciola hepatica*) in cattle.**

**General Instructions:  
SHAKE WELL BEFORE USE**

**Precaution:** In areas where Black Disease is known to occur, adequate vaccination procedures are advised.

FASINEX 240 Oral Flukicide for Cattle is a ready to use, free flowing aqueous suspension for the treatment and control of acute and chronic fascioliasis of cattle.  
FASINEX 240 contains triclabendazole, a member of the *benzimidazole* family of drenches. It is effective against triclabendazole sensitive strains of *Fasciola hepatica* (liver fluke).  
Resistance may develop to any drench.  
FASINEX 240 when used at the recommended rate of 12 mg triclabendazole/kg bodyweight for cattle, i.e. 2.5 mL FASINEX 240 per 50 kg bodyweight, is highly effective against susceptible early immature fluke as well as immature and adult fluke, and has a high safety margin.  
Ask your local veterinary practitioner or animal health adviser for recommended parasite management practices for your area to reduce development of resistance. It is advisable that a drench resistance test be conducted before any drench is used.

### **WITHHOLDING PERIODS**

**MEAT - DO NOT USE less than 21 days before slaughter for human consumption.**

**MILK - DO NOT USE in lactating cows where milk or milk products may be used for human consumption.**

**DO NOT USE less than 21 days before calving in cows where milk and milk products from treated cattle may be used for human consumption. Where FASINEX 240 is accidentally given within this period or should any cows calve earlier than 21 days after treatment, milk will contain residues. This milk must not be used for human consumption, or supplied for processing for at least 21 days following treatment. Calves fed this milk should not be slaughtered for human consumption within 10 days. Lambs or kids fed this milk should not be slaughtered for human consumption within 7 days.**

**Export Slaughter Interval: 56 days**

**Product name:** FASINEX® 240 Oral Flukicide for Cattle  
**Date of update:** 20 November 2003      **Page:** 8 of 9  
**Today's date:** 2 June, 2005      **Type of label:** Composite: Primary label and leaflet  
**Pack sizes:** 0.8, 2.2, 5, 10, 13, 15, 20 L      **Version:** 13  
**File:** FASINEX 240 JB1Jan04.doc      **Reason:** New promotional pack. Update addresses (JB)  
Text above this line is not included in the actual label.

---

## **SAFETY DIRECTIONS**

**Harmful if absorbed by skin contact or swallowed. Avoid contact with skin. Wash hands after use.**

## **FIRST AID**

**If poisoning occurs contact a doctor or Poisons Information Centre (Ph: 13 1126).**

**Material Safety Data Sheet:** If additional hazard information is required refer to the Material Safety Data Sheet. For a copy phone 1800 633 768.

## **Protection of Livestock, Wildlife and Others**

Dangerous to fish. DO NOT contaminate dams, rivers or streams with the drench or used container.

**Disposal:** Triple rinse containers before disposal and dispose of rinsate in a disposal pit away from desirable plants and their roots, and watercourses. On-site disposal of undiluted chemicals is unacceptable.

Destroy empty containers by breaking, crushing, puncturing or shredding them where applicable.

Dispose of the containers at a local authority landfill that does not burn its refuse. If there is no local authority landfill readily available in your area, bury the containers at a depth of 500 mm or more at a licensed/approved disposal site. In some States wastes can only be buried at a licensed landfill. DO NOT burn empty containers or product.

**Storage:** Store below 30°C (Room Temperature) in original container, tightly closed, in a cool dry place. Protect from frost.

## **WARRANTY AND EXCLUSION OF LIABILITY**

This product is warranted fit for the purposes specifically recommended by Novartis Animal Health Australasia Pty Limited when used strictly as directed in this leaflet. All other warranties and obligations or liabilities, whether expressed or implied by statute or otherwise, are excluded to the full extent that exclusion is permitted by law.

APVMA Approval No. 51262/1203

® Registered trademark of Novartis AG, Basel, Switzerland

Novartis Animal Health Australasia Pty Limited, ACN 076 745 198,  
54 Waterloo Road, NORTH RYDE NSW 2113

Product name: FASINEX® 240 Oral Flukicide for Cattle

Date of update: 20 November 2003 Page: 9 of 9

Today's date: 2 June, 2005

Type of label: Composite: Primary label and leaflet

Pack sizes: 0.8, 2.2, 5, 10, 13, 15, 20 L Version: 13

File: FASINEX 240 JB1Jan04.doc

Reason: New promotional pack. Update addresses (JB)

Text above this line is not included in the actual label.

### Directions for Use

**Restraints: DO NOT USE in lactating cows where milk or milk products may be used for human consumption.**

Parasite Controlled	Bodyweight (BW) kg	Oral Dose (mL)	No. treated per litre	Critical Comments
<b>Liver Fluke</b>	<b>Cattle</b>			
<i>(Fasciola hepatica)</i>  Early Immature, Immature and Mature	Up to 100	0.5 mL/10 kg liveweight		
	101-150	7.5	133	
	151-200	10	100	
	201-250	12.5	80	
	251-300	15	66	
	301-400	20	50	
	401-500	25	40	
	501-600	30	33	
	601-650	32.5	30	
	Over 650	2.5 mL/50 kg liveweight		
				<ol style="list-style-type: none"><li>1. FASINEX 240 may be administered at the same time as animals are treated for lice.</li><li>2. FASINEX 240 may be administered to calves, pregnant cows or weak or debilitated animals.</li><li>3. Wash out equipment with water after use.</li><li>4. FASINEX 240 is palatable to cattle.</li><li>5. Cattle in excess of 650 kg should be dosed at 2.5 mL per 50 kg. A representative sample of animals should be weighed before treatment either with scales or a weighband. Dose rate to be based on heaviest cattle in each group (bulls, cows, steers, calves, etc.). DO NOT underdose. Where there is a large variation in size within the group, draft into two or more lines based on bodyweight, to avoid excessive overdosing.</li></ol>