



## LABELLING STANDARD

### ANTHELMINTICS

I) **Description:**

This Labelling Standard applies to those single ingredient products intended to be taken by mouth in the form of capsules, tablets, oral suspension or reconstituted powder for the treatment of pinworm infection (enterobiasis or oxyuriasis).

As roundworm and other helminthic infections are not considered to be self-diagnosable conditions and often require medical intervention, they have not been included in this labelling standard.

II) **Pharmaceutical Quality:**

a) All ingredient (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B to the Food and Drugs Act, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:**

- i) Pharmacopoeial standards (Schedule B) for formulated single ingredient anthelmintic preparations are shown in Appendix I. Note that this list is intended only as a guide and is not necessarily current or all inclusive.
- ii) Finished product specifications should include tests for identification and an assay with suitable limits for the medicinal ingredient(s) including its components. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing e.g., pH, specific gravity, viscosity, appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. Antimicrobial preservative effectiveness should be determined in order to establish that the product is capable of resisting microbial contamination.

III) **Ingredients:**

a) **Single Medicinal ingredients:**

**Ingredient**

Pyrantel Pamoate

(Note: 2.9 g of pyrantel pamoate is equal to 1 gram of base (pyrantel).)

Piperazine\* hexahydrate

(100mg piperazine hydrate is equivalent to 120mg piperazine adipate, 125mg piperazine citrate and 104mg piperazine phosphate).

Pyrvinium Pamoate

(Note: 1.5 g of pyrvinium pamoate is equal to 1 gram of base (pyrvinium).)

\*Available in different salts - adipate, citrate or phosphate

b) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients should be restricted to those substances, necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the bioavailability, therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives.

IV) **Labelling:**

a) This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the *Regulations to the Food and Drugs Act* and in the *Guide for the Labelling of Drugs for Human Use* must also be met.

b) **Directions for Use:**

i) **Indications**

For the treatment of pinworm infection (Enterobiasis, oxyuriasis). Pinworm is also commonly known as seatworm. This may be mentioned on the label secondarily, provided the primary condition of pinworm infection is stated on the label.

ii) **Unacceptable Claims:**

Reference to any other type of helminth infection.

iii) **Dosage Directions:**

a) **Pyrantel Pamoate:**

Dosages should be indicated on the label according to weight of patient and in terms of the appropriate dosage unit (tablets, teaspoon, ml. etc.). A suitable dosage chart (similar to the one below) should be provided on the label.

1. Weight of Person	2. Reference Dose (Optional)	3. Product Dose
Adults and Children > 2 (12 kg)	11mg/kg base (31.9 mg/kg Pyrantel Pamoate)	required dosage units (tablet, teaspoonful, ml, etc.)
12-23 kg (26-51 lb.)	132-253 mg base (383-734mg Pyrantel Pamoate)	Liquid: x to y ml (dropperful, teaspoonful, etc) Solid: x to y tablets, caplets, packets,etc
24-45 kg (53-99 lb)	264-495 mg base (766-1436mg Pyrantel Pamoate)	Liquid: x to y ml (dropperful, teaspoonful, etc) Solid: x to y tablets, caplets, packets,etc
46-68 kg (101-150 lb.)	506-748 mg base (1467-2169mg Pyrantel Pamoate)	Liquid: x to y ml (dropperful, teaspoonful, etc) Solid: x to y tablets, caplets, packets,etc
69-90 kg (152-198 lb.)	759-990 mg base (2201-2871mg Pyrantel Pamoate)	Liquid: x to y ml (dropperful, teaspoonful, etc) Solid: x to y tablets, caplets, packets,etc
> 90 kg (198 lb.)	Max 1 gram base (2.9g Pyrantel Pamoate)	Liquid: x ml (dropperful, teaspoonful, etc) Solid: x tablets, caplets, packets, etc

For liquids and powders involving a low volume, a calibrated measuring device capable of delivering the required dose must be included in the package and referred to in the instructions.

Take as a single dose.

Dose may be repeated in 2 weeks (range of 10 days - 3 weeks) if symptoms persist following the initial treatment.

Children less than 2 years or weighing less than 12kg: Consult a doctor.

**b) Piperazine:**

Note: All salts (adipate, citrate and phosphate) form piperazine hexahydrate (hydrate) in solution and are equally effective.

dosages should be indicated on the label according to weight of patient and in terms of the appropriate dosage unit

(tablets, teaspoon, ml. etc.). A suitable dosage chart for the particular piperazine salt (similar to "B" below) should be provided on the label.

A) Reference dosage chart (mg amounts) for piperazine (optional)

	Piperazine hydrate	Piperazine adipate*	Piperazine citrate*	Piperazine Phosphate*
<b>&gt;2 years</b>	65mg/kg max 2.5g	78mg/kg max 3g	81.25mg/kg max 3.125g	67.6mg/kg max 2.6g
13.5-27.5 kg (30-61 lb.)	878-1788mg	1053-2145mg	1097-2234mg	913-1859mg
27.5-38.5 kg (61-85 lb.)	1788-2500 mg	1053-3000 mg	2234-3125 mg	1622-2600 mg
>38.5kg (> 85lb)	Maximum 2500 mg	Maximum 3000 mg	Maximum 3125 mg	Maximum 2600 mg

\*100mg piperazine hydrate is equivalent to 120mg piperazine adipate, 125mg piperazine citrate and 104mg piperazine phosphate.

B)

1. Weight of Person	2. Product Dose
> 2 years	required dosage units (tablet, teaspoonfull, ml, etc) depending on salt used
13.5-27.5 kg (30-61 lb.)	Liquid: x to y ml (dropperful, teaspoonful, etc)  Solid: x to y tablets, caplets, packets, et
27.5-38.5 kg (61-85 lb.)	Liquid: x to y ml (dropperful, teaspoonful, etc)  Solid: x to y tablets, caplets, packets, et
>38.5kg (> 85lb)	Liquid: x ml (dropperful, teaspoonful, etc)  Solid: x tablets, caplets, packets, et

For liquids and powders involving a low volume, a calibrated measuring device capable of delivering the required dose must be included in the package and referred to in the instructions.

Taken daily (single or divided doses) for 7 consecutive days followed by retreatment in 2 weeks (7 days after completion of last dose).

Children less than 2 years or weighing less than 13.5kg: Consult a doctor.

Piperazine is best taken on an empty stomach.

**c) Pyrvinium Pamoate:**

dosages should be indicated on the label according to weight of the patient and in terms of the appropriate dosage unit (tablets, teaspoon, ml. etc.). A suitable dosage chart (similar to the one below) should be provided on the label.

<b>1. Weight of Person</b>	<b>2. Reference Dose (Optional)</b>	<b>3. Product Dose</b>
Adults and Children > 2	5mg/kg base (7.5 mg/kg Pyrvinium Pamoate)	required dosage units (tablet, teaspoonful, ml, etc.)
10-20 kg (22-44 lb.)	50-100 mg base (75-150mg Pyrvinium Pamoate)	Liquid: x to y ml (dropperful, teaspoonful, etc)  Solid: x to y tablets, caplets, packets, etc
20-40 kg (44-88 lb.)	100-200mg base (150-300 mg Pyrvinium Pamoate)	Liquid: x to y ml (dropperful, teaspoonful, etc)  Solid: x to y tablets, caplets, packets, et
40-50 kg (88-110 lb.)	200-250 mg base (300-375 mg Pyrvinium Pamoate)	Liquid: x to y ml (dropperful, teaspoonful, etc)  Solid: x to y tablets, caplets, packets, et
50-70kg (110-154 lb)	250-350 mg base (375-525 mg Pyrvinium Pamoate)	Liquid: x ml (dropperful, teaspoonful, etc)  Solid: x tablets, caplets, packets, et
over 70kg (> 154lb)	Max 350mg base (525mg Pyrvinium Pamoate)	Liquid: x ml (dropperful, teaspoonful, etc)  Solid: x tablets, caplets, packets, et

For liquids and powders involving a low volume, a calibrated measuring device capable of delivering the required dose must be included in the package and referred to in the instructions.

Taken as a single dose.

Retreatment after 2 weeks (range 10 to 14 days) is recommended.

Children under 2 years or weighing less than 10 kg: consult a doctor

**All Ingredients:**

- i) Take only according to directions and do not exceed recommended dosage unless directed by a physician;
- ii) When one member of the household has pinworms, the entire household should be treated, unless otherwise

advised by a physician;

- iii) Consult a physician if symptoms are still present after a second treatment;
- iv) This product can be taken any time of day. Use of a laxative is not necessary prior to, during, or after medication.
- v) A discussion of the symptoms suggestive of pinworm infestation (eg. irritating itching and scratching in the perianal and perineal regions) including a statement that pinworms must be visually identified before taking this medication;
- vi) A detailed description of how to find and identify the pinworm; Although exact wording is not specified, the following points should be made:

- Diagnosis must be made before taking the medication. For confirmed diagnosis, the adult worms or eggs must be observed.

- Female adult worms are about 1/3 of an inch (10mm) long and look like little pieces of white thread. Examination of the child's anal site at night (1 hour after bedtime) with a flashlight may show worms crawling from the anus.

**OR**

- Swab the perianal region with a strip of cellulose tape for examination of the eggs under a microscope by a doctor.

- vii) A commentary on the life cycle of the pinworm; Although exact wording is not specified, the following points should be made:

- Ingestion of the eggs starts the cycle which results in the mature worm working its way out through the anus during the night to deposit worm eggs on the skin.

- Ingestion of these eggs repeats the cycle

- viii) A commentary on the ways in which pinworms may be spread from person to person and hygienic procedures to follow to avoid such spreading; Although exact wording is not specified, the following points should be made:

- Pinworm infection starts when children swallow worm eggs that have been picked up from sources such as shared play items, school toilet seats, family pets, soil or food that has been handled by soiled hands

- Even with treatment, re-infection and the passing of the problem from one family member to another can occur if the eggs are not completely eradicated from all areas.

■Particular attention should be paid to personal hygiene and household cleanliness (bedroom, bathrooms and laundry.

■Keep children`s nails cut and scrubbed;

■Be sure that children know they should wash their hands regularly, particularly before meals and after toilet use;

■Wash all clothing, towels, and linen that have come into family contact since the problem was discovered;

V) **Warnings:**

**a) Pyrantel Pamoate**

- i) Abdominal cramps, nausea, vomiting, diarrhoea, headache or dizziness sometimes occurs after taking this drug. If any of these conditions persist, consult a doctor;
- ii) If you are pregnant or have liver disease, do not take this product unless directed by a physician;
- iii) Consult a doctor before the use of other pinworm medications (eg. piperazine)at the same time.

**b) Piperazine**

- i) Abdominal cramps, nausea, vomiting, diarrhoea, headache,dizziness and rash sometimes occurs after taking this drug. If any of these conditions persist, consult a physician;
- ii) Consult a physician before use in any of the following situations: pregnancy or breast feeding, liver disease, renal impairment, epilepsy, severe malnutrition or anemia.
- iii) Consult a doctor before the use of other pinworm medications (eg. pyrantel)at the same time.

**c) Pyrvinium Pamoate**

- i) Abdominal cramps, nausea and vomiting sometimes occurs after taking this drug. If any of these conditions persist, consult a physician;
- ii) This medication will colour stools red for 24-48 hours. Pyrvinium may also stain clothing red. If vomiting occurs, the vomit will be red in colour.

Note: If there is insufficient space on the label, warning statements/directions may be placed on a package insert provided there is a statement on the label which instructs the consumer to consult the package insert before use for complete user instructions.

created: May 17, 1996

## REFERENCES

1. **United States Federal Register**, Vol. 51, No. 148, 1986, pp. 27756-27760, Anthelmintic Drug Products for Over-the-Counter Human Use; Final Monograph.
2. **United States Federal Register**, Vol. 47, No. 164, 1982, pp. 37062-37066, Anthelmintic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph.
3. **Self Medication**, 4th Edition, Canadian Pharmaceutical Association, 1992.
4. **Remington's Pharmaceutical Sciences**, 17th Edition, Mack Publishing Co., 1985.
5. **American Handbook of Nonprescription Drugs**, 9th Edition, American Pharmaceutical Association, 1990.
6. **United States Pharmacopoeia Dispensing Information**, USPDI II, Advice for the Patient, 12th Edition, 1992.
7. **Martindale, The Extra Pharmacopoeia**, 29th Edition, Philadelphia College of Pharmaceutical Sciences, 1990.
8. **Canadian Drug Identification Code Book**, 18th Edition, Health and Welfare Canada, 1992.
9. **Drug Evaluations Annual 1992**, 7th Edition, American Medical Association, 1992.
10. **Drug Facts and Comparisons**, 1989 Edition, Facts and Comparisons, St. Louis, 1989.
11. **Goodman and Gilman`s The Extra Pharmacological Basis of Therapeutics**, 8th ed., Pergamon Press, 1990
12. **American Hospital Formulary Service**, Drug Information 1992

**Appendix I**  
**Single Ingredient Preparations**

<b>FORMULATED PROPER NAME</b>	<b>U.S.P.23 (1995)</b>	<b>B.P. (1993)</b>	<b>B.P.C.* (1973)</b>
Pyrantel Pamoate oral suspension	X		
Piperazine Adipate Tablets			X
Piperazine Citrate Elixir		X	X
Piperazine Citrate Oral Solution		X	
Piperazine Citrate Syrup	X		
Piperazine Citrate Tablets	X		
Piperazine Phosphate Tablets		X	X
Pyrvinium Pamoate Oral Suspension	X		
Pyrvinium Pamoate Tablets	X		

\*Presently called "The Pharmaceutical Codex" (11th edition, 1979, 12th edition, 1994)