Approved: 30.06.2014
Revised: 06.01.2020

Statens legemiddelverk

OTC use in Norway for pyrvinium embonate, ATC-code: P02CX01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing pyrvinium embonate. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing pyrvinium embonate. In addition, an overview of the approvable strength(s), pharmaceutical form(s) and pack size(s) exempt from medical prescription in Norway is included.

- The proposed OTC indication and posology in the OTC package leaflet and labelling must be covered by the information approved in the corresponding SmPC.

Preparations for oral use, up to 10 mg/ml or 50 mg per unit

1. Package leaflet

1.1 Indication

Voksne og barn over 1 år (10 kg): behandling av småmark.

1.2 Posology

Change the quantity from the given strength to the number of entities to be taken (e.g. 1-2 tablets, 1 suppository, 20 ml…).

Voksne og barn over 1 år (10 kg): 50 mg pr. 10 kg kroppsvekt som engangsdose. Hele husstanden behandles. Behandlingen gjentas etter 14 dager.

Dosage example:

Alder	Vekt i kg	Antall doseringsskjeer (5ml) mikstur eller tabletter (50 mg) gitt som engangsdose
1 år	10	1
6 år	20	2
10 år	30	3
13 år	40	4
Eldre barn	50	5
Voksne	60	6
	70	7

2. Labelling

2.1 Indication

State the indication as in the PIL.

2.2 Posology

State the dosage as in the PIL. However, the abbreviation below can be used.

Tablet
1 tablett per 10 kg kroppsvekt som engangsdose til alle i husstanden. Gjenta etter 2 uker.

Oral suspension
5 ml per 10 kg kroppsvekt som engangsdose til alle i husstanden. Gjenta etter 2 uker.

2.3 Other information

Pyrvinium farger avføringen og evt. oppkast rødt.

Tablet/capsule
Bør ikke tygges, da de kan misfarge tenner og munnhule.

3. Content of the pack

The table below presents the highest level of the terms for approvable pharmaceutical forms, if possible. For example: the term "tablets" includes all types of tablet formulations as for example film coated tablets or chewable tablets. For active substances where some pharmaceutical forms are exempt from approval due to safety concern, this is stated explicitly below the table.

Pharmaceutical form	**Maximum strength**	**Maximum pack size**
Tablets, capsules, oral suspension in sachet	50 mg	32
Oral suspension	10 mg/ml	30 ml