SUMMARY OF PRODUCT CHARACTERISTICS

1- NAME OF THE MEDICINAL PRODUCT

Helmintox 125 mg, scored film-coated tablet

2- QUALITATIVE AND QUANTITATIVE COMPOSITION

PYRANTEL EMBONATE .....360.50 mg
quantity corresponding to pyrantel base .....125.00 mg

For a scored film-coated tablet

Excipient: sunset yellow FCF (E110)

For a full list of excipients, see section 6.1.

3- PHARMACEUTICAL FORM

Scored film-coated tablet.

4 - CLINICAL PARTICULARS

4.1 Therapeutic indications

- Oxyuriasis
- Ascariasis
- Ancylostomiasis

4.2 Posology and method of administration

Oral route.

FOR ADULT AND CHILDREN ABOVE 6 YEARS ONLY.

For children less than 6 years, use the oral suspension which is more adapted.

The drug can be taken at any time and neither empty stomach nor purging is required before intake.

Oxyuriasis and ascariasis

The usual posology is 10 mg/kg to 12 mg/kg as a single dose i.e.:

- Children : 1 tablet per 10 kg as a single dose
- Adults under 75 kg: 6 tablets as a single dose.
- Adults over 75 kg: 8 tablets as a single dose.

For oxyuriasis, to eradicate the parasites completely, strict hygiene measures must be implemented and the whole family treated. To avoid self-reinfestation, a second dose has to be taken 3 weeks after the first one.

Ancylostomiasis

In endemic areas, in the event of *Necator americanus* infestation, or severe *Ankylostoma duodenale* infestation, the posology is 20 mg/kg/day (in 1 or 2 administrations) for 2 to 3 days, i.e.:

- Children: 2 tablets per 10 kg, per day.
- Adults under 75 kg: 12 tablets per day.
- Adults over 75 kg: 16 tablets per day.

In the event of mild *Ankylostoma duodenale* infestation (which is usually the case in non-endemic areas), a 10 mg/kg as a single dose may be enough.

4.3 Contraindications

Hypersensitivity to one of its components.

4.4 Special warnings and precautions for use

In the event of hepatic insufficiency, reduce the doses.

Oxyuriasis: to prevent reinfestation, strict hygiene measures must be implemented by the treated subjects: washing the anal region every day, brushing the nails several times a day. Cut childrens' nails short. Change underwear and pyjamas regularly. Prevent the subject from scratching himself. Treat all members of the family simultaneously because infestation is frequently asymptomatic.

This medicinal product contains an azo colouring agent, sunset yellow FCF (E110) and can induce allergic reactions.

4.5 Interactions with other medicinal products and other forms of interactions

Not relevant.

4.6 Pregnancy and lactation

Pregnancy
Due to the lack of teratogenic effect in animals, a malformative effect in humans is not expected. To date, substances responsible for malformations in humans have been shown to be teratogenic in animals through well-conducted studies performed on 2 species. Clinically, to date no malformative or foetotoxic effect has been reported. Nevertheless, monitoring pregnancies under pyrantel is not enough to exclude all risk. Therefore, this drug will be used only if strictly necessary during pregnancy.

Lactation
Due to the lack of study, it should not be used during breast-feeding except if strictly necessary.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

- Rarely: gastrointestinal disorders (anorexia, nausea, vomiting, abdominal pain, diarrhoea), low and temporary increase of transaminases.
- Exceptionally: headache, dizziness, asthenia, skin rash, sleep disorders.

4.9 Overdose

Because of its slight absorption rate, the plasmatic concentrations are low. An overdose, even important, brings about some low digestive disorders and some low transitory disorders of the central nervous system (asthenia, dizziness, headache). Sometimes, overdose brings about an increase of the hepatic transaminases (ASAT). We do not know any

specific antidote. An early gastric wash is recommended, and also the monitoring of the respiratory and cardiovascular functions.

5- PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classs:

ANTHELMINTIC

(P: parasitology)

Pyrantel is an anthelmintic. It is active on *Enterobius vermicularis*, *Ascaris lumbricoïdes*, *Ankylostoma duodenale* and *Necator americanus*. The pyrantel acts by neuromuscular blocking, paralysing the helminths so that they can be evacuated in the faeces by peristalsis. The pyrantel acts against the sensitive mature and immature forms. Worms's larvae migrating through the tissues are not affected.

5.2 Pharmacokinetic properties

Intestinal resorption is very low. After oral administration, plasma levels of pyrantel are very low (0.05 – 0.13 µg/ml) and are reached in 1 to 3 hours. More than 50% of the product is excreted in unchanged form in the faeces. Less than 7% are found in urine in unchanged form and in metabolised form. The product does not colour the faeces in red.

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised starch, povidone, croscarmellose sodium, magnesium stearate, SEPIFILM 002*, SEPISPERSE AP3065 yellow**.

* Composition of SEPIFILM 002: hypromellose, microcrystalline cellulose, macrogol 400 monostearate.

**Composition of SEPISPERSE AP3065 yellow: propylene glycol, hypromellose, titanium dioxide, sunset yellow FCF (E110) aluminium lake.

6.2 Incompatibilities

Not relevant.

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

Store below 30 °C.

6.5 Nature and contents of container

Blister (PVC/Aluminium) of 6 tablets.

6.6 Special precautions for disposal

No special requirements.

7- MARKETING AUTHORIZATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22, avenue Aristide Briand
94110 Arcueil
FRANCE

8 - MARKETING AUTHORIZATION NUMBER

03934/5175/NMR/2017

9- DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Jul 12, 2019

10 - DATE OF REVISION OF THE TEXT

April 24th, 2017.

11. DOSIMETRY

Not relevant.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not relevant.