ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

HELMINTOX 250 mg, scored film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Pyrantel embonate .....721.00 mg
Quantity corresponding to pyrantel base .....250.00 mg
For a scored film-coated tablet.

Excipient with known effect: sunset yellow FCF (E110).
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Scored film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

HELMINTOX 250 mg, scored film-coated tablet is indicated in adults and children above 6 years old only.

- Oxyuriasis,
- Ascariasis,
- Ancylostomiasis.

4.2 Posology and method of administration

FOR ADULT AND CHILDREN ABOVE 6 YEARS ONLY.
For children less than 6 years, it exists pharmaceutical forms more adapted.

Posology

Oxyuriasis and ascariasis
The usual posology is 10 mg/kg to 12 mg/kg as a single dose i.e.:
- children: 1 tablet per 20 kg as a single dose
- adults under 75 kg: 3 tablets as a single dose
- adults over 75 kg: 4 tablets as a single dose

For oxyuriasis, in order to obtain permanent parasite eradication, use strict hygiene measures and also treat members of the family. In order to avoid reinfestation, a second dose should 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: 1 tablet per 10 kg per day
- adults under 75 kg: 6 tablets per day

- adults over 75 kg: 8 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.

Method of administration
Oral route.
The dose can be absorbed at any time and neither purging nor empty stomach is required before intake.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

In case of hepatic impairment, reduce the doses.

Oxyuriasis: to prevent reinfestation, strict hygiene measures must be implemented in 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 medicine contains an azo colouring agent, sunset yellow FCF (E110) and can induce allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Current available data does not show evidence of clinically significant interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy
Given that there are no teratogenic effects in animals, malformations are not expected in humans. To date, substances responsible for malformations in humans have always shown teratogenic effects in animals in rigorous studies in both species. In clinical studies, no deformation or foetotoxic effects have been observed to date. However, monitoring pregnancies where pyrantel is taken is insufficient to exclude all risks. Therefore, this medicine will be used only if strictly necessary during pregnancy.

Breast-feeding
In the absence of studies, avoid while breast-feeding unless absolutely 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: headaches, dizziness, asthaenia, skin rash, sleep disorders.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

Agence nationale de sécurité du médicament et des produits de santé (ANSM - French Health Products Safety Agency) and Regional Pharmacovigilance Centers - Website: www.ansm.sante.fr.

4.9 Overdose

Due to its weak absorption rate, plasma concentrations are not very high. Even a significant overdose generally only leads to some digestive disorders and some slight and transitory central nervous system disorders (fatigue, dizziness, headaches) and possible increase of hepatic transaminases (ASAT). There is no known specific antidote. Early gastric lavage is recommended as well as monitoring of respiratory and cardiovascular functions.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ANTIHELMINTIC, ATC code: P02CC01.

Mechanism of action
Pyrantel is an antihelmintic. It is active on *Enterobius vermicularis*, *Ascaris lumbricoides*, *Ankylostoma duodenale* and *Necator americanus*. Pyrantel acts as a neuromuscular blocking agent, paralysing helminthes and allowing their expulsion in faecal stream, by peristalsis. Pyrantel is active on both the mature and immature forms of sensitive helminthes. Worm larvae migrating in the tissues are not affected.

5.2 Pharmacokinetic properties

Digestive resorption is very low. After oral administration, the pyrantel plasma levels are minimal (0.05–0.13 µg/mL) and achieved within 1 to 3 hours. More than 50% of the product is excreted unchanged in stools. Less than 7% is eliminated in urine unchanged and in the form of metabolites. The product does not produce red stools.

5.3 Preclinical safety data

Not documented.

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 aluminium lacquer (E110).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister (PVC/Aluminium) of 3 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

8. MARKETING AUTHORISATION NUMBER(S)

- 34009 330 563 9 1: 3 tablets in blister (PVC/Aluminium).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 March 1988
Date of latest renewal: 21 March 2013

10. DATE OF REVISION OF THE TEXT

15 November 2018

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY
Medicinal product not subject to medical prescription.