Summary of Product Characteristics

1. Name of the medicinal product
DETRAX
(Levamisole Hydrochloride Tablets USP)

2. Qualitative and quantitative composition
Each film coated tablet contains
Levamisole…….40 mg
(As Levamisole Hydrochloride USP 47.2 mg)

For a full list of excipients, see section 6.1

3. Pharmaceutical form
Tablet

4. Clinical particulars
4.1 Therapeutic indications
For the treatment of ascariasis and mixed ascariasis/hookworm infections.

4.2 Posology and method of administration
Adults and children: a single dose of 2.5 mg/kg is used widely for both individual treatment and community-based campaigns. In cases of severe hookworm infection, a second standard dose may be given 7 days after the first.

4.3 Contraindications
Pre-existing blood disorders; pregnancy and lactation; rheumatoid arthritis; severe renal impairment.

4.4 Special warnings and precautions for use
Hepatic impairment, Epilepsy. Sjögren's syndrome.

4.5 Interaction with other medicinal products and other forms of interaction
May increase toxicity of phenytoin. Increases bioavailability of ivermectin; decreases bioavailability of albendazole. Alcohol causes disulfiram-like reaction.

4.6 Fertility, pregnancy and breastfeeding
Embryotoxic in animal studies. Levamisole should be avoided during pregnancy and lactation.

4.7 Effects on ability to drive and use machines
No specific information available on effects on levamisole on ability to drive and use machines.

4.8 Undesirable effects
Nausea, vomiting, diarrhoea, abdominal pain, dizziness and headache, fever, influenza-like syndrome, arthralgia, muscle pain, rash, taste disturbances and cutaneous vasculitis, convulsions, insomnia, seizure (long term use).
Potentially Fatal: Agranulocytosis, leucopenia, thrombocytopenia

4.9 Overdose
Emesis or gastric lavage may be of value if undertaken within a few hours of ingestion. Treatment is otherwise symptomatic and supportive.

5. Pharmaceutical properties

5.1 Pharmacodynamic properties

Levamisole, the (-)-isomer of tetramisole, acts by paralysing the musculature of susceptible nematodes. Unable to maintain their anchorage, the worms are ejected by normal peristaltic action, usually within 24 hours.

5.2 Pharmacokinetic properties

Levamisole is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations occur within 2 hours and the plasma half-life is about 4 hours. It is extensively metabolized in the liver and is excreted in the urine as metabolites and unchanged drug.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the Summary of Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Maize Starch BP
Dibasic Calcium Phosphate BP
Sodium Methyl Hydroxybenzoate BP
Purified Talc BP
Magnesium Stearate BP
Opadry Red II85G55186
Purified Water BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store in cool, dry place. Protect from light.

6.5 Nature and content of container

- Blister pack of 20 x 3's packed in a carton along with leaflet.
- Jar of 500 Tablets.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing Authorization Holder

UNIQUE PHARMACEUTICAL LABORATORIES
(A Division of J. B. Chemicals & Pharmaceuticals Ltd.)
Neelam center, B Wing, 4th floor, Hind cycle road,
Worli, Mumbai 400 030, INDIA

8. Marketing Authorization Number

06009/07741/REN/2020

9. Date of First Authorization/Renewal of the Authorization
Date of First Authorization: 26/05/2021

10. Date of revision of the text
27/07/2023