

## LEVAMISOLE TABLETS 40 MG

# RETRAX

### PRESENTATION

RETRAX Is presented as dark red round biconvex film coated tablet each tablet containing 47.2mg Levamisole Hydrochloride USP (equivalent to 40 mg Levamisole).

### Composition:

Each tablet contains:

Levamisole...40mg as Levamisole hydrochloride USP

### CLINICAL PHARMACOLOGY

#### *Pharmacological Properties*

Levamisole is a fast-acting drug which acts on nematode nerve ganglia paralyzing the worm's muscular within minutes of contact. Unable to maintain their position, the worms are then ejected by normal peristaltic movement, usually within 24hours of Levamisole administration. Although it is certain that Levamisole primarily influences the neuromuscular system of nematodes, it is possible that in some helminths the inhibition of the fumarate reductase system contributes to the anthelmintic efficacy of Levamisole.

#### *Pharmacokinetic Properties*

Levamisole is rapidly and almost completely absorbed from the gastrointestinal tract. A dose of 2.5mg/kg gives peak plasma levels of 0.5-0.7 microgram/ml within two hours. The drug is rapidly and extensively metabolized in the liver. One metabolite (hydroxylevamisole) has been identified in the urine of man, but several other identified metabolites are formed. The elimination of the drug is rapid (a plasma half-life of about four hours). Approximately 70% of the dose is eliminated in urine within 72 hours and only 4% in faeces. Less than 6% of the dose is excreted unchanged.

### INDICATIONS

RETRAX is indicated for the treatment of infections by the following gastrointestinal worm species. *Ascaris lubricoides*, *Necator americanus*, *Ancylostoma duodenale*, *Enterobius vermicularis*, *Trichuris trichiura*, *Strongyloides stercoralis*, *Trichostrongylus colubriformis*.

### CONTRAINDICATIONS

Previous allergy to Levamisole or any of its components.

### WARNINGS AND PRECAUTIONS

In case of concurrent microfilaraemia, transient fever may occur.

### PREGNANCY AND LACTATION

Pregnancy: although studies in animal have shown that RETRAX has no teratogenic effects, current medical practice requires that the benefits of any drug used during pregnancy should be weighed against the possible dangers. Lactation: No special precaution.

### Effect on ability to drive or operate machinery

There is no evidence to suggest that Levamisole, used for anthelmintic purposes, will produce sedation. Mild and transient giddiness (Dizziness) is an infrequent side effect of treatment. No precautions are suggested concerning the ability to drive or operate machinery.

#### **POSSIBLE ADVERSE DRUG REACTIONS**

These are infrequent. They are usually mild, transient and include nausea, vomiting, abdominal pain, giddiness and headache.

An encephalopathy – like syndrome has been reported to have occurred in a few patients two or three weeks after treatment.

Allergic after reactions have been reported following repeated exposure.

#### **DOSAGE AND ADMINISTRATION**

The following doses of RETRAX are given as a single administration, preferably after a light meal.

<b>Patient's age in years</b>	<b>Number of tablets</b>
1-4	1 5ml
5-15	2 10ml
16 and over	3 15ml

In case of severe hookworm infection it is suggested that a second standard dose be given one week or seven days after the first, whichever timing is feasible.

#### **OVERDOSAGE**

Counter possible anticholinesterase activity with e.g. Atropine. Control blood pressure and respiration. Do not give sedatives.

#### **HOW SUPPLIED**

Retrax is available in blister strips of 3 tablets in a carton and 500 tablets in a jar.

#### **STORAGE CONDITION**

Store at room temperature protected from moisture.

Keep all medicines away from children.

#### *Manufactures by:*

ECOMED PHARMA LTD  
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