Issued to the Medical Profession only

'KETRESS' کیٹریس

(Levamisole HCl.) (لیوامیسول ہائیڈروکلورائیڈ)

Presentation

'Ketress' is presented as tablets each containing 47.2 mg Levamisole Hydrochloride Ph Eur (equivalent to 40 mg levamisole) and as a syrup containing 47.2 mg Levamisole Hydrochloride Ph Eur in 5 ml (equivalent to 40 mg levamisole).

Indications

'Ketress' is indicated for the treatment of infections by the following gastro-intestinal worm species:

Ascaris lumbricoides
Necator americanus
Ancylostoma duodenale
Enterobius vermicularis
Trichuris trichiura
Strongyloides stercoralis
Trichostrongylus colubriformis

Dosage And Administration

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

Patient's age in years	Number of tablets	Dose of Syrup
1-4	1	5 ml
5-15	2	10 ml
16 and over	3	15 ml

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

Contraindications

Previous allergy to 'Ketress' or any of its components.

Warnings/Precautions

In case of concurrent microfilaraemia transient fever may occur.

Interactions with other medicaments and other forms of interaction

None known.

Pregnancy and Lactation

Pregnancy: Although studies in animals have shown that 'Ketress' produces 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 precautions.

Effects 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 to three weeks after treatment.

Allergic reactions have been reported following repeated exposure.

Overdose

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

Pharmacological Properties

Pharmacodynamic Properties

Levamisole is a fast acting drug which acts on nematode nerve ganglia paralysing the worm's musculature within minutes of contact. Unable to maintain their position, the worms are then ejected by normal peristaltic movement, usually within 24 hours 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 2.5 mg/kg gives peak plasma levels of 0.5- 0.7 microgram/ml within two hours. The drug is rapidly and extensively metabolised in the liver. One metabolite (hydroxylevamisole) has been identified in the urine of man, but several other unidentified 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.

Pharmaceutical Particulars

Storage

Tablets: Store below 30°C protected from moisture.

Syrup: Store below 25°C protected from light.

Pack Presentation

'Ketress' Tablets are available in packing of 30's and 500's.

'Ketress' Syrup is available in packing of 10 ml and 15 ml.

Reg. No. 001318 ('Ketress' Tablets)
001317 ('Ketress' Syrup)

M.L.No. 000016.

Manufactured by
Searle Pakistan Limited,
F-319 S.I.T.E., Karachi.
For **ICI Pakistan Limited,**
Life Sciences Business,
Pharmaceuticals Division,
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