SAMTREX TABLETS

Levamisole Hydrochloride 40mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. NAME OF THE MEDICINAL PRODUCT

SAMTREX TABLETS 40MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains 40mg of Levamisole Hydrochloride

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

Pink circular coated tablets with 'SAMTREX' marked one side and the reverse face has a plain.
Oral Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

It is used as an anthelmintic. It is active against intestinal nematode worms. Lavaamisole is especially effective in the treatment of ascariasis (roundworm infection). It is also used in hookworm infections, enterobius vermicularis, Trichuris trichuria, Stronglyloides stercoralis and Trichostrongylus colubriformis.

4.2 Posology and method of administration.

Doses are expressed in terms of the equivalent amount of Levamisole. The usual dose is 120 to 150mg of Levamisole by mouth as a single dose: Children have been given 3mg per kg body-weight as a single dose. In severe hookworm infection, a second dose or 7 days after the first dose has been suggested.

4.3 Contraindications

The use of Levamisole should be avoided in ptients with advance liver or kidney disease and in patients with pre-existing blood disorders.

4.4 Special warnings and precaution for use.

During administration and for at least 24 hours following intake alcohol consumption is prohibited.

Samtrex should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Keep out of reach of children.

4.5 Interaction with other medicinal product and other forms of interaction.

Samtrex produces disulfiram-like side effects when given concomitantly with alcohol. Caution is necessary when Samtrex is used in combination with medicines that may affect haemopoiesis.

During concurrent intake of levamisole and coumarin type anticoagulants the prolongation of prothrombin time can be expected, therefore the dose of oral anticoagulants should be re-adjusted.

Levamisole increases plasma levels of phenytoin; therefore plasma levels of phenytoin should be monitored.

Levamisole should not be administered simultaneously with lipophilic preparations such as carbon tetrachloride, tetrachloroethylene, chenopodium oil, chloroform or ether, because the toxicity of levamisole might increase

4.6 Pregnancy and Lactation.

Pregnancy

There are no adequate data from the use of Samtrex in pregnant women. The potential risk for humans is unknown. Not to be used during pregnancy unless considered essentially by a physician.

Lactation

It is not known whether levamisole is excreted in human milk. To protect nursing infants, a decision should be made whether to discontinue nursing or to discontinue the preparation, taking into account the importance of the medicine to the mother.

Not to be used during lactation unless considered essential by a physician.

4.7 Effect on the ability to drive and use machine.

Decaris has minor influence on the ability to drive and use machines. Caution is recommended for patients when they are driving cars or operating machinery.

There is no evidence to suggest that levamisole, used for anthelmintic purposes, produces sedation.

4.8 Undesirable effect.

The undesirable effects are Headache, dizziness, dyspeptic events, such as nausea, vomiting, and abdominal pain.

4.9 Overdose.

Symptoms

The following toxic effects were observed with high doses of levamisole: nausea, vomiting, diarrhoea, headache, dizziness, confusion.

Treatment

In case of accidental overdosage, if performed early after ingestion, gastric lavage is recommended.

Monitoring of vital signs and supportive therapy are suggested.

When there are symptoms of anticholinesterase activity, the use of atropine may be considered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

The active substance of Samtrex tablets, levamisole is a fast-acting anthelmintic. It causes depolarizing neuromuscular paralysis by acting on nematode nerve ganglia. The paralysed worms are then expelled from the organism by normal peristaltic movement, usually within 24 hours of levamisole administration.

5.2 Pharmacokinetic properties.

Levamisole is rapidly absorbed from the gastrointestinal tract after a single oral dose of 40mg.

Mean peak plasma concentration is achieved within 1.5 - 2 hours.

Levamisole is extensively metabolised in the liver; its main metabolite is p-hydroxylevamisole and its glucuronide.

The plasma elimination half-life of levamisole is 3-6 hours. Less than 5% of the dose is excreted in an unchanged form in the urine and less than 0.2 % in the faeces.

5.3 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Di-calcium phosphate

Gelatine

Purified Talcum

Magnesium Stearate

Methyl Paraben

6.2 Incompatibilities

None known

6.3 Shelf-life

30 Months

6.4 Special precautions for storage

Protect from heat and light and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Bulk pack tablet whose quality has been approved by the quality control department in polythene bags in 500's by weight. Seal the bags and place them in previously cleaned 350cc plastic securi-containers.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

04 – 2016.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 1st June 2021

10. DATE OF REVISION OF THE TEXT

17th August 2025