SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

WORMTEX® TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Levamisole Hydrochloride B.P. 47.2 mg equivalent to Levamisole 40 mg base

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets (film coated)

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Levamisole is an anti-parasitic agent used for the treatment of roundworm and hookworm infections. This medicine is not recommended for use in patients suffering from severe kidney diseases due to the increased risk of serious adverse effects.

4.2 Posology and method of administration

Oral
Missed Dose
This medicine is usually administered/taken as a single dose.
Overdose
Seek emergency medical treatment or contact the doctor in case of an overdose.

4.3 Contraindications

Must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.

Levamisole hydrochloride is contraindicated in patients with a known hypersensitivity to the drug or its components, in patients with pre-existing blood disorders. Caution in rheumatoid arthritis, Sjogren syndrome, epilepsy and liver disease where dose adjustment may be necessary.

4.4 Special Warnings and precautions for use

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

Too frequent and repeated use of anthelmintics from the same class, over an extended period.
Underdosing, which may be due to misadministration of the product.
Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g., Fecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Do not exceed the recommended dosage.

4.5 Adverse effects/ Side effects

Nausea, diarrhea, and leukopenia being the most significant adverse effects with fatigue, dermatitis, and stomatitis.

Major & minor side effects for Levamisole

- Nausea
- Abdominal pain
- Vomiting
- Fatigue
- Chest pain
- Headache
- Dizziness
- Rash

4.6 Pregnancy and lactation

This medicine is not recommended for use in pregnant women unless necessary. All the risks and benefits should be discussed with the doctor before taking this medicine. Your doctor may prescribe a suitable alternative based on your clinical condition.

This medicine is not recommended for use in breastfeeding women unless necessary. All the risks and benefits should be discussed with the doctor before taking this medicine.

4.7 Interaction with other medicinal products and other forms of interaction

Consumption of alcohol is not recommended while receiving this medicine since it may increase the risk of adverse effects such as severe headaches, nausea, vomiting, dizziness, etc.

Interaction with Medicine

Anticoagulants

Phenytoin

Disease interactions

Disease

Information not available.

Food interactions

Information not available.

General warnings

Driving or Operating machinery

Use of this medicine may cause symptoms such as dizziness, sleepiness, etc. in some patients. It is advised that you do not perform any activities such as driving a vehicle or operating machinery if you experience any of these symptoms during treatment with this medicine.

Hepatic impairment

This medicine should be used with caution in patients with a history of liver diseases due to the increased risk of severe adverse effects. Regular monitoring of liver function tests, appropriate dose adjustments, or replacement with a suitable alternative may be required in some cases based on the clinical condition of the patient.

Renal impairment

This medicine should be used with caution in patients with a history of kidney diseases due to the increased risk of severe adverse effects. Regular monitoring of kidney function tests, appropriate dose adjustments, or replacement with a suitable alternative may be required in some cases based on the clinical condition of the patient.

4.8 Overdose (symptoms, emergency procedures, antidotes), if necessary

Missed Dose
This medicine is usually administered/taken as a single dose.
Overdose
Seek emergency medical treatment or contact the doctor in case of an overdose.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Imidazothiazoles

5.1 Pharmacodynamic properties

Levamisole is a synthetic imidazothiazole derivative that has been widely used in the treatment of worm infestations in both humans and animals. As an anthelmintic, it probably works by targeting the nematode nicotinergic acetylcholine receptor. As an immunomodulator, it appears that Levamisole is an immunostimulant which has been shown to increase NK cells and activated T-cells in patients receiving this adjuvant along with 5FU for Stage III colon cancer.

5.2 Pharmacokinetic properties

The peak effect of this medicine can be observed within 2 hours of administration of the dose.
Protein binding: 20-25%
Half Life: 4.4-5.6 hours (biphasic)
Metabolism: Primarily hepatic (extensive) with both active and inactive metabolites.

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic calcium phosphate
Maize Starch
Methyl paraben sodium
Propyl paraben
Magnesium stearate Sodium starch glycolate
Talcum Purified Aerosil
PVPK-30
Hypromellose
Talc purified.
Titanium dioxide
Color Ponceau 4R
Propylene glycol
Polyethylene glycol

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30ºC.
Keep all medicines out of reach of children.

6.5 Nature and composition of immediate packaging

PVC Blister pack

6.6 Special precautions for the disposal

Should be disposed of in accordance with local requirements.

7.0 MARKETING AUTHORISATION HOLDER

Krishat Pharma Industries Limited

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8.0 Marketing Authorization numbers

NAFDAC Reg. No. : A4-8773