SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

ROMISOLE TABLETS, film coated tablet

2. Qualitative and quantitative composition

Active Ingredient:

Each film coated tablet contains 40mg of Levamisole Hydrochloride USP

Excipients with known effect:

Each tablet contains 98.0mg Lactose mono hydrate

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

White coloured, round shaped, film coated tablets plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

Levamisole Hydrochloride tablets are indicated for the treatment of intestinal helminth infections caused by susceptible nematodes.

It is effective against roundworm (Ascaris lumbricoides) and hookworms including Ancylostoma duodenale and Necator americanus, and may be used for mixed worm infestations.

Levamisole acts as a broad-spectrum anthelmintic that eliminates worms through neuromuscular paralysis. In select clinical situations, it may also be used as an immunomodulator, only under strict medical guidance.

4.2 Posology & Method of Administration

1.1 Posology

Weight (Age)	Dose per administration	Administration interval	**Maximum** daily dose
Adults and children ≥ 12 years (≥50 Kg)	40–150 mg	Once daily	150 mg/day

Usual adult dose: 40–150 mg once daily depending on indication.

Paediatric dose: 2.5 mg/kg/day, not exceeding adult maximum.

Treatment duration varies with clinical condition.

Therapy may be intermittent or short course based on physician judgment.

Hepatic impairment

Metabolism primarily hepatic:

- Initiate treatment cautiously with reduced dose
- Monitor liver enzymes regularly
- Avoid prolonged high-dose treatment in significant hepatic disease

Renal impairment

Elimination may be reduced:

- Use lowest effective dose
- Extend dosing interval if needed
- Monitor for neurological or gastrointestinal toxicity

Special clinical situations

Use minimum effective dose in:

- Elderly patients (higher risk of neuropathy)
- Patients with compromised immunity
- Individuals with prior bone marrow suppression
- Patients with autoimmune disorders receiving concurrent therapy

Discontinue immediately if neutropenia, persistent vomiting, CNS effects, or signs of infection develop.

Method of administration Oral use.

Tablet should be swallowed whole with a glass of water.

May be taken with or without food, though food may reduce nausea.

Frequency of administration

- Doses are administered once daily
- Night-time dosing may improve tolerance if nausea occurs
- In chronic regimens, drug-free intervals may be prescribed to reduce toxicity

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Levamisole Hydrochloride tablets are contraindicated in patients with known hypersensitivity to levamisole or any formulation component. Use is contraindicated in individuals with a history of agranulocytosis, bone-marrow depression, or other significant

blood dyscrasias. It should not be administered in severe hepatic or renal impairment. Levamisole is not recommended in pregnancy or breastfeeding unless clearly required. Avoid use in patients with active severe infections or serious systemic illness.

4.4 Special warnings and precautions for use Special warnings

This medicinal product must not be used in children under 2 years of age due to the risk of serious adverse reactions including central nervous system toxicity and agranulocytosis.

Use with caution in:

- children and adolescents (dose monitoring required)
- elderly patients (increased susceptibility to adverse effects)

Levamisole may cause:

- dizziness, headache, or confusion
- gastrointestinal disturbances (nausea, abdominal cramps, vomiting)
- hypersensitivity reactions including rash or fever

Patients should be advised to avoid tasks requiring mental alertness such as driving or operating machinery if dizziness or confusion occurs.

Serious but rare adverse reactions may include:

- agranulocytosis
- severe skin reactions
- vasculitis or flu-like syndrome

Immediate medical attention is required if sore throat, fever, mouth ulcers, or easy bruising develop.

Precautions for use

Levamisole should be administered cautiously in patients with:

- Hepatic impairment (reduced metabolism; dose reduction may be necessary)
- History of blood dyscrasias or immune disorders
- Renal impairment (monitor toxicity; adjust dose or interval if needed)
- Pre-existing gastrointestinal disease
- Epilepsy or seizure history (risk of CNS effects)

Avoid use in:

- patients with documented agranulocytosis or history of drug-induced blood disorders
- severe liver or kidney disease unless strictly necessary

Levamisole may interact with:

- alcohol (may increase adverse CNS and GI effects)
- immunosuppressive agents
- antiepileptics
- anticoagulants (monitor INR if relevant)

Regular clinical monitoring (including periodic blood counts when indicated) is recommended during prolonged therapy or repeated courses.

Warnings related to excipients

- Lactose monohydrate – Not suitable for patients with lactase deficiency, galactose intolerance or glucose- galactose malabsorption.
- Sodium benzoate – May cause mild irritation; avoid use in infants.
- PVP, MCC, crospovidone, croscarmellose sodium, sodium starch glycolate – Generally well tolerated;

rare allergy or GI discomfort may occur.

- Talc, colloidal silicon dioxide, magnesium stearate – Very low risk; occasional GI upset or hypersensitivity possible.
- Film coating mix – May cause allergic rash in sensitive individuals.

4.5 Interaction with other medicinal products and other forms of interaction

Central nervous system depressants

Levamisole is not strongly sedative, but caution is advised when combined with CNS depressants due to possible enhancement of adverse effects such as dizziness or impaired alertness:

1. Alcohol

o May worsen dizziness, nausea and impaired alertness.

o Advise patients to avoid alcohol during therapy.

2. Benzodiazepines

o May potentiate CNS-related side effects (drowsiness, confusion).

3. Opioid analgesics

e.g., tramadol, morphine, codeine

o Increased risk of dizziness, nausea or vomiting.

4. Sedating antihistamines

e.g., chlorpheniramine, diphenhydramine

o Additive drowsiness and psychomotor impairment.

5. Hypnotics and sedatives

e.g., zolpidem

- Increased risk of impaired coordination.

6. Anxiolytics

- May enhance CNS depression; monitor for excessive sedation.

Anticholinergic medicines

Levamisole may rarely contribute to mild anticholinergic-like adverse effects; risk is higher when combined with:

7. Tricyclic antidepressants

e.g., amitriptyline, imipramine

- Additive dry mouth, constipation and blurred vision.

8. Antipsychotics

e.g., chlorpromazine, olanzapine

- May enhance constipation, dizziness, urinary retention.

9. Antiparkinsonian agents

e.g., benztropine, trihexyphenidyl

- Increased risk of constipation, confusion or blurred vision.

10. Antispasmodics

e.g., hyoscine, dicyclomine

- Additive reduction in GI motility; risk of urinary retention.

4.6 Fertility, pregnancy and lactation

Pregnancy

Levamisole should be avoided during pregnancy, particularly in the first trimester, as adequate and well- controlled human studies are lacking and potential risk to the fetus cannot be ruled out. Animal studies have shown embryotoxic effects at high doses. Levamisole should only be used in pregnancy if the expected clinical benefit outweighs potential fetal risks and no safer alternative is available. Use requires careful medical supervision.

Breastfeeding

Levamisole is excreted in small amounts into breast milk, and potential effects on the nursing infant cannot be excluded. Because of the risk of adverse reactions, including possible hematological toxicity, use during breastfeeding is not recommended unless clearly necessary. If treatment is essential, temporary interruption of breastfeeding may be

considered, or an alternative medication with a better safety profile should be used under medical guidance.

Fertility

There are no adequate human data assessing the effects of levamisole on male or female fertility. Animal studies have not demonstrated consistent reproductive toxicity at therapeutic doses; however, effects on fertility at higher exposures cannot be excluded. As a precaution, levamisole should be used with care in individuals planning conception, and only when the expected benefit justifies any potential risk.

4.7 Effects on ability to drive and use machines

Levamisole may cause dizziness, headache, fatigue or confusion in some individuals. If such symptoms occur, patients should be advised to avoid driving, operating machinery, or performing tasks requiring mental alertness. Until the patient's response to treatment is known, caution is recommended with activities that require concentration or coordination.

4.8 Undesirable effects

Levamisole may cause immune-mediated, gastrointestinal and neurological reactions. Agranulocytosis is the most serious adverse effect.

Immune System

- Common: flu-like symptoms (fever, malaise)
- Rare: hypersensitivity reactions (rash, urticaria)
- Very rare: vasculitis, autoimmune reactions

→ Discontinue if hypersensitivity or vasculitis suspected.

Blood and Lymphatic System

- Rare: leukopenia
- Very rare but serious: agranulocytosis, neutropenia

→ Stop treatment immediately if fever, sore throat or infection develops.

Nervous System

- Common: headache, dizziness
- Uncommon: fatigue, confusion
- Rare: peripheral neuropathy (tingling, numbness)

Gastrointestinal

- Common: nausea, abdominal pain, vomiting
- Uncommon: diarrhoea, loss of appetite
- Very rare: mouth ulcers

Skin

- Uncommon: rash, pruritus
- Rare: purpura or vasculitic skin lesions

→ Stop therapy if painful purpura or ulcerative lesions appear.

Reporting of Adverse Drug Reactions

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

4.9 Overdose

Overdose risk is greater in children, elderly patients, and those with hepatic/renal impairment or immune dysfunction.

Symptoms usually appear within a few hours and may include:

- nausea, vomiting, abdominal pain, diarrhoea
- dizziness, headache, confusion
- metallic taste, fever, muscle weakness
- hypotension, tachycardia

Severe poisoning may lead to seizures, agranulocytosis, or respiratory depression. Children may develop irritability, convulsions, and rapid dehydration due to vomiting/diarrhoea.

Symptoms

Symptoms generally appear within a few hours and may include:

- marked drowsiness, confusion, agitation or hallucinations
- anticholinergic signs: dry mouth, dilated pupils, flushed skin, fever, blurred vision
- gastrointestinal symptoms: nausea and vomiting
- tachycardia, urinary retention, ataxia

Severe poisoning may progress to seizures, hypotension, respiratory depression and coma. Children may develop paradoxical excitation, convulsions and hyperthermia.

Management

There is no specific antidote to levamisole. Recommended emergency measures include:

- Immediate transfer to hospital
- Maintain airway, breathing and circulation
- Consider gastric lavage or activated charcoal if early after ingestion
- Control seizures with benzodiazepines if required
- Correct dehydration and electrolyte imbalance

- Monitor full blood count for neutropenia Supportive therapy is the mainstay.

Most patients recover with adequate symptomatic care.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ANTHELMINTICS – IMIDAZOTHIAZOLES

ATC code: P02CE01

Levamisole is a broad-spectrum anthelmintic that acts by selectively stimulating nicotinic acetylcholine receptors on the neuromuscular junction of susceptible nematodes. This results in tetanic contraction followed by flaccid paralysis, allowing the worms to be expelled by normal intestinal peristalsis. Levamisole exhibits activity primarily against roundworms and hookworms.

5.2 Pharmacokinetic properties

Absorption:

Levamisole is rapidly and almost completely absorbed following oral administration. Peak plasma concentrations are typically achieved within 1.5 to 2 hours. Oral bioavailability is high, although first-pass metabolism slightly reduces systemic levels. Food does not significantly alter the extent of absorption but may delay peak concentration slightly. Plasma levels decline biphasically, consistent with rapid distribution followed by metabolic elimination.

Distribution:

After absorption, levamisole is widely distributed throughout body tissues and fluids. Protein binding is moderate, with approximately 20–30% bound to plasma proteins. The drug crosses the placental barrier and trace amounts are detectable in breast milk. Levamisole penetrates into the central nervous system to a limited extent but achieves therapeutic levels in the gastrointestinal tract and systemic circulation sufficient to exert its anthelmintic activity.

Metabolism:

Levamisole undergoes extensive hepatic metabolism, primarily via oxidative pathways to several inactive metabolites. The liver converts the parent compound to p-hydroxy-levamisole and other polar derivatives, which are subsequently conjugated. Only a small fraction of the administered dose remains unchanged in systemic circulation. Metabolic clearance is rapid and contributes significantly to the elimination profile. Liver impairment may delay metabolism and increase systemic exposure, requiring caution in such patients.

Elimination:

Levamisole is cleared predominantly through renal excretion of metabolites, with approximately 70% of the administered dose eliminated in the urine within 3 days, mainly as inactive metabolites. A small proportion (less than 5%) is excreted unchanged. Fecal elimination accounts for a minor fraction. The elimination half- life averages 3–6 hours, though this may be prolonged in hepatic or renal impairment. Clearance is generally rapid following single-dose therapy.

5.3 Preclinical safety data

Preclinical studies show levamisole has low to moderate acute toxicity. Chronic high doses may cause hematological changes such as leukopenia. Genotoxicity and carcinogenicity studies indicate no significant risk at therapeutic levels. Reproductive studies show embryotoxicity at high doses. Overall, animal data support safety at recommended doses.

6 Pharmaceutical particulars

6.1 List of excipients

Lactose mono hydrate

PVP K30

Sodium benzoate

Cross povidone

Talcum

Magnesium stearate

Croscarmellose Sodium

Sod. starch glycollate

Colloidal silicone dioxide

Microcrystalline cellulose

Ready mix white film coating

IPA

P water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from moisture, freezing and excessive heat

6.5 Nature and contents of container

10 Tablets are packed in one Blister. 10 Blisters are packed in a carton with insert. Such 100 cartons are packed in one shipper

6.6 Special precautions for disposal and other handling

No special requirements.

7 Marketing Authorization Holder

LEXINE TECHNOCHEM PVT. LTD.

Opp Ramakaka Deri, Chhani,

Vadodara- 391

740, Gujarat, India

8 Marketing Authorisation Number(s)

10669

9 Date of First Authorisation/Renewal of the Authorisation

Date of Re-registration: 27/02/2026

10 Date of revision of the text

27/02/2026