

ELMISOL® 5, 10, 25 and 50

levamisole hydrochloride



Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others.
- It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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1. WHAT ELMISOL IS AND WHAT IT IS USED FOR

Elmisol contains levamisole, which belongs to the group of immunomodulating agents. Immunomodulating agents like levamisole change the activity of the immune system in the body.

Elmisol is used to treat Steroid Sensitive Nephrotic Syndrome (SSNS). It is used during and following a therapy with prednisone or prednisolone.

2. BEFORE YOU TAKE ELMISOL

Do not take Elmisol

- If you are allergic (hypersensitive) to levamisole or any of the other ingredients of the Elmisol tablet.

Take special care with Elmisol

- If you have a liver or kidney disease, please consult your doctor, who possibly adapts the dose accordingly.
- If changes in the blood cells occur. Levamisole can induce changes in white blood cells. Therefore blood controls are required at regular intervals (e.g. every 3 weeks) during treatment. Treatment must be stopped immediately if significant changes in blood cells occur. Such changes in blood may be preceded by influenza-like symptoms, such as fever and shiverings. In such instances, you should immediately report these symptoms to your doctor. It should be noted that influenza-like symptoms might also occur without changes in blood.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including any medicines that have been obtained without prescription. It is imperative that you tell your doctor

- if you use anticoagulants (blood-thinners)
- if you use medicines that contain phenytoin (medicine prescribed for epilepsy) levamisole may increase the blood level of phenytoin.
- if you use other medicines that effect the formation of blood cells (hematopoiesis)

Taking Elmisol with food and drink

You should not drink any alcohol during treatment. Unpleasant side effects might emerge such as severe headaches, nausea, and vomiting.

Pregnancy

There is no information available regarding the possible harmful effects of levamisole during pregnancy. Do not take Elmisol while you are pregnant or if you intend to become pregnant. Ask your doctor for advice before taking any medicine.

Breast-feeding

Do not take Elmisol when you are breastfeeding. Ask your doctor for advice before taking any medicine.

Driving or using machines

You can drive and use tools or machines during treatment.

Important information regarding some of the ingredients of Elmisol

One tablet of Elmisol 5, 10, 25, and 50 contains 48, 61, 69, and 104 mg of lactose respectively. If you have been informed by your doctor that you have an intolerance to some sugars, please ask your doctor before taking this medicinal product.

3. HOW TO USE ELMISOL

Always take Elmisol exactly as your doctor told you. You should ask your doctor if you are not sure.

The usual dose is 2.5 mg per kg bodyweight, to be taken every other day. The maximum dose is 150 mg, to be taken every other day.

Ingest whole tablets. The tablet can be taken with some water or, if necessary, with custard or any appropriate liquid.

Elmisol treatment will be started during treatment with prednisone or prednisolone as soon as the urine is free of proteins for at least three days. The dosage and frequency of administration of prednisone/prednisolone will be cut down following a schedule provided by your doctor. Treatment will be continued for a period of at least 6 months. Treatment will be stopped if a relapse of SSNS occurs.

If you take more Elmisol than you should

In case of accidental intake by a child (in dosages higher than indicated), you should let the child vomit and contact your doctor immediately.

Possible signs of an overdose: Extreme lethargy or sleepiness, confusion,

dizziness, headaches and complaints of the intestines or stomach, such as diarrhea, cramps, nausea, and vomiting.

If you forget to take Elmisol

If you forget to take Elmisol at your usual time, you can safely take the dose later the same day. If the next day you realise that you forgot to take the dose from the previous day, do not take the dose that was missed.

Simply continue with the regular next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Elmisol

Do not stop taking Elmisol without first consulting your doctor.

If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Elmisol can cause side effects, although not everybody gets them. Stop taking Elmisol and contact your doctor if you get the following side effects.

- Changes in white blood cells (neutropenia). These changes might cause flu-like symptoms such as chills, fever, fatigue (please also see the section 'Take special care with Elmisol').
- Changes in blood platelets (trombocytopenia).
- Disorders of the brain and nerves (leukoencephalopathy). Symptoms of these disorders are confusion, loss of memory, unusual sleepiness, an unusual itching or tingling feeling that occurs without a clear reason, weakness of the muscle, seizures, coma or speech disturbances.
- Hypersensitive reactions such as skin rash, itching, a swollen face or tightness of the chest.

Other side effects that may occur.

- Nervousness, sleepiness, depression.
- Nausea, vomiting, reduced appetite, diarrhea, constipation.
- Inflammation of the pancreas (pancreatitis). A symptom of this inflammation is a suddenly occurring stomach pain.
- Skin rash and inflammation, malformations of the skin such as red swollen spots.
- Muscle and joint pain.
- Inflammation of the mouth, change to your odour.

If any of the side effects becomes serious, or if you experience any side effects not listed in this leaflet, please contact your doctor immediately.

5. HOW TO STORE ELMISOL

Keep out of reach and sight of children.

Store in original package. Store below 25 °C. Do not freeze.

Do not use Elmisol after the expiry date stated on the carton and blister. After 'EXP' month (2 digits) and year (4 digits) are stated. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Elmisol 5, 10, 25, and 50 contains

The active substance is levamisole hydrochloride, equivalent to 5, 10, 25 and 50 mg levamisole respectively.

The other ingredients are lactose monohydrate, maize starch, Sodium starch glycolate, hydroxypropyl cellulose, microcrystalline cellulose, sodium stearyl fumarate, hydroxypropylmethyl cellulose, talc, polyethylene glycol, saccharin sodium and titanium dioxide.

What Elmisol looks like and the contents of the pack

An Elmisol tablet is a white, round, filmcoated tablet without inscriptions. Ten tablets are packed in an aluminium/pvc blister. A carton contains 5 blisters of 10 tablets.

Manufacturer

ACE Pharmaceuticals BV
Schepenveld 41
3891 ZK Zeewolde
The Netherlands
T +31 36 55474091 (Medical Information)

Miscellaneous

An Orphan Drug Designation (EU/3/05/324) for Elmisol has been granted to ACE Pharmaceuticals BV in October 2005.

This leaflet is last adapted in July 2018.