



# ELITAN 10mg/2ml solution for injection / infusion

## Metoclopramide hydrochloride

### PACKAGE LEAFLET: INFORMATION FOR THE USER

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 or pharmacist.

**In this leaflet:**

1. What ELITAN is and what it is used for
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#### 1. WHAT ELITAN IS AND WHAT IT IS USED FOR

ELITAN belongs to the group of medicines for nausea and vomiting, and works by an effect of ELITAN on the vomiting centre.

ELITAN is used in treatment of nausea and vomiting, either alone or with chemotherapy.

In connection with the large risk for certain locomotor disorders (extrapyramidal symptoms) in children, metoclopramide is only used with severe nausea and vomiting of known cause, where the treatment with other medicines turned out to be insufficient or impossible.

#### 2. BEFORE YOU TAKE ELITAN.

**Do not use ELITAN:**

- If you are allergic (hypersensitive) to metoclopramide or any of the other ingredients of ELITAN;
- If you suffer from a gastrointestinal bleeding, blockage or perforation of the gastrointestinal tract;
- If you have epilepsy;
- If you ever had tardive dyskinesia (a locomotor disorder) after taking metoclopramide or some medicines called neuroleptics for severe mental illness;
- If you have suffer from high blood pressure due to a tumour near the kidney (a condition known as phaeochromocytoma)

In combination with an anti-Parkinson drug called levodopa because they have opposite effect. ELITAN contains benzyl alcohol that must not be given to premature babies or neonates.

**Take special care with ELITAN and tell your doctor if:**

- You have a renal or hepatic disease
- You notice abnormal movements of some muscles;
- Mainly in children and young adults and/or when high dosages are given, certain abnormal movement disorders (extrapyramidal symptoms) can occur. These complains disappear after stopping the therapy.

ELITAN should not be used when you have or had the so-called ' neuroleptic malignant drug syndrome". This syndrome is a serious condition as a result of the use of certain medicines for serious mental illness (neuroleptics) that can express in muscle stiffness, strong motion urge, high fever, sweating, salivation and a reduced consciousness.

There were rare cases when he presence of methaemoglobin (a protein) in the blood was observed after administration of metoclopramide. In such a case ELITAN therapy must be stopped immediately and it should not be used again.

*Consult your doctor if any of the above warnings apply to you, or has applied to you in the past.*

**Taking other medicines**

Tell your doctor or pharmacist if you use or recently have used any other medicines. This also applies to the medicines that can be obtained without a prescription.

*Do not use ELITAN with levodopa (an anti-Parkison medicine).*

*Be careful* when ELITAN is used at the same time with medicines against cramps of the digestive tract (anticholinergic) and some strong active analgesics (morphine derivatives) because these treatments have an opposite effect on the activity of the intestines. Also ELITAN should be used with caution together with medicines that depress the central nervous system such as strong active analgesics (morphine derivatives), sleeping pills (hypnotics), medicines that reduce fear and unrest (anxiolytics), some medicines against hypersensitivity reactions (antihistamines), some medicines against dejection (antidepressants), a medicine against increased blood pressure (clonidine), certain medicines against serious sleep disorders (barbiturates), because the effect of drowsiness and sleepiness of these substances can be strengthened by this combination. ELITAN can have a strengthening effect on abnormal movement disorders (extrapyramidal disorders) induced by medicines called neuroleptics used for serious mental illness (psychosis).

ELITAN may affect the absorption of other medicines.

The effect of a medicine against cardiac arrhythmias (digoxin) and possibly of a medicine against intestinal ulcers (cimetidine) is reduced, while the effect of a drug to suppress the immune response (cyclosporine) is increased.

The duration of the muscle relaxing effect of mivacurium and suxmethonium (these are medicines that relax the skeletal muscles during operations) can be extended by ELITAN.

**Taking ELITAN with food and drink**

Concurrent use of ELITAN with alcohol should be avoided, because the effect of drowsiness and sleepiness is strengthened.

**Pregnancy and breast-feeding**

Research has, to date, not demonstrated harmful effect of ELITAN during pregnancy. ELITAN can if necessary be used during pregnancy if the doctor prescribes. ELITAN is excreted in breast milk. To occasionally use ELITAN breastfeeding does not have to be interrupted. Long-term use is not recommended during breast-feeding. Always consult your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Drowsiness may occur. This complaint can be strengthened by use of alcohol or medicines that suppress the central nervous system. This must be taken into account when driving of vehicles or operating machines.

**Important information about some of the ingredients of ELITAN:**

ELITAN contains benzyl alchohol. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

### 3. HOW TO TAKE ELITAN

**Dose**

*Nausea and vomiting during chemotherapy*

Adults: 2 to 10 mg/kg per day in 3 to 4 doses or as a bolus of 2 to 3 mg/kg, 15 minutes before chemotherapy, followed by a continuous infusion of 0.5 mg/kg/hour, only in a vein (intravenous) for 6 to 8 hours.

*Post-operative*

Adults: 10 to 20 mg per injection.

Children: 0,1 mg/kg per injection.

The daily dosage in children may not exceed the maximum of 0.5 mg/kg/day. The dosage should be followed strictly to prevent certain movement disorders (extrapyramidal phenomena).

Please note: the dosage can be reduced by your doctor in patients with renal impairment.

**Duration of the treatment**

The doctor will tell you how long you should use ELITAN.

**If you take more ELITAN than you should**

*When you used too much of ELITAN, please immediately contact your doctor or pharmacist.*

An excessively large amount of ELITAN causes complaints such as drowsiness, reduced level of consciousness, confusion, hallucinations or certain movement disorders.

**If you forget to take ELITAN**

If you have forgotten to take a dose, you should still take it. However, if it is almost time to take the next dose, skip the forgotten dose. Do not take a double dose. If you have forgotten to take more than one dose, consult your doctor.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines ELITAN may cause side effects, although not everybody gets them.

The following side effects can occur when using ELITAN:

**Nervous system disorders**

*Common (1 out of 100 to 1 out of 10 users can have it):*

- Drowsiness

*Uncommon (1 in 1000 to 1 in 100 users can have it):*

- Certain movement disorders (extrapyramidal symptoms) may occur, mainly in children and young adults or when high dosages are administered. Sometimes after administering a single dose: sudden (acute) disorder in the tension of the muscles (dystonia) and movement disorder (dyskinesia), Parkinson-ish symptoms, inability to sit or lie in the same position for some time (akathisia). (see Take special care with ELITAN).

*Not known (frequency cannot be determined with the available details):*

- Reduced level of consciousness
- During long-term treatment a certain movement disorder (tardive dyskinesia) may occur, especially in elderly.
- Cases of convulsions/seizures (convulsions) and a serious condition caused by use of neuroleptic drugs that can express in muscle stiffness, strong motion urge, high fever, sweating, salivation,
- Reduced awareness (Neuroleptic malignant syndrome).

**Psychiatric disorders**

*Not known (frequency cannot be determined with the available details):*

- Confusion, hallucination
- Dejection (depressive)

**Cardiac disorders**

*Not known (frequency cannot be determined with the available details):*

- Reduced blood pressure (hypotension), especially after administration into a vein
- Slowed heart rate (bradycardia) and a certain disorder in the conduction of the heart, leading to arrhythmia (heart block)

- Cardiac arrest, shortly after administration by injection and which can follow a slowed heart rate (bradycardia)

**Blood and lymphatic system disorders**

*Not known (frequency cannot be determined with the available details):*

- The presence of methemoglobinaemia (a protein) in the blood.
- The presence of sulphemoglobinaemia (a green haemoglobin)

**Gastrointestinal disorders**

*Uncommon (1 in 1000 to 1 in 100 users can have it):*

- Diarrhea

**Endocrine disorders**

*Not known (frequency cannot be determined with the available details):*

- During long-term treatment in conjunction with an excess of prolactin (hyperprolactinemia): the absence of menstruation (amenorrhoea), milk secretion (galactorrhoea) and excessive development of male mammary glands (gynaecomastia).

**General disorders and administration site conditions**

*Common (1 out of 100 to 1 out of 10 users can have it):*

- Fatigue (asthenia)

*Not known (frequency cannot be determined with the available details):*

- Hypersensitivity reactions (allergic reactions) including drop in blood pressure, pallor, unrest, weak rapid pulse, clammy skin, reduced consciousness by a sudden vasodilatation as consequence of serious hypersensitivity to certain substances (anaphylaxis).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### 5. HOW TO STORE ELITAN

Keep out of the reach and sight of children.

Store below 25°C, in the original package. Do not refrigerate or freeze.

Do not use ELITAN after the expiry date which is stated on the carton and the ampoule.

The expiry date refers to the last day of that month

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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 ELITAN contains:**

The active substance of ELITAN is: metoclopramide hydrochloride 5 mg/ml.

The other ingredients are: Edetate disodium, citric acid, sodium chloride, benzyl alcohol and water for injections.

**What ELITAN looks like and contents of the pack**

ELITAN is presented as clear colorless or almost colorless solution for intramuscular /intravenous administration primary packed in amber glass ampoule of 2 ml filling capacity. Each 2 ml ampoule contains 5 mg metoclopramide hydrochloride per ml.

Amber glass ampoules are packed in a carton box. Boxes of 10 and 100 ampoules are available. Not all boxes may be marketed.

**Marketing Authorisation Holder and Manufacturer:** Medochemie Ltd,

P.O Box 51409, Limassol, Cyprus

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