**PATIENT INFORMATION LEAFLET**

**PRİMSEL 10 mg/2 mL I.M./I.V. Ampoule Containing Solution for Injection**

**Sterile**

**Administered by intramuscular or intravenous injection.**

***Active ingredient:*** Each ampoule (2 mL) contains 10 mg of metoclopramide hydrochloride.

***Excipients:*** Sodium chloride, sodium metabisulfite and water for injection.

**Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medication is prescribed solely for you, do not offer it to others.*
- *If you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Follow the recommendations on this leaflet exactly as described. Do not use **higher or lower dose** except the dose you have been recommended for the medicine.*

**In this Information Leaflet:**



**Headings are included.**

## 1. What PRİMSEL is and what is it used for?

Each PRİMSEL 2 mL ampoule contains 10 mg of metoclopramide hydrochloride.
PRİMSEL is presented in ampoules containing a clear, colorless, odorless solution for injection. There are 5 ampoules of 2 mL in each box.
PRİMSEL is an anti-vomiting drug (antiemetic) containing the active substance metoclopramide.
It is used in adults:

- to treat nausea and vomiting,
- to prevent nausea and vomiting that may occur after surgery
- to prevent nausea and vomiting that may occur after radiotherapy
- to treat nausea and vomiting including nausea and vomiting which may occur with a migraine

PRİMSEL is used in children and young adults (aged 1-18 years) only if other treatment does not work or cannot be used:

- to prevent delayed nausea and vomiting that may occur after chemotherapy
- to treat nausea and vomiting that has occurred after surgery

## 2. What you need to know before you use PRİMSEL?

**DO NOT USE PRİMSEL if;**

- You are allergic to Metoclopramide or any of the other ingredients of this medicine,
- You have bleeding, obstruction or a tear in your stomach or gut,
- You have or may have a rare tumour of the adrenal gland, which sits near the kidney(pheochromocytoma).
- You have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine.
- You have epilepsy
- You have Parkinson's disease
- You are taking levodopa (a medicine for Parkinson's disease) or dopaminergic agonists (see "Concomitant use with other drugs")
- You have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency.
- You have had gastrointestinal surgery in the last 3-4 days.

Do not give PRİMSEL to a child less than 1 year of age.

**USE PRİMSEL CAREFULLY if;**

- You have a history of abnormal heart beats (QT interval prolongation) or any other heart
- You have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- You are using other medicines known to affect the way your heart beats
- You have any neurological (brain) problems
- You have liver or kidney problems. The dose may be reduced.
- You have hypertension (high blood pressure),
- You have a history of atopy (prone to developing allergies (including asthma)) or porphyria (rare inherited blood disease)

Your doctor may perform blood tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinemia), the treatment should be immediately and permanently stopped.

Do not exceed 3-month treatment because of the risk of involuntary muscle spasms.

If these warnings are applicable to you even for any period of time in the past, please consult your doctor.

**Use of PRİMSEL with food and drinks**

Do not drink alcohol while using this medicine, as the sedative effects (drowsiness, feeling sleepy) may increase if PRİMSEL is used together with alcohol.

**Pregnancy**

*Consult your doctor or your pharmacist before using the drug.*

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or for advice before being given this medicine. If necessary, PRİMSEL may be used during pregnancy. Your doctor will decide whether or not you should be given this medicine.

*If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

**Breast-feeding**

*Consult your doctor or your pharmacist before using the drug.*

PRİMSEL is not recommended if you are breast-feeding because metoclopramide passes into breast milk and may affect your baby.

**Driving and using machines**

PRİMSEL can cause drowsiness, dizziness and involuntary muscle movements. This may affect your vision and also interfere with your ability to drive and use machines.

**Important information about some excipients presents in PRİMSEL**

PRİMSEL contains less than 1 mmol sodium (23mg) per 2mL dose, i.e. is essentially “sodium free”.

Contains sodium metabisulfite. Rarely, it may cause severe, hypersensitivity reactions and spasm of the bronchi (bronchospasm).

**Use with other medicines**

PRİMSEL may interact with some drugs and affect the mechanism of PRİMSEL, or

PRİMSEL may change the mechanism of action of some drugs. These drugs are:

- levodopa or other medicines used to treat Parkinson’s disease
- anticholinergics (medicines used to relieve stomach cramps or spasms)
- morphine derivatives (medicines used to treat severe pain)
- sedative medicines
- any medicines used to treat mental health problems
- digoxin (medicine used to treat heart failure)
- cyclosporine (medicine used to treat certain problems with the immune system).
- mivacurium and suxamethonium (medicines used to relax muscles)
- fluoxetine and paroxetine (medicine used to treat depression)
- alcohol
- mexiletine (medicine used in heart rhythm disorders)
- apomorphine (emetic drug)
- bromocriptine (used in Parkinson's disease)
- aspirin or paracetamol (pain killer, antipyretic)
- atovaquone (to treat pneumonia)

*If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.*

## 3. How to use PRİMSEL?

**Instructions for appropriate use and dose / administration frequency:**

Adults:

Nausea and vomiting associated with acute migraine; for the treatment of nausea and vomiting, including prevention of nausea and vomiting after radiotherapy:

The recommended single dose is 10 mg, repeated up to 3 times daily.

For the prevention of nausea and vomiting that may occur after surgery prevention: a single dose of 10mg is recommended.

The maximum recommended daily dose is 30 mg or 0.5 mg/kg body weight.

The duration of injectable treatment should be as short as possible and the transition to oral therapy should be made as soon as possible.

Young adult and children 1-18 years old:
The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to 3 times daily, given by slow injection into a vein.

The maximum applicable daily dose within 24 hours should not exceed 0.5 mg/kg body weight.

Dosing Table:

| Age | Body Weight | Dose | Frequency |
|---|---|---|---|
| 1-3 years | 10-14 kg | 1 mg | Up to 3 times daily |
| 3-5 years | 15-19 kg | 2 mg | Up to 3 times daily |
| 5-9 years | 20-29 kg | 2.5 mg | Up to 3 times daily |
| 9-18 years | 30-60 kg | 5 mg | Up to 3 times daily |
| 15-18 years | Over 60 kg | 10 mg | Up to 3 times daily |

The treatment should not exceed 5 days for prevention of delayed nausea and vomiting that may occur after chemotherapy.

The treatment should not exceed 48 hours for treatment of nausea and vomiting that has occurred after surgery.

**Route and method of administration:**

PRİMSEL is administered by your doctor or nurse as a slow injection into a vein or intramuscularly.
Between the two administrations, a 6-hour break should be allowed, including vomiting and subtracting the dose taken.

**Various age groups:**
**Use in children:**
Involuntary movements (extrapyramidal disorders) may occur in children and young adults.
PRİMSEL should not be used in children under 1 year of age because of the increased risk of involuntary movements.

**Use in elderly:**
In the elderly, dose reduction can be made by considering kidney disorders, liver disorders and general health status of the patient.

**Special conditions**
**Renal impairment:**
PRİMSEL dose should be reduced if you have moderate or severe kidney problems. Talk to your doctor if you have kidney problems.

**Hepatic impairment:**
PRİMSEL dose should be reduced if you have severe liver problems. Talk to your doctor if

you have liver problems.

*If you have the impression that the efficacy of PRİMSEL is too strong or too weak, talk to your doctor or pharmacist.*

**If you have used more PRİMSEL than you should**

If you have taken more PRİMSEL than you should use, contact your doctor or pharmacist immediately. You may experience uncontrollable movements (extrapyramidal disorders), feel drowsy, have some troubles of consciousness, be confused, have hallucination and heart problems. Your doctor may prescribe you a treatment for these signs if necessary.

*If you have used more than you should use from PRİMSEL, talk to a doctor or pharmacist.*

**If you forget to use PRİMSEL**
If you forget to take a dose of PRİMSEL, skip the missed dose. Take the next dose at the usual time.

*Do not use a double dose to make up for a forgotten dose.*

**Effects which may occur when treatment with PRİMSEL is discontinued**

Do not terminate the treatment without the advice of your doctor. If you encounter any problems while using the drug, consult your doctor.

**4. What are the possible side effects?**

As with all medicines, there may be side effects in people who are sensitive to the ingredients of PRİMSEL.

**If any of the following occur, stop using PRİMSEL and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:**

- uncontrollable movements (often involving head or neck). These may occur in children or young adults and particularly when high doses are used. These signs usually occur at the beginning of treatment and may even occur after one single administration. These movements will stop when treated appropriately.
- high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome.
- Itching or skin rashes, swelling of the face, lips or throat, difficulty in breathing. These may be signs of an allergic reaction, which may be severe.

A list of side effects that occur in some people after PRİMSEL treatment is listed as shown in the following categories. This list is classified according to the frequency of occurrence of side effects in descending order:

-Very common : May occur in at least 1 in 10 patients
-Common : May occur less than 1 in 10 patients, but more than 1 in 100 patients.
-Uncommon : May occur less than 1 in 100 patients, but more than 1 in 1,000 patients.
-Rare : May occur in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
-Very rare : May occur less than 1 of 10,000 patients.
-Unknown : Cannot be estimated from the available data

**Very common:**

- feeling drowsy.

**Common:**

- depression
- uncontrollable movements such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity)
- symptoms similar to Parkinson disease (rigidity, tremor)
- feel restless
- blood pressure decrease (particularly with intravenous route)
- diarrhoea
- feeling weak

**Uncommon:**

- raised levels of a hormone called prolactin in the blood which may cause: milk production in men and women(hyperprolactinemia)
- irregular periods(amenorrhea)
- hallucination
- decreased level of consciousness
- slow heartbeat (bradycardia, particularly with intravenous route)
- hypersensitivity
- movement disorder caused by involuntary contractions of the muscles (dystonia)
- impairment of voluntary movements (dyskinesia)

**Rare:**

- confusional state
- convulsion (especially in patients with epilepsy).
- Milk discharge from the breasts (galactorrhea)

**Unknown:**

- abnormal blood pigment levels: which may change the colour of your skin(methemoglobinemia, sulfhemoglobinemia)
- abnormal development of breasts (gynaecomastia)
- involuntary muscle spasms (mouth, tongue, limbs such as arms and legs) after prolonged use, particularly in elderly patients (tardive dyskinesia)
- high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome
- changes in heart beat, which may be shown on an ECG test
- cardiac arrest
- shock (severe decrease of heart pressure) (particularly with injection route)
- fainting (particularly with intravenous route)
- allergic reaction which may be severe (particularly with intravenous route)
- very high blood pressure (in patients with pheochromocytoma)

*If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store PRİMSEL

*Keep PRİMSEL out of the sight and reach of children, and in its packaging.*

Store at room temperature below 25°C, protected from light.

**Use in compliance with the expiry date.**

*Do not use PRİMSEL after the expiration date stated on the packaging.*

If you notice any defects in the product and / or packaging, do not use PRİMSEL.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

**Marketing Authorization Holder:**
Osel İlaç San. ve Tic. A.Ş.
Akbaba Mah. Maraş Cad. No: 52 34820
Beykoz / İSTANBUL/ TURKEY

**Manufacturing Site:**
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*This patient information leaflet is approved on ../../….*