**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Name of the preparation, its form and strength

# Motilium® 10 mg Tablets

**Each tablet contains Domperidone 10 mg**

Inactive ingredients and allergens in the preparation - see section 6 "Further Information".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment/for you. Do not pass it on to others. It may harm them, even if it seems to you that their ailment/medical condition is similar.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

Motilium is used to treat nausea and vomiting in adults and adolescents over 12 years of age and weighing over 35 kg.

**Therapeutic group:** dopamine receptor antagonist.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6 - "Further Information")
- you suffer from abdominal bleeding or if you regularly suffer from severe abdominal pain or persistent black stools
- you suffer from intestinal obstruction or perforation
- you suffer from a tumor in the pituitary gland (prolactinoma)
- you suffer from moderate to severe liver disease
- you have an ECG that indicates a heart problem called "prolongation of the QT interval"
- you have or had a problem where the heart cannot pump the blood around your body as well as it should (a condition called heart failure)
- you have a problem that causes a low level of potassium or magnesium, or a high level of potassium in the blood
- have or may have a rare tumour of the adrenal gland

(pheochromocytoma) because it could elevate your blood pressure
- you are taking certain medicines (see below **"Drug interactions"**)

**Special warnings regarding use of the medicine:**
**Before treatment with Motilium, tell the doctor if:**
- you suffer from liver problems (liver function problems or liver failure) (see "Do not use the medicine if").
- you suffer from kidney problems (kidney function problems or kidney failure). It is advisable to consult the doctor in case of prolonged treatment, as you may need to take a lower dosage or take the medicine less frequently. In addition, the doctor may want to examine you regularly.

Domperidone may be associated with an increased risk of heart rhythm disorders and cardiac arrest. This elevated risk may be in patients aged 60 and over and in patients taking a dose that is higher than 30 mg per day. The risk also increases when domperidone is taken together with certain medicines. Tell the doctor if you are taking medicines to treat infections (fungal infections or bacterial infections) and/or if you have heart problems or AIDS (HIV) (see below **"Drug interactions"**).
Motilium should be used at the lowest effective dosage.
While taking Motilium, contact the doctor if you experience heart rhythm disturbances such as palpitations, breathing difficulties, loss of consciousness. Stop treatment with Motilium.

**Adolescents weighing less than 35 kg and children**
Motilium should not be given to adolescents 12 years of age and older weighing less than 35 kg, or to children less than 12 years of age.

**Drug interactions**
**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially if you are taking:
Do not take Motilium if you are taking medicines to treat:
- fungal infections, such as pentamidine or antifungal azoles, especially itraconazole, oral ketoconazole, fluconazole, posaconazole or voriconazole
- bacterial infections, especially erythromycin, clarithromycin, telithromycin, levofloxacin, moxifloxacin, spiramycin (these are antibiotics)

- heart problems or high blood pressure (e.g., amiodarone, dronedarone, ibutilide, disopyramide, dofetilide, sotalol, hydroquinidine, quinidine)
- psychoses (e.g., haloperidol, pimozide, sertindole)
- depression (e.g., citalopram, escitalopram)
- gastro-intestinal problems (e.g., cisapride, dolasetron, prucalopride)
- allergy (e.g., mequitazine, mizolastine)
- malaria (especially halofantrine, lumefantrine)
- AIDS/HIV, e.g., ritonavir or saquinavir (protease inhibitors)
- hepatitis C (e.g., telaprevir)
- cancer (e.g., toremifene, vandetanib, vincamine)

Do not take Motilium if you are taking some other medicines (such as: bepridil, diphemanil, methadone).
Tell the doctor if you are taking medicines to treat infections, heart problems, AIDS/HIV or Parkinson's disease.
Before you use Motilium and apomorphine, your doctor will ensure that you can tolerate both medicines when given simultaneously. Ask your doctor or specialist for personalized advice. Please refer also to the apomorphine leaflet.

## Use of the medicine and food

Take Motilium before a meal, since if taken after a meal, the absorption of the medicine is slightly delayed.

## Pregnancy, breastfeeding and fertility

It is not known if use of Motilium is harmful during pregnancy. If you are pregnant or think that you are pregnant, inform your doctor, who will decide if you can take Motilium.
Small quantities of domperidone have been detected in breast milk. Motilium may cause unwanted side effects affecting the heart in a breastfed baby. Do not use Motilium when breastfeeding unless the doctor considers its use necessary. Consult the doctor before taking the medicine.

## Driving and using machines

Some patients have reported feeling dizzy and sleepy after taking Motilium. Do not drive or use machinery while taking Motilium until you know how Motilium affects you.

## Important information about some of the ingredients of the medicine

The medicine contains lactose (a type of sugar).

Each tablet contains 54.2 mg lactose monohydrate.
If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before using the medicine.
Each tablet contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium- free”.

## 3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor’s instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.
Always take Motilium before meals, as when taken after meals, the absorption of the medicine is slightly delayed.
**Do not exceed the recommended dosage**

**Duration of treatment:**
The symptoms generally disappear after 3-4 days of treatment with the medicine. Do not take Motilium for more than 7 days without consulting the doctor.
Swallow the tablets with a small amount of water or other liquid. The tablets are coated to mask the taste. They should therefore not be chewed, crushed or halved.

**Overdose**
If you take too high a dose of Motilium, contact the doctor immediately. If you took an overdose, you may need symptomatic treatment. You may need ECG monitoring, because of the possibility of a heart problem called prolonged QT interval.

**If you forget to take the medicine,** take it as soon as you remember. If you remembered very close to the time for taking the next dose, do not take the forgotten dose. Wait until the time comes to take it and take the next dose only. Then continue as normal.
Do not take a double dose to make up for a forgotten dose.
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult**

**the doctor or pharmacist.**

## 4. SIDE EFFECTS

As with any medicine, use of Motilium may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Uncommon side effects** – effects that occur in 1-10 in 1,000 users:

- Involuntary movements of the face, arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm.

**Side effects of unknown frequency (effects whose frequency has not been determined):**

- Seizures.
- A type of reaction that may occur immediately after administration and which can be identified by skin rash, itching, shortness of breath, and/or swelling of the face.
- A severe hypersensitivity reaction that may occur immediately after taking the medicine, and is characterized by hives (a skin disease), itching, flushing, fainting, and difficulty breathing, among other possible symptoms.
- Disorders of the cardiovascular system: heart rhythm problems (rapid or irregular heartbeat) have been reported. If this happens, you must stop treatment immediately. Domperidone may be associated with an increased risk of heart rhythm problems and cardiac arrest. This increased risk may be more likely in people aged 60 or over or in patients taking doses higher than 30 mg per day. Use the lowest effective domperidone dosage.

**Stop treatment with Motilium and contact the doctor immediately** if you experience any of the side effects listed above.

Additional side effects reported upon use of Motilium are presented below:

**Common side effects** – effects that occur in 1-10 in 100 users:

Dry mouth

**Uncommon side effects** – effects that occur in 1-10 in 1,000 users:

Anxiety
Agitation
Nervousness
Loss of interest in sex or diminished interest in sex
Headache
Sleepiness

Diarrhea
Rash
Itchiness
Hives (a skin disease)
Painful or tender breasts
Milk discharge from breasts
A general feeling of weakness
Feeling dizzy

**Side effects of unknown frequency (effects whose frequency has not been determined):**
Upward eye movement
Stopped menstrual periods in women
Breast enlargement in men
Inability to urinate
Changes in certain laboratory test results
Restless legs syndrome (uncomfortable feeling, with an irresistible urge to move the legs and sometimes arms and other body parts)
Some patients who took Motilium for conditions and in dosages requiring medical supervision experienced the following side effects:
Restlessness, enlarged or swollen breasts, unusual discharge from the breasts, irregular menstrual periods in women, breastfeeding problems, depression, hypersensitivity.
**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

- Store at a temperature between 15° C to 30° C.

## 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, maize starch, microcrystalline cellulose, pregelatinized potato starch, hypromellose 2910 5mPas, polyvidone K90, magnesium stearate, hydrogenated cottonseed oil, sodium lauryl sulphate.
What the medicine looks like and the contents of the package:
A round, film-coated, biconcave, white to pale cream-colored tablet. “M10” is imprinted on one side of the tablet and “Janssen” on the other side.
Each package contains 30 tablets.

**Registration Holder and address:** Kenvue Hellas Commercial Single Member S.A., Yakum, 6097200, Israel.

**Manufacturer and address:** JNTL Consumer Health (Belgium) BV, Antwerpen, Belgium.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 0130324314