



PACKAGE LEAFLET

MOTIS 1 mg/ml Oral Suspension Taken through mouth.

Active substance: Each ml oral suspension contains 1 mg domperidone.

Excipients: Microcrystalline cellulose & sodium carboxymethyl cellulose, methyl parahydroxy benzoate, propyl parahydroxy benzoate, sorbitol 70% (non-crystalline), sodium saccharin, polysorbate 20, sodium hydroxide, purified water.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. See the end of section 4 for how to report side effects.

Read all of this PACKAGE LEAFLET carefully before you start using this medicine. It contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Tell your doctor that you use this medicine when you go to the hospital.*
- *Please follow the instructions in this leaflet. Do not use any **higher** or **lower** doses than the recommended dose of this medicine.*

What is in this leaflet:

- 1. What MOTIS is and what it is used for***
- 2. What you need to know before you use MOTIS***
- 3. How to use MOTIS***
- 4. Possible side effects***
- 5. How to store MOTIS***

1. WHAT MOTIS IS AND WHAT IT IS USED FOR

- MOTIS is in the form of oral suspension containing 1 milligram of domperidone in each milliliter.

MOTIS oral suspension is supplied with a dose adjustment syringe.

- Domperidone, the active substance of MOTIS, belongs to a group of medicines called propulsives.

The medicines belonging to this group increase and regulate the movements of the stomach and bowel. Thus, they facilitate the emptying of the stomach and prevent the stomach from moving back towards the food pipe.

- MOTIS is used to treat nausea and vomiting in adults and children.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MOTIS

DO NOT USE MOTIS in the following conditions:

- If you are allergic (hypersensitive) to domperidone or any of the excipients of MOTIS.
- If you have a pituitary tumor (prolactinoma) that secretes prolactin.
- If you have stomach bleeding or regular severe abdominal pain or persistent black stools.
- If you have a blocked or perforated intestine.
- If have moderate or severe liver disease.



- If you have an ECG (electrocardiogram) showing a heart problem called "prolonged QT interval".
- If your heart cannot pump blood throughout your body as needed (a condition called heart failure).
- If you have a problem that lowers your levels of potassium or magnesium or raises your levels of potassium in the blood.
- If you are using certain medicines (see section ‘Using with other medicines’).

USE MOTIS WITH SPECIAL CARE in following conditions:

- If you have liver problems (liver dysfunction or failure) (see section “DO NOT USE MOTIS in the following conditions”).
- If you have kidney problems (kidney dysfunction or failure).

Consult your doctor before using this medicine. Since you may need to use a lower dose or use the medicine less frequently in case of prolonged treatment, you are advised to consult your doctor, and your doctor may want to monitor you regularly.

Domperidone may increase the risk of heart arrhythmia and cardiac arrest. This risk is probably greater in people over the age of 60 or in those using doses higher than 30 mg per day. This risk also increases when domperidone is used with some medications. If you are using medicines to treat infections (fungal infections or bacterial infections) and/or if you are using medicines for any problem related to your heart or for AIDS/HIV (see section “Using with other medicines”) consult your doctor or pharmacist.

MOTIS should be used in adults and children at the lowest effective dose possible.

Consult your doctor if you experience heart rhythm disorders such as palpitations, difficulty breathing, or loss of consciousness while using MOTIS. In such a case, your treatment with MOTIS should be stopped.

If any of these warnings apply to you, even if in the past, please consult your doctor.

Using MOTIS with food and drinks

Use MOTIS on an empty stomach. Using it after meals may slightly delay its absorption.

Pregnancy

Ask your doctor or pharmacist before using this medicine.

It is not known whether using MOTIS during pregnancy is harmful. If you are pregnant or think you may be pregnant, your doctor will carefully evaluate your situation and decide whether to prescribe MOTIS for you.

Tell your doctor or pharmacist immediately if you realize you are pregnant during treatment.

Breastfeeding

Ask your doctor or pharmacist before using this medicine.

MOTIS passes into breast milk in small amounts. MOTIS may cause undesired side effects affecting the heart of the breast-fed baby. MOTIS should be used during breastfeeding only when deemed clearly necessary by your doctor. Consult your doctor before using the medicine.

Driving and using machines

Some patients have reported dizziness and sleepiness after using domperidone. Do not drive or use machinery while using MOTIS until you find out how MOTIS affects you.



Important information about some of the excipients of MOTIS

MOTIS contains sorbitol that may cause mild laxative effect. If your doctor has told you that you have an intolerance to some sugars, talk to your doctor before you use this medicine.

MOTIS contains methyl parahydroxy benzoate (E218) and propyl parahydroxy benzoate (E216). These excipients may cause allergic reactions (possibly delayed).

Using with other medicines

Do not use MOTIS if you are using any of the following medicines:

- Pentamidine or azole antifungals, especially itraconazole, oral ketoconazole, fluconazole, posaconazole or voriconazole, which are used to treat fungal infections.
- Antibiotics for the treatment of bacterial infections, especially erythromycin, clarithromycin, telithromycin, azithromycin, roxithromycin, levofloxacin, moxifloxacin, spiramycin,
- Medicines to treat heart problems or high blood pressure (amiodarone, dronedarone, ibutilide, disopyramide, dofetilide, sotalol, hydroquinidine, quinidine, diltiazem, verapamil)
- Medicines to treat psychosis (haloperidol, pimozide, sertindole)
- Medicines to treat depression (citalopram, escitalopram)
- Medicines to treat gastrointestinal disorders (cisapride, dolasetron, prucalopride)
- Medicines to treat allergies (mequitazine, mizolastine)
- Medicines to treat malaria (especially halofantrine and lumefantrine)
- Medicines to treat Parkinson's disease (levodopa)
- Medicines to treat AIDS/HIV (protease inhibitors such as ritonavir or saquinavir)
- Medicines to treat hepatitis C (telaprevir)
- Medicines to treat cancer (toremifene, vandetanib, vincamine).

Do not use MOTIS if you are using other medications containing some active ingredients such as bepridil (used for some heart conditions), diphemanil (used in stomach and intestinal ulcers), and methadone (used to relieve chronic pain).

When medicines that reduce stomach acid or prevent gastric secretion are used together with MOTIS, they should be used after meals but not before. These medicines should not be used concomitantly with MOTIS oral formulations.

If you are using medicines to treat infections, heart problems, AIDS/HIV or Parkinson's disease (levodopa), consult your doctor or pharmacist.

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

3. HOW TO USE MOTIS

Follow the instructions below unless your doctor recommends otherwise.

Instructions for appropriate use and dose/frequency of administration:

Use MOTIS before meals since its absorption is slightly delayed when used after meals.

Duration of treatment:

Symptoms usually resolve within 3 or 4 days after using the medicine. Do not use MOTIS for more than 7 days without consulting your doctor.

Adults and adolescents (12 years and older, weighing 35 kg or more):

- Do not dilute MOTIS oral suspension or mix it with other liquids.
- The usual dose is 10 ml up to 3 times daily, before meals if possible. Do not use it more than 30 ml per day.

MOTIS should be used in adults and children at the lowest effective dose.

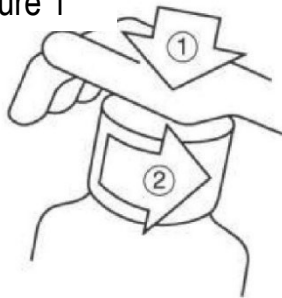
Route and method of administration:

Before use, shake the bottle gently, avoiding foam formation.

The bottle comes with a child-resistant cap and it should be opened as follows:

- Press the plastic cap downwards and turn it counter clockwise to open (Figure 1).

Figure 1



How to use the kg-marked syringe to prepare the correct dose for children:

- Remove the plastic cap on the bottle.
- Dip the syringe into the bottle.
- Keep the ring on downside of the syringe fixed.
- Draw the medicine into the syringe by pulling its upper ring up to the mark corresponding to the child's weight in kilograms (unless otherwise directed by your doctor) (Figure 2).
- Draw the whole syringe out of the bottle (Figure 3).
- Give the medicine present in the syringe by emptying it into the child's mouth.
- Clean the syringe with water.
- Close the bottle with the plastic cap.

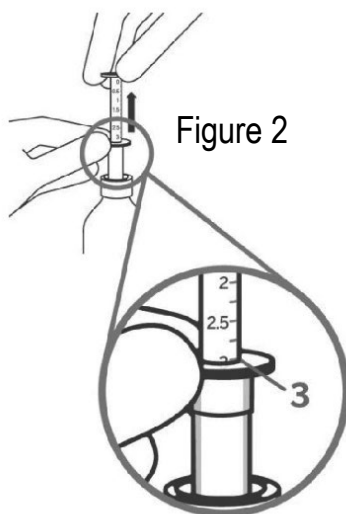


Figure 2

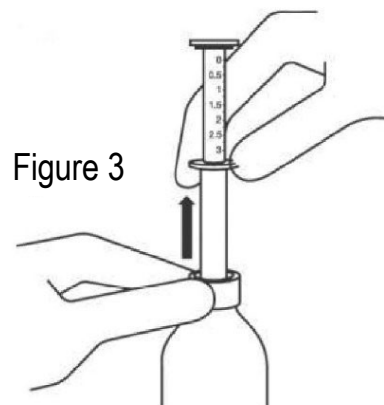


Figure 3



Special age groups:

Use in the elderly: No dose adjustment is required in patients aged 65 years and above. MOTIS may increase the risk of heart arrhythmia and cardiac arrest. This risk is probably greater in people over the age of 60 or in those using doses higher than 30 mg per day.

Use in children:

Newborns, infants and children under 12 years old, or adolescents weighing less than 35 kg:

- Your doctor will explain exactly how much and how often you should give this medicine to your child.
- Give MOTIS to children with the syringe intended for use in administering the medicine.
- The dose for children depends on the body weight. For example, for a child weighing 10 kg, each dose is adjusted by pulling the plunger up to the mark that corresponds to the child's body weight of 10 kg.
- If possible, give a maximum of 3 doses daily, at least 4-6 hours apart, before meals/breastfeeding. Do not give more than 3 doses in a 24-hour period.

Special conditions for use:

Kidney/Liver failure: It is contraindicated in patients with moderate to severe liver failure. It should be used with caution in kidney failure. The dose should be reduced depending on the severity of the failure.

If you think that the effect of MOTIS is too strong or too weak, talk to your doctor or pharmacist.

If you use more MOTIS than you should:

If you have used too much MOTIS, especially if a child has used too much MOTIS, consult your doctor or pharmacist. In the event of overdose, supportive treatment should be applied. The possibility of a heart problem called a 'prolonged QT interval' requires ECG monitoring.

Information for the doctor: Close monitoring of the patient, gastric lavage, administration of activated charcoal and general supportive measures are recommended. Anticholinergic anti-parkinson medicines may help reverse extrapyramidal effects.

Contact your doctor or pharmacist if you have used more MOTIS than you should.

If you forget to use MOTIS:

If you forget a dose, use it as soon as you remember. However, if it is time for the next dose, skip the missed dose and then continue using your medicine as usual.

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

Possible effects if you stop using MOTIS:

The doctor who treats you will decide how long MOTIS treatment will last.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, MOTIS may cause side effects in people with sensitivity to its ingredients.

Stop using MOTIS and IMMEDIATELY tell your doctor or refer to your nearest hospital emergency department if any of the following occurs:

Uncommon:

- Involuntary movements of the face, arms or legs, excessive shaking, excessive muscle contraction or muscle spasm.



Not known:

- Seizures
- A type of reaction that may occur shortly after administration, characterized by skin rash, itching, shortness of breath and a swollen face.
- A serious hypersensitivity (allergic) reaction that may occur shortly after administration, characterized by hives, itching, rash, fainting, and difficulty breathing among other possible symptoms.
- Cardiovascular system disorders: Heart arrhythmias (fast or irregular heartbeat) have been reported; if this occurs, you should stop the treatment immediately.
- MOTIS may be associated with an increased risk of cardiac arrhythmia and cardiac arrest. This risk may be higher in patients older than 60 years or in those using doses higher than 30 mg per day.

MOTIS should be used at the lowest effective dose in adults and children.

These are all very serious side effects. If you have any of them, you are seriously allergic to MOTIS. You may need immediate medical intervention or hospitalization. These very serious side effects occur quite rarely.

The other undesired effects listed below may occur due to the use of MOTIS.

If you notice any of the following, tell your doctor:

The frequency of side effects are as follows:

| | |
|-------------|--|
| Very common | : Affecting more than 1 in 10 patients. |
| Common | : Affecting more than 1 but less than 10 in 100 patients. |
| Uncommon | : Affecting more than 1 but less than 10 in 1,000 patients. |
| Rare | : Affecting more than 1 but less than 10 in 10,000 patients. |
| Very rare | : Affecting less than 1 in 10,000 patients. |
| Not known | : Cannot be estimated from the available data. |

Common:

- Dry mouth

Uncommon:

- Anxiety
- Restlessness
- Nervousness
- Loss of sexual interest or decreased sexual interest
- Headache
- Sleepiness
- Diarrhea
- Rash
- Hives
- Itching
- Pain or tenderness in the breasts
- Milk discharge from breasts
- General weakness
- Dizziness



Not known:

- Involuntary abnormal movements of the eyelids (oculogyric crisis)
- Stopping of menstrual cycle in women
- Enlargement of breast in men
- Inability to urinate
- Changes in some laboratory test results
- Restless legs syndrome (feeling uncomfortable associated with an irresistible desire to move your legs and sometimes your arms and other parts of your body)

The following undesirable effects have been observed in some patients using domperidone at doses and in conditions that require medical supervision:

Restlessness, swelling or enlargement of breasts, unexpected discharge from breasts, irregular menstrual cycle in women, difficulty in breastfeeding, depression, hypersensitivity.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MOTIS

Keep MOTIS out of the reach and sight of children and in its original package.

Store at room temperature below 25°C and in its original package.

Once opened, store the product at room temperature.

Use it in accordance with the expiry date.

Do not use MOTIS after the expiry date stated on the package, which refers to the last day of the specified month.

Once opened, do not use the product for longer than 3 months.

Do not use MOTIS if there are any defects in the product and/or the package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing authorization holder:

DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing site:

DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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