PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MOTILIUM® 10 mg tablets

Domperidone

Read all of this leaflet before you start taking MOTILIUM tablets

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MOTILIUM tablets been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MOTILIUM TABLETS CONTAINS

The active ingredient in MOTILIUM tablets is domperidone. Each tablet contains 10 milligrams of domperidone. The tablet also contains: lactose monohydrate, maize starch, microcrystalline cellulose, pregelatinised potato starch, polyvidone, magnesium stearate, hydrogenated cottonseed oil, sodium lauryl sulphate and hypromellose.

2. WHAT MOTILIUM TABLETS IS USED FOR

MOTILIUM is used in adults and children over 35 kg of weight for:

- Stomach discomfort due to food moving slowly through the stomach and intestines, where you may feel symptoms such as:

  - fullness during or shortly after a meal
  - a “heavy stomach”
  - bloated feeling
  - excessive belching
  - passing wind (flatulence)
  - nausea
  - vomiting
  - a burning feeling and/or pain in the stomach area
- Discomfort due to backflow of stomach acid, where you may experience belching and/or heartburn
- Nausea and vomiting from various causes (including chemotherapy, radiotherapy or other medicines).

3. BEFORE YOU TAKE MOTILIUM TABLETS

MOTILIUM tablets are unsuitable for use in children weighing less than 35 kg. To avoid overdosing children, use the oral suspension. Do not use MOTILIUM tablets.

Do not take MOTILIUM tablets:

- if you are hypersensitive (allergic) to domperidone or any of the other ingredients of MOTILIUM tablets.
- if you suffer from a disease of the pituitary gland called prolactinoma.
- if you have severe stomach cramps or persistent black stools.
- if you have a liver disease.
- if you are taking certain medicines that slow down the breakdown (metabolism) of other medicines in the body and can affect your heart rhythm, such as:
  - itraconazole, ketoconazole, posaconazole or voriconazole, which are used to treat fungal infections

- erythromycin, clarithromycin or telithromycin or quinolones which are antibiotics
- amiodarone, a heart medicine
- ritonavir or saquinavir which are medicines for HIV/AIDS

If in doubt, ask your pharmacist or doctor for advice.

Stop taking MOTILIUM tablets and contact your doctor immediately if you experience an abnormal heart beat.

Take special care with MOTILIUM tablets:

Before taking MOTILIUM tablets, you should let your doctor know if you:

- have or had heart problems including heart failure, a previous heart attack, angina (chest pains), or heart rhythm disorders including a rapid or slow or irregular heart beat
- have kidney problems

Stop taking MOTILIUM tablets and contact your doctor immediately if you experience an abnormal heart beat.

Children

The following side effects occur more frequently in children than adults:

- Movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement
- Seizures
- Feeling agitated

Taking MOTILIUM tablets with food and drink:

MOTILIUM tablets are most effective if taken a quarter to a half hour before the meal and, if needed, before you go to bed. Take MOTILIUM tablets with some liquid.

Pregnancy and Breastfeeding:

Pregnancy: If you are pregnant or think you may be, you should inform your doctor, who will decide if you can take MOTILIUM.

Breastfeeding: MOTILIUM can end up in the mother's milk. Breastfeeding is not recommended for mothers who are taking MOTILIUM. Talk to your doctor if you have any questions.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

Do not drive or operate machines if you feel tired, sleepy or dizzy after taking MOTILIUM tablets.

Important information about some of the ingredients of MOTILIUM tablets:

The film coated tablets contain lactose and may not be suitable for people with:

- lactose intolerance (inability to digest lactose, which is a sugar found in milk and milk products);
- galactosemia or glucose-galactose malabsorption (inability to digest carbohydrates and sugars which are found in many foods including starches, milk and milk products).

Using other medicines with MOTILIUM tablets:

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines).

Do NOT take MOTILIUM tablets if you are taking certain medicines that slow down the breaking down (metabolism) of other medicines in the body and can also affect your heart rhythm; such as:

- itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole, which are used to treat fungal infections
- erythromycin, clarithromycin or telithromycin or quinolones which are antibiotics
- ritonavir or saquinavir which are medicines for HIV/AIDS

If in doubt, ask your doctor or pharmacist for advice.

Tell your doctor or pharmacist if you are taking medicine to treat:

- fungal or bacterial infection
- heart problems
- malaria
- HIV/AIDS
- depression
- mental illness
- stomach problems
- cancer
- pain
- addictions

Your doctor will decide if these medicines can be taken together with MOTILIUM tablets or if you will need to be monitored closely for heart problem side effects.

Tell your doctor if you are taking anticholinergics (medicines to treat allergy, asthma, incontinence, gastrointestinal cramps, muscular spasms, depression or sleep disorders, for example, dextromethorphan or diphenhydramine) as these may affect MOTILIUM tablets.

Tell your doctor if you are taking medicine(s) for stomach acid. These medicines can be taken if you are also taking MOTILIUM tablets but they should not be taken at the same time. You should take oral MOTILIUM tablets before meals and the stomach acid medicine after meals.

4. HOW TO USE MOTILIUM TABLETS

Do not share medicines prescribed for you with any other person.
Always take MOTILIUM tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Your doctor will tell you how long your treatment with MOTILIUM tablets will last.
Do not stop early because your symptoms may reappear. If you have the impression that the effect of MOTILIUM tablets is too strong or too weak, tell your doctor or pharmacist.

When a doctor has prescribed MOTILIUM tablets for you, the following information applies: If MOTILIUM tablets are for nausea and vomiting, you should not usually need to take it for more than one week. Talk to your doctor if your nausea and vomiting lasts for more than one week.

If MOTILIUM tablets are for stomach discomfort, stomach acid backflow or nausea and vomiting due to chemotherapy, radiotherapy or other medicines, do not take MOTILIUM tablets for longer than 4 weeks without talking to your doctor.

The following amounts are generally used, but your doctor may adjust them to your personal needs:

ADULTS AND ADOLESCENTS (OVER 12 YEARS AND WEIGHING 35 kg OR MORE)

Take 1 of the 10 mg tablets three to four times per day. **Do not take more than 4 tablets per day.** The maximum dose per day is 40 mg.

MOTILIUM tablets are not suitable for use in children weighing less than 35 kg.

If you take more MOTILIUM tablets than you should:

If you have taken too much MOTILIUM tablets you may experience agitation, altered state of awareness or trance, seizure, sleepiness, confusion, uncontrolled movements, such as irregular eye movements, or abnormal posture, such as twisted neck. See your doctor, especially if a child has taken the medicine.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

MOTILIUM tablets can have side effects. Listed below are side effects (also called adverse drug reactions) related to treatment with MOTILIUM tablets:

Stop treatment with MOTILIUM tablets and contact your doctor immediately if you experience any of the side-effects described below.

Less frequent side effects:

- Movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement
- Severe allergic reaction that may include:
    - a swollen face, lips, mouth, tongue or throat
    - difficulty swallowing or breathing
    - itchy rash (hives)
- Palpitations
- Seizures (fits)

Other side effects that have been observed with MOTILIUM tablets are listed below:

Frequent side effects:

- Depression
- Anxiety
- Loss of interest in sex or diminished interest in sex
- Headache
- Sleepiness
- Restlessness
- Diarrhoea
- Rash
- Itchiness
- Enlarged or swollen breasts
- Painful or tender breasts
- Milk discharge from breasts or difficulty breast feeding
- Irregular or stopped menstrual periods
- A general feeling of weekness

- Dry mouth
- Feeling dizzy

Other less frequent side effects:

- Hypersensitivity
- Hives
- Unusual discharge from breasts
- Feeling agitated
- Nervousness
- Inability to urinate
- Changes in certain laboratory test results

Side effects in children

The following side effects occur more frequently in children than adults:

- Movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement
- Seizures
- Feeling agitated

Not all side effects reported for MOTILIUM tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOTILIUM tablets, please consult your doctor, pharmacist or other healthcare professional for advice.

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

6. STORING AND DISPOSING OF MOTILIUM

Store MOTILIUM tablets at or below 25 ° C (this is at a normal room temperature) and protect from light.

This medicine can be kept for only a limited period. Do not use MOTILIUM tablets after the date (month and year) printed after "EXP", even if it has been stored properly. You are advised to return old medicine to your pharmacist.

Store all medicines out of reach of children.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MOTILIUM TABLETS

MOTILIUM tablets are available in cartons containing one or more blister packs of 10.

8. IDENTIFICATION OF MOTILIUM TABLETS

White circular, biconvex, film coated tablet 6,5 mm diameter engraved "M" 10 on one side and "JANSSEN" on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

K/5.7.2/261

Namibia Reg. No.: 90/5.7.2/..628 NS 2 Botswana Reg. No.: BOT2203863/A S3 Zimbabwe Reg. No.: 78/16.4/1180 PID

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Johnson & Johnson (Pty) Ltd

241 Main Road, Retreat,

7945, Cape Town

11. DATE OF PUBLICATION

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