SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Motilium 10 mg, film-coated tablets (domperidone maleate)
Motilium 10 mg, film-coated tablets (domperidone)
Motilium 1 mg/ml, oral suspension
Motilium Instant 10 mg, orodispersible tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One orodispersible tablet contains 10 mg of domperidone.
One film-coated tablet contains 10 mg of domperidone.
One film-coated tablet contains 12,72 mg of domperidone maleate equivalent to 10 mg of domperidone.
The oral suspension contains 1 mg of domperidone per ml.

Excipients with known effect:
Each orodispersible tablet contains 0,75 mg aspartame.
Each film-coated tablet (domperidone) contains 54.2 mg lactose monohydrate and less than 1 mmol sodium (23 mg), that is to say essentially 'sodium-free'.
Each film-coated tablet (domperidone maleate) contains 53.88 mg lactose monohydrate.
Each ml of the oral suspension contains 455 mg sorbitol liquid non-crystallizing, 1.8 mg methyl parahydroxybenzoate, 0.2 mg propyl parahydroxybenzoate and less than 1 mmol sodium (23 mg), that is to say essentially 'sodium-free'.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Domperidone film-coated tablet:
White to slightly cream-coloured, round, biconvex tablet.

Domperidone maleate film-coated tablet:
Off-white, round, biconvex tablet

Oral suspension:
White homogenous suspension.

Orodispersible tablet:
White to slightly off-white, round, freeze-dried tablets.

4. CLINICAL DATA

4.1. Therapeutic indications

Motilium is indicated for relieving the symptoms of nausea and vomiting.

4.2. Posology and method of administration

The lowest effective dose of Motilium must be used during the shortest time needed to control the nausea and vomiting.

It is recommended to take the oral forms of Motilium before meals. If the product is taken after the meal the absorption of the medicine is somewhat delayed.

Patients must take each dose as much as possible on the scheduled dose time. If a scheduled dose is missed, skip the missed dose and resume the normal dosing scheme. Do not take a double dose to make up for a forgotten dose.

The maximum duration of treatment is usually not more than one week.

Adults and adolescents (from 12 years of age with a body weight of 35 kg or more)

Tablets:
One tablet of 10 mg, maximum 3 times per day, with a maximum dose of 30 mg per day.

Orodispersible tablets
One tablet of 10 mg, maximum 3 times per day, with a maximum dose of 30 mg per day.

The orodispersible tablet quickly dissolves in the mouth using the saliva and can be taken with or without water. If the tablet is taken without water, it must be placed on the tongue and dissolve in the mouth before ingesting it. This may be followed by a glass of water if desired.

Oral suspension:
10 ml (of the oral suspension at 1 mg of domperidone per ml), maximum 3 times per day, with a maximum dose of 30 ml per day.

Liver insufficiency
Motilium is contraindicated in case of moderate or serious hepatic impairment (see section 4.3). However, the dose does not have to be adapted in subjects with moderate hepatic impairment (see section 5.2).

Kidney insufficiency
Since the elimination half-life of domperidone is prolonged in case of serious kidney insufficiency, the administration frequency of Motilium at repeated administration must be reduced to 1 or 2 times per day, dependent on the seriousness of the disorder, and it may be necessary to reduce the dose.

Paediatric population
The efficacy of Motilium in children less than 12 years of age has not been established (see section 5.1).
The efficacy of Motilium in adolescents 12 years of age and older and weighing less than 35 kg has not been established.

4.3. Contraindications

Domperidone is contraindicated in the following situations:
- hypersensitivity to the active substance or to one of the excipients mentioned in section 6.1.
- prolactin-secreting hypophysis tumour (prolactinoma);
- if a stimulation of the gastric motility is harmful, e.g. in patients with gastrointestinal bleeding, mechanical obstruction or perforation;
- in patients with moderate or serious hepatic impairment (see section 5.2);
- in patients with a known, existing prolongation of the cardiac conduction interval, particularly QTc, and patients with significant electrolytes disorders or underlying heart diseases, such as congestive heart failure (see section 4.4);

- concomitant administration of medicines which prolong the QT interval, excluding apomorphine (see sections 4.4 and 4.5);
- concomitant administration with strong CYP3A4 inhibitors (irrespective of their QT-prolonging effects) (see section 4.5).

4.4. Special warnings and precautions for use

Kidney insufficiency
The elimination half-life of domperidone is prolonged in case of serious kidney insufficiency. In case of repeated administration the administration frequency of domperidone must be decreased to 1 or 2 times per day, dependent on the seriousness of the disorder. It may also be necessary to reduce the dose.

Cardiovascular effects
Domperidone has been associated with prolongation of the QT interval on the electrocardiogram. During post-marketing surveillance there have been very rare cases of QT prolongation and *Torsade de Pointes* in patients using domperidone. These reports also included patients with disturbed risk factors, electrolyte deviations and concomitant treatment, which may have been a contributing factor (see section 4.8).

Epidemiological studies indicated that domperidone is associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death (see section 4.8.). A higher risk was observed in patients over 60 years of age, patients taking a daily dose of more than 30 mg, and patients on concomitant administration with QT-prolonging medicines or CYP3A4 inhibitors.

The lowest effective dose of domperidone must be used.

Domperidone is contraindicated in patients with a known, existing prolongation of the cardiac conduction interval, particularly QTc, and in patients with significant electrolytes disorders (hypokalaemia, hyperkalaemia, hypomagnesaemia) or bradycardia or in patients with underlying heart disorders such as congestive heart failure caused by an increased risk of ventricular arrhythmia (see section 4.3). Electrolytes disorders (hypokalaemia, hyperkalaemia, hypomagnesaemia) and bradycardia are known to increase the risk of proarrhythmia.

The treatment with domperidone must be discontinued in case of complaints or symptoms which may be associated with cardiac arrhythmia. In that case, patients should consult their doctor.

The patient should be recommended to report any heart problems immediately.

Use with apomorphine
Domperidone is contraindicated with QT-prolonging medicines including apomorphine, unless the benefit of concomitant administration with apomorphine outweighs the risks, and only if the recommended precautions for concomitant administration mentioned in the summary of product characteristics of apomorphine are strictly observed.
Please consult the summary of product characteristics of apomorphine.

Precautions for use
The film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
The oral suspension contains sorbitol, which may cause gastrointestinal discomfort and a mild laxative effect. Sorbitol is a source of fructose, and patient with hereditary fructose intolerance (HFI) should not be given this medicinal product. It also contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed) and exceptionally bronchospasm.

Use in patients who are at risk of hyperphenylalaninaemia
The orodispersible tablets contain aspartame which is a source of phenylanlanine. It may be harmful in patients with phenylketonuria (PKU). Do not use them in patients who are at risk of hyperphenylalaninaemia.

4.5. Interactions with other medicinal products and other forms of interaction

When antacids or antisecretory medicines are used simultaneously, they must not be taken simultaneously with oral forms of administration of Motilium (domperidone base) and should therefore be taken after meals and not before meals.

Concomitant administration with levodopa
Although a dose adaptation of levodopa is not considered necessary, an increase (maximum 30-40%) of the plasma concentration was observed when domperidone was taken simultaneously with levodopa.

Domperidone is metabolized mainly by CYP3A4. *In vitro* data suggest that the concomitant use of medicines which strongly inhibit this enzyme may cause an increase in the plasma concentration of domperidone.

Increased risk of QT interval prolongation by pharmacodynamic and/or pharmacokinetic interactions.

The concomitant use of the following products is contraindicated:
Medicines which prolong the QTc interval (risk of Torsades de Pointes):
- class IA antiarrhythmics (e.g. disopyramide, hydrokinidine, kinidine)
- class III antiarrhythmics (e.g. amiodarone, dofetilide, dronedarone, ibutilide, sotalol)
- certain antipsychotics (e.g. haloperidol, pimozide, sertindol)
- certain antidepressants (e.g. citalopram, escitalopram)
- certain antibiotics (e.g. erythromycin, levofloxacin, moxifloxacin, spiramycin)
- certain antifungal medication (e.g. fluconazole, pentamidine)
- certain antimalarial medication (particularly halofantrine, lumefantrine)
- certain gastrointestinal medicines (e.g. cisapride, dolasetron, prucalopride)
- certain antihistamines (e.g. mequitazine, mizolastine)
- certain cancer medicines (e.g. toremifene, vandetanib, vincamine)
- some other medicines (e.g. bepridil, difemanil, methadone)
- apomorphine, unless the benefit of concomitant administration outweighs the risks, and only if the recommended precautions for concomitant administration are strictly observed. Please consult the summary of product characteristics of apomorphine.

(see section 4.3).

Strong CYP3A4 inhibitors (irrespective of their QT-prolonging effect), such as:
- protease inhibitors (e.g. ritonavir, saquinavir, telaprevir)
- systemic azole antifungal medication (e.g. itraconazole, ketoconazole, posaconazole, voriconazole)
- some macrolide antibiotics (e.g. clarithromycin and telithromycin)

(see section 4.3).

Concomitant use of the following products is not recommended.
Moderate CYP3A4 inhibitors such as diltiazem, verapamil and some macrolides (see section 4.3).

Caution should be exercised with the concomitant use of the following products.
Caution should be exercised when using bradycardia- and hypokalaemia-inducing medicines and when using the following marcolides which are involved in the prolongation of the QT interval:

azithromycin and roxithromycin (clarithromycin is contraindicated, since this medicinal product is a strong CYP3A4 inhibitor).

The above list of products is representative but not restrictive.

4.6. Fertility, pregnancy and lactation

Pregnancy
There are limited post-marketing data available about the use of domperidone in pregnant women. A study in rats has shown reproduction toxicity at a high, maternally toxic dose. The possible risk in humans is not known. Therefore Motilium may be used only during the pregnancy if it is justified by the expected therapeutic benefit.

Breast feeding
Domperidone is excreted into human breast milk and breast-fed infants receive less than 0.1% of the maternal dose, adapted according to their weight. The occurrence of adverse effects after exposure via the human breast milk, particularly effects on the heart, cannot be ruled out. The decision must be taken to either stop the breastfeeding or to stop or not start the treatment with domperidone, whereby the benefit of breastfeeding for the child and the benefit of treatment for the woman must be taken into consideration. Caution should be exercised in case of risk factors for QTc prolongation in breast-fed infants.

4.7. Effects on ability to drive and use machines

Dizziness and drowsiness were observed after the use of domperidone (see section 4.8). Therefore patients must be recommended not to drive vehicles or use machines or to perform other activities requiring mental alertness and coordination until they have established what the influence of Motilium is on them.

4.8. Undesirable effects

The safety of domperidone was evaluated by examining clinical studies and during post-marketing experience. The clinical studies involved 1275 patients suffering from dyspepsia, gastro-oesophageal reflux disorder (GERD), irritable bowel syndrome (IBS), nausea and vomiting or other related conditions and 31 double-blind, placebo-controlled examinations were carried out. All patients were at least 15 years old and received at least one dose of Motilium (domperidone base). The median total daily dose was 30 mg (spreading 10 to 80 mg), and the median duration of the exposure was 28 days (spreading 1 to 28 days). Examination in case of diabetic gastroparesis or symptoms as a result of chemotherapy or parkinsonism were excluded.

The following terms and frequencies are used: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10.000 to <1/1000) and very rare (<1/10.000). Where the frequency cannot be estimated from clinical examination, it is recorded as “Not known”.

System/organ class	**Side effect Frequency**		
	Common	**Uncommon**	**Not known**
Immune system disorders			Anaphylactic reactions (inclusive of anaphylactic shock)
Psychiatric disorders		Loss of libido Anxiety Restlessness Nervousness	

Nervous system disorders		Dizziness Drowsiness Headache Extrapyramidal disorders	Convulsions “Restless leg” syndrome*
Eye disorders			Rolling eyes
Cardiac disorders			Ventricular arrhythmia Prolongation of the QTc interval, Torsade de Pointes Sudden cardiac death (see section 4.4)
Gastrointestinal disorders	Dry mouth	Diarrhoea	
Skin and subcutaneous tissue disorders		Rash Itching Hives	Angioedema
Renal and urinary disorders			Urinary retention
Reproductive system and breast disorders		Galactorrhoea Chest pain Sensitivity in the breasts	Gynaecomastia Amenorrhea
General disorders and administration site conditions		Asthenia	
Examinations			Deviating liver function tests, Increased prolactin level in the blood

*worsening of “restless leg” syndrome in patients suffering from Parkinson's disease

In 45 clinical examinations where domperidone in higher doses was used over a longer period of time and for other indications, including diabetic gastroparesis, the frequency of adverse reactions (except dry mouth) was considerably higher. This was particularly obvious for pharmacologically predictable events as a result of an increased prolactin level. Apart from the above-mentioned reactions also akathisia, breast secretion, fuller breasts, swelling of the breasts, depression, oversensitivity, breastfeeding disorder and irregular menstruation were observed.

Notification of possible adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report all suspected adverse reactions via the Federal Agency for Medicines and Health Products, Vigilance Department, Eurostation II, Victor Hortaplein 40/40, B-1060 Brussels (www.fagg.be; adversedrugreactions@fagg-afmps.be).

4.9. Overdose

Symptoms
Overdose was reported mainly in infants and children. The symptoms of overdose may be: restlessness, altered consciousness, convulsions, disorientation, drowsiness and extrapyramidal reactions.

Treatment

There is no specific antidote against domperidone. In case of overdose a standard symptomatic treatment must be started immediately. ECG monitoring must be carried out, because of the possibility of prolongation of the QT interval. Close medical monitoring and supporting measures are recommended. Anticholinergic, anti-Parkinson medicines may be useful for treating extrapyramidal disorders.

It is advisable to contact a poison control centre to obtain the latest recommendations for the management of an overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic category: Propulsives, ATC code: A03F A 03

Domperidone is a dopamine antagonist with antiemetic properties. Domperidone does not easily penetrate the blood-brain barrier. Domperidone users, especially adults, very rarely get extrapyramidal disorders, but domperidone stimulates the secretion of prolactin from the hypophysis. The antiemetic effect is probably attributable to a combination of peripheral (gastrokinetic) effects and an antagonism of dopamine receptors in the trigger zone of the chemoreceptor, which is located outside the blood-brain barrier in the area postrema. Experiments on animals, together with the low concentrations found in the brain, indicate a predominantly peripheral effect of domperidone on the dopamine receptors. Examinations in humans have shown that oral domperidone increases the lower oesophageal pressure, improves the antroduodenal motility and accelerates the emptying of the stomach. There is no effect on the excretion of gastric juices.

In accordance with the ICH-E14 guidelines a thorough QT study was carried out. This study, in which a placebo, an active comparator and a positive control was used, was carried out in healthy subjects who received maximum 80 mg of domperidone per day (10 or 20 mg of domperidone 4 times per day). On day 4 of this study a maximum QTc difference of 3.4 msec was found between domperidone and the placebo in the LS average change compared to baseline in a dose of 20 mg of domperidone 4 times per day. The two-sided 90% BI (1.0 to 5.9 msec) did not exceed 10 msec. When administering domperidone in a dosing of maximum 80 mg/day (i.e. more than two times the maximum recommended dose) no clinically relevant QTc effects were observed in this study.
However, two previous medicine interaction studies gave some indication for QTc prolongation when using domperidone as a monotherapy (10 mg 4 times per day). The biggest time-matched average difference in QTcF between domperidone and the placebo was 5.4 msec (95% BI: -1.7 to 12.4) and 7.5 msec (95% BI: 0.6 to 14.4), respectively.

Clinical study in infants and children 12 years of age and younger
A multicentre, double blind, randomised, placebo controlled, parallel group, prospective study was conducted to evaluate the safety and efficacy of domperidone in 292 children with acute gastroenteritis aged 6 months to 12 years (median age 7 years). In addition to oral rehydration treatment (ORT), randomised subjects received domperidone oral suspension at 0.25 mg/kg (up to a maximum of 30 mg domperidone/day), or placebo, 3 times a day, for up to 7 days. This study did not achieve the primary objective, which was to demonstrate that domperidone suspension plus ORT is more effective than placebo plus ORT at reducing the symptoms of vomiting during the first 48 hours after the first treatment administration (see section 4.2).

5.2 Pharmacokinetic properties

Absorption
Domperidone is absorbed quickly after oral administration, with peak plasma concentrations approximately 1 hour after administration. Within the dose range of 10 mg to 20 mg the C_{max} and AUC values of domperidone increased proportionally with the dose. A two- to threefold accumulation

in the AUC of domperidone was observed at repeated doses of domperidone of 4 times per day (every 5 hours) for 4 days.

Although the bioavailability of domperidone is increased in ordinary subjects when taken after a meal, patients with gastrointestinal problems must take domperidone 15-30 minutes before a meal. The absorption of domperidone is decreased by low acid levels in the stomach. The oral bioavailability is decreased by prior concomitant administration of cimetidine and sodium bicarbonate.

Distribution
Domperidone binds for 91-93% to plasma proteins. Examinations of the distribution with radioactively marked medicine in animals has shown a broad tissue distribution, but a low concentration in the brain. Small quantities of the medicine penetrate the placenta in rats.

Biotransformation
Domperidone undergoes a quick and extensive liver metabolism by hydroxylation and N-dealkylation. *In vitro* experiments of the metabolism with diagnostic inhibitors have shown that CYP3A4 is one of the main isozymes of cytochrome P-450, which is involved in the N-dealkylation of domperidone, while CYP3A4, CYP1A2 and CYP2E1 are involved in the aromatic hydroxylation of domperidone.

Elimination
The amount excreted in the urine and faeces is 31 and 66% of the oral dose, respectively. The proportion of the medicine excreted in unchanged form is small (10% of the faecal excretion and approximately 1% of the urine excretion). The plasma half-life after a single oral dose is 7-9 hours in healthy subjects, but longer in patients with a serious kidney insufficiency.

Liver insufficiency
In subjects with moderate hepatic impairment (Pugh Score 7 to 9, Child-Pugh score B) the AUC and C_{max} of domperidone are 2.9 and 1.5 times higher, respectively, than in healthy subjects. The free fraction increases by 25%, and the terminal elimination half-life is prolonged from 15 to 23 hours. Patients with moderate hepatic impairment show a slightly lower systemic exposure than healthy subjects based on the C_{max} and the AUC, with no change in the protein binding of the terminal half-life. Subjects with serious hepatic impairment were not studied. Domperidone is contraindicated in patients with moderate to serious hepatic impairment (see section 4.3).

Kidney insufficiency
In subjects with serious kidney insufficiency (creatinine clearance<30 ml/min/1.73m$^{2)}$ the elimination half-life of domperidone increased from 7.4 to 20.8 hours, but the medicine concentration in the plasma was lower than in healthy volunteers s
Since a very small amount of medicine (approximately 1%) is excreted in unchanged form via the kidneys, it is unlikely that the dose of one administration should be adapted in patients with kidney insufficiency.
However, in case of repeated administration the administration frequency must be reduced to 1 or 2 times per day, dependent on the seriousness of the disorder, and a dose reduction may be necessary.

5.3. Preclinical safety data

Electrophysiological *in vitro* and *in vivo* examinations indicate a generally moderate risk of QTc prolongation by domperidone in humans. In *in vitro* experiments on isolated cells that were transfected with hERG and on isolated myocytes of the guinea pig, the exposure ratios were approximately 26 to 47 times higher, based on the IC50 values, whereby electric currents through IK_r ion channels were inhibited compared to the free plasma concentration in humans after administration of the maximum daily dose of 10 mg 3 times per day. The safety margins for prolongation of the duration of the action potential in *in vitro* experiments on isolated heart tissue exceeded the free plasma concentration in people at the maximum daily dose (10 mg 3 times per day) with a factor 45.

The safety margins in *in vitro* pro-arrhythmic models (isolated perfused heart according to Langendorff) exceeded the free plasma concentration in humans at the maximum daily dose (10 mg 3 times per day) with a factor 9 to 45. In *in vivo* models the levels which had no effect on QTc prolongation in dogs and the induction of arrhythmia in a rabbit model were sensitised for *Torsade de Pointes*, 22 and 453 times higher, respectively, than the free plasma concentration in humans at the maximum daily dose (10 mg 3 times per day). In the model with sedated guinea pigs no effects on QTc were observed after slow intravenous infusions at a total plasma concentration of 45.4 ng/ml, which is 3 times higher than the total plasma level in humans at a maximum daily dose (10 mg 3 times per day). The relevance of the last examination for humans after exposure to orally administered domperidone is not clear.

If the metabolism is inhibited via CYP3A4, the free plasma concentration of domperidone can increase to 3 times.

At a high, maternally toxic dose (more than 40 times the recommended dose for humans), teratogenic effects were observed in rats. No teratogenicity was observed in mice and rabbits.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Film-coated tablets (domperidone maleate):
Lactose monohydrate, maize starch, microcrystalline cellulose, povidone K90, pregelatinized potato starch, magnesium stearate, colloidal anhydrous silica, polysorbate 20, hypromellose, propylene glycol.

Film-coated tablets (domperidone):
Lactose monohydrate, maize starch, microcrystalline cellulose, pregelatinized potato starch, povidone K90, magnesium stearate, hydrogenated cotton seed oil, sodium lauryl sulphate, hypromellose.

Orodispersible tablets:
Gelatine, mannitol (E421), aspartame (E951), mint flavour, poloxamer 188.

Oral suspension:
Sorbitol liquid non-crystallizing (E420), microcrystalline cellulose and sodium carboxymethyl cellulose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium saccharine, polysorbate 20, sodium hydroxide and purified water.

6.2. Incompatibilities

Not known

6.3. Shelf life

Film-coated tablets (domperidone maleate): 5 years
Film-coated tablets (domperidone): 3 years
Oral suspension: 3 years. After opening of the bottle the suspension can be kept for another 3 months.
Orodispersible tablets: 2 years

6.4. Special precautions for storage

Film-coated tablets (domperidone maleate), film-coated tablets (domperidone), orodispersible tablets, oral suspension: These medicinal products do not require any special storage conditions.
Keep Motilium out of sight and reach of children.

6.5. Nature and contents of the pack

Film-coated tablets (domperidone maleate):
Blister pack with 30 or 100 tablets (unit dose pack for hospital use).

Film-coated tablets (domperidone):
Blister pack containing 20, 30 or 100 tablets.

Orodispersible tablets:
Blister pack containing 10, 20 or 30 tablets.

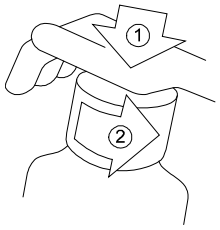
Oral suspension:
Bottle containing 200 ml of drinkable liquid (with plastic dosing cap of 10 ml; the dosing cap has marks for 2.5 and 5 ml).

Oral suspension:
Bottle containing 100 ml of drinkable liquid (with plastic dosing cap of 10 ml; the dosing cap has marks for 2.5 and 5 ml).

Not all pack sizes may be marketed.

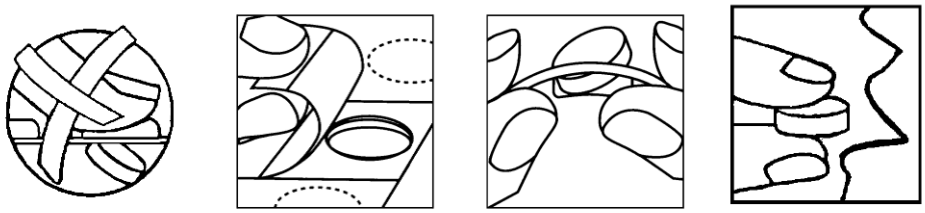
6.6. Special precautions for disposal and other handling

Oral suspension:
The bottle containing drinkable liquid "adults" must be opened as follows:
Push the plastic screw cap down while turning it counter-clockwise (see figure). Mix the contents of the bottle completely, with a gentle movement to prevent foam formation.



Orodispersible tablets
Motilium orodispersible tablets are dispensed in a blister pack containing 10 tablets. The orodispersible tablets are fragile and dissolve easily, which means that they should not be pushed through the foil. This would crush the tablet.
To take the tablet from the blister:
- do not push the tablet through the foil
- pull the side of the foil up and completely pull the foil away
- push the tablet upwards
- take the tablet from the blister

Then place the Motilium orodispersible tablet on the tongue. It melts on the tongue within a few seconds and is swallowed with the saliva. There is no need to take them with liquid.



7. MARKETING AUTHORISATION HOLDER

Johnson & Johnson Consumer NV/SA
Antwerpseweg 15-17
B-2340 Beerse

8. MARKETING AUTHORISATION NUMBERS

Film-coated tablets (domperidone maleate):	BE109986
Film-coated tablets (domperidone):	BE272167
Orodispersible tablets:	BE274827
Oral suspension 200 ml:	BE190662
Oral suspension 100 ml:	BE110013

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Film-coated tablets (domperidone maleate):	01/03/1978
Film-coated tablets (domperidone):	25/04/2005
Orodispersible tablets:	25/01/1999
Oral suspension 200 ml:	23/03/1978
Oral suspension 100 ml:	01/03/1978

10. DATE OF REVISION OF THE TEXT

November 2020
Date of approval of the text: November 2020