PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MOTIVOM 10 ODT orodispersible tablets

Domperidone

Contains sugar alcohol: Each orodispersible tablet contains 187 mg mannitol.

Contains sweetener: Each orodispersible tablet contains 7,5 mg aspartame.

Read all of this leaflet carefully before you start taking MOTIVOM 10 ODT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MOTIVOM 10 ODT has 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.

What is in this leaflet

1. What MOTIVOM 10 ODT is and what it is used for.
2. What you need to know before you take MOTIVOM 10 ODT.
3. How to take MOTIVOM 10 ODT.
4. Possible side effects.
5. How to store MOTIVOM 10 ODT.
6. Contents of the pack and other information.

1. What MOTIVOM 10 ODT is and what it is used for

MOTIVOM 10 ODT contain domperidone as the active ingredient, which belongs to a group of medicines called dopamine antagonists. It is used in adults and adolescents (12 years of age and older and weighing 35 kg or more) to:

- Treat stomach discomfort and acid reflux which is the result of decreased stomach movements;
- Treat nausea (feeling sick) and vomiting (being sick);
- Treat nausea during cancer treatment (radio- or chemotherapy);
- Make radiological examinations of the stomach easier.

2. What you need to know before you take MOTIVOM 10 ODT

Do not take MOTIVOM 10 ODT:

- If you are hypersensitive (allergic) to domperidone or any of the other ingredients of MOTIVOM 10 ODT (see section 6);
- If you have a tumour of the pituitary gland (prolactinoma);
- If you suffer from a blockage or a tear (perforation) in your intestines, or you have bleeding in your stomach or intestines causing black tarry stools or blood in your bowel movements;
- If you suffer from moderate or severe liver problems;
- If your electrocardiogram (ECG) shows a heart problem called “prolonged QT corrected interval”, or you have a family history thereof;
- If you have an imbalance of electrolytes in your body causing too low levels of potassium or magnesium, or too high levels of potassium in your body;
- If you have or had a problem where your heart cannot pump the blood round your body as well as it should, a condition called heart failure;
- If your heart beats excessively slow (bradycardia) or if you heart condition known as a heart block;
- If you are taking medicines known as CYP3A4 inhibitors (see “Other medicines and MOTIVOM 10 ODT” below);

- If you are taking medicines which can affect your heart, causing changes in the way your heart beats (see "Other medicines and MOTIVOM 10 ODT" below).

Warnings and precautions

Take special care with MOTIVOM 10 ODT:

- If you are older than 60 years of age;
- If you suffer from severe kidney disorders. It is advisable to ask your doctor for advice in case of prolonged treatment as you may need to take a lower dose or take MOTIVOM 10 ODT less often, and your doctor may want to examine you regularly.

MOTIVOM 10 ODT can cause heart problems including changes in your heart rhythm (how your heart beats) and cardiac arrest (where the heart stops beating due to changes in heart rhythm). This is more likely to occur if you are taking higher doses of MOTIVOM 10 ODT (above 30 mg a day), if you are over 60 years of age or if you have an electrolyte (salt) imbalance (which can happen if you are dehydrated or suffering from severe diarrhoea and/or vomiting). The risk also increases when MOTIVOM 10 ODT is given together with some other medicines. See "Other medicines and MOTIVOM 10 ODT" below.
If you experience any changes in the way your heart beats, for example palpitations, breathing problems or fainting (you experience black-outs also known as loss of consciousness) while taking MOTIVOM 10 ODT, stop taking it and contact your doctor immediately.

MOTIVOM 10 ODT should be used at the lowest effective dose to treat your condition. Your doctor will tell you what dose is right for you.

Children and adolescents

MOTIVOM 10 ODT is not suitable for use in children under the age of 12 years or weighing less than 35 kg.

Other medicines and MOTIVOM 10 ODT

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

Do not take MOTIVOM 10 ODT if you are currently using:

- Antidysrhythmic medicines, including disopyramide, hydroquinidine, quinidine, amiodarone, dofetilide, dronedarone, ibutalide, sotalol (used to treat an abnormal heartbeat);
- Certain antipsychotic medicines, including haloperidol, pimozide, sertindole (used to treat psychosis or mood disorders);
- Certain antidepressant medicines, including citalopram, escitalopram (used to treat depression);
- Certain antibiotics, including erythromycin, levofloxacin, moxifloxacin, spiramycin, clarithromycin, telithromycin (used to treat bacterial infections);
- Certain antifungal medicines, including pentamidine, azole antifungals (used to treat fungal infections);
- Certain antimalarial medicines, including halofantrine, lumentrine (used to treat malaria);
- Certain gastrointestinal medicines, including cisapride (used to enhance the bowel movements), dolasetron (used to treat nausea and vomiting during cancer treatment), prucalopride (used to normalise bowel movements);
- Certain medicines used in cancer, including toremifene and vandetanib, vincamine;
- Bepridil (used to treat angina);
- Diphemanil (used to treat stomach ulcers or stomach problems);
- Methadone (used to treat chronic pain);
- Protease inhibitors (used to treat HIV);
- Apomorphine (used to treat difficulty in moving in Parkinson’s disease).

Tell your doctor or pharmacist if you are currently using:

- Diltiazem or verapamil (used to treat high blood pressure, abnormal heart beats or angina);
- Azithromycin and roxithromycin (used to treat bacterial infections);

- Ketoconazole (used to treat fungal infections);
- Antacid medicines, cimetidine, sodium bicarbonate (used to treat heart burn, stomach ulcers). You should not take your antacid medicines with MOTIVOM 10 ODT. If you have to take them together, you must take MOTIVOM 10 ODT before your meal and your antacid medicine after your meal;
- Dextromethorphan (used to treat cough);
- Diphenhydramine (used to treat colds or allergies (hay-fever));
- Medicines that reduce prolactin levels in your body.

MOTIVOM 10 ODT with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MOTIVOM 10 ODT.

Safety of MOTIVOM 10 ODT during pregnancy has not been established. MOTIVOM 10 ODT is excreted in breast milk. Do not use MOTIVOM 10 ODT if you are pregnant or breastfeeding.

Driving and using machines

MOTIVOM 10 ODT can cause side effects, such as drowsiness or dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how MOTIVOM 10 ODT affects you.

MOTIVOM 10 ODT contains aspartame

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take MOTIVOM 10 ODT

Do not share medicines prescribed for you with any other person.

Always take MOTIVOM 10 ODT exactly as your doctor have told you. Check with your doctor if you are not sure.

The usual dose is 1 tablet taken up to three time per day.

Your doctor will determine the correct dose for you.

Do not exceed the recommended dosage.

Take the tablets 15 to 30 minutes before a meal.

It is recommended to take MOTIVOM 10 ODT before meals, as when taken after meals the absorption of MOTIVOM 10 ODT is slightly delayed.

MOTIVOM 10 ODT is an orodispersible tablet; that means that it dissolves rapidly in the mouth in the saliva, and can be taken without water.

To take MOTIVOM 10 ODT, let the tablet dissolve in the mouth without chewing. A drink of water may be taken after, if necessary.

If you have the impression that the effect of MOTIVOM 10 ODT is too strong or too weak, tell your doctor or pharmacist.

If you take more MOTIVOM 10 ODT than you should

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

Take this leaflet and the rest of the remaining MOTIVOM 10 ODT with you so the doctor will know what you have taken.

If you forget to take MOTIVOM 10 ODT

If you forget to take MOTIVOM 10 ODT, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue as normal. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MOTIVOM 10 ODT can have side effects.

Not all side effects reported for MOTIVOM 10 ODT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOTIVOM 10 ODT, please consult your health care provider for advice.

If any of the following happens, stop taking MOTIVOM 10 ODT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MOTIVOM 10 ODT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- convulsions (fit/seizure);
- uncontrolled movements, including irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness;
- changes in the way your heart beats, including changes seen on an electrocardiogram (ECG).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- feeling depressed;
- inability to stay still (restlessness);
- drowsiness or weakness;
- headache;
- dry mouth;
- diarrhoea;
- mild rash or itchiness;
- enlarged breasts, absent or irregular period (menstrual cycle), unusual production of breast milk, breast pain or tenderness.

Side effects occurring less frequently:

- feeling anxious;
- loss of libido (sex drive);
- hives;
- breast discharge or swelling.

The following side effects may occur, but the frequency is not known:

- feeling agitated or nervous;
- dizziness;
- involuntary upward movement of your eyes;
- inability to empty your bladder;
- blood test shows changes in the way your liver is working;
- an increased level of the hormone prolactin present in the blood (determined through blood tests).

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of MOTIVOM 10 ODT.

5. How to store MOTIVOM 10 ODT

- Store at or below 30 °C.
- Keep the blister strips in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MOTIVOM 10 ODT contains

Each orodispersible tablet contains 10 mg of domperidone.

The other ingredients are aspartame, colloidal silicon dioxide, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose and peppermint flavour.

What MOTIVOM 10 ODT looks like and contents of the pack

White to off-white, round, flat, bevelled edged tablets, plain on both sides, with a peppermint odour.

Aluminium-Aluminium blister strips containing 10 tablets, packed into an outer carton.

Pack size: 10 or 100 tablets.

Holder of certificate of registration

Activo Health (Pty) Ltd

Block B, Arena Office Park

272 West Avenue

Centurion, 0157

South Africa

Tel: +27 12 848 7600

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