PROPOSED CLEAN PATIENT INFORMATION LEAFLET

DOMPERIDONE CIPLA

SCHEDULING STATUS: S4

DOMPERIDONE CIPLA 10 mg orally disintegrating tablets

Domperidone 10 mg

Contains sugar: Mannitol (187 mg)

Contains sweetener: Aspartame (7.5 mg)

Read all of this leaflet carefully before you start taking DOMPERIDONE CIPLA

- 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.
- DOMPERIDONE CIPLA 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 DOMPERIDONE CIPLA is and what it is used for.
2. What you need to know before you take DOMPERIDONE CIPLA.
3. How to take DOMPERIDONE CIPLA.

4. Possible side effects.
5. How to store DOMPERIDONE CIPLA.
6. Contents of the pack and other information.

1. What DOMPERIDONE CIPLA is and what it is used for

DOMPERIDONE CIPLA contains domperidone which belongs to a group of medicines called anti-emetics (nausea) and anti-vertigo (dizziness) medicines.

DOMPERIDONE CIPLA is used to treat adults and children over 35 kg for:

- Reflux and /or indigestion caused by delayed emptying of the stomach.
- Nausea and vomiting.
- Nausea related to receiving chemotherapy and radiation therapy.
- Facilitation of radiological examination of the upper part of the stomach.

2. What you need to know before you take DOMPERIDONE CIPLA

Do NOT take DOMPERIDONE CIPLA

- If you are hypersensitive (allergic) to domperidone or any of the other ingredients of DOMPERIDONE CIPLA (listed in **section 6**).
- If you have prolactin-releasing tumour on your pituitary gland (prolactinoma).
- If you have bleeding in your stomach (can be identified by blood in your stool).
- If you have a blockage or tear in your stomach.
- If you are taking other medicines which inhibit CYP3A4 (an important enzyme in the body, mainly found in liver) such as:

    - Antifungal medicines such as fluconazole, itraconazole, ketoconazole, voriconazole, posaconazole.
    - Antibiotics such as clarithromycin, erythromycin, azithromycin, roxithromycin, telithromycin, quinolones.
    - Medicines used to treat heart conditions such as amiodarone.
    - Medicines used to treat viral infections which fall under the class called protease inhibitors such as amprenavir, atazanavir, fosamprenavir, indinavir, nelfinavir, ritonavir.
- If you are taking medicines that are known to cause an abnormal type of heart rhythm such as cisapride.
- If you have low blood potassium levels (hypokalaemia).
- If you have low blood magnesium levels (hypomagnesaemia).
- If you have a slow heart rate or heart block.
- If you have pre-existing heart disease.
- If you have a family history of a disturbance in your heart rhythm (Called QT interval prolongation).
- If you have been diagnosed with moderate or severe liver damage.
- If you have been diagnosed with kidney disease.

Warnings and precautions

Special care should be taken with DOMPERIDONE CIPLA:

- If you are older than 60 years of age.

- If you are taking an oral dose of DOMPERIDONE CIPLA more than 30 mg per day.
- If you are also taking other medicines causing a disturbance in your heart rhythm such as cisapride.
- If you are taking antacids. When taken together with DOMPERIDONE CIPLA, antacids should be taken after meals while DOMPERIDONE CIPLA should be taken before meals.
- DOMPERIDONE CIPLA contains mannitol and may have laxative effect.
- Domperidone Cipla 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.

Children and adolescents

DOMPERIDONE CIPLA is not suitable for use in children weighing less than 35 kg.

Other medicines and DOMPERIDONE CIPLA

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

The following medicines may increase the effect of DOMPERIDONE CIPLA:

- Medicines used to treat abnormal rhythms of the heart such as quinidine and disopyramide, amiodarone, dofetilide, dronedarone, ilbutilide, sotalol.

- Medicines used to treat abnormal conditions of the brain such as delusions, hallucinations, bipolar disorder etc such as haloperidol, pomizide, sertindole.
- Medicines used in the treatment of depression such as citalopram, escitalopram.
- Certain antibiotics such as levofloxacin, moxifloxacin and quinolones.
- Certain anti-fungal medicines such as pentamidine.
- Certain anti-malarial medicines such as halofantrine.
- Certain medicines used to treat stomach related conditions such as dolasetron.
- Certain antihistamine medicines used to treat allergies and allergic reactions such mequitazine, mizolastine.
- Certain medicines used in cancer treatment such as toremifene, vandetanib.
- Apomorphine (A medicine used to treat patients with advanced Parkinson's disease).
- A class of medicines used in the treatment of patients with HIV/AIDS Protease inhibitors such as ritonavir.
- Antifungal medicines such as fluconazole.
- Antibiotics which fall under a class called macrolides such as erythromycin, clarithromycin and telithromycin.
- Medicines used to treat high blood pressure such as diltiazem and verapamil.

The following medicines may reduce the effects of DOMPERIDONE CIPLA:

- Medicines which fall under a class called anticholinergics such as dextromethorphan and diphenhydramine.
- Medicines which reduce the acidity of the stomach such as cimetidine and sodium bicarbonate.

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 this medicine.

The safety of DOMPERIDONE CIPLA during pregnancy has not been established.

If you are breastfeeding, then DOMPERIDONE CIPLA is not recommended for you as it passes into the breast milk.

Driving and using machines

DOMPERIDONE CIPLA may make you feel drowsy and sleepy. Therefore, if you are using DOMPERIDONE CIPLA you should not drive, use any machines until you are aware of the measure to which DOMPERIDONE CIPLA affects you.

3. How to take DOMPERIDONE CIPLA

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

Always take DOMPERIDONE CIPLA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 30 mg daily (three DOMPERIDONE CIPLA tablets).

The maximum dose is 40 mg daily (four DOMPERIDONE CIPLA tablets).

You should take DOMPERIDONE CIPLA orally, 15 to 30 minutes before a meal.

If you take more DOMPERIDONE CIPLA 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.

The symptoms of DOMPERIDONE CIPLA overdose include:

- Agitation (A state of anxiety or nervous excitement).
- Altered consciousness (A state of feeling drowsy or dream like state).
- Convulsion (A violent irregular movement of the body).
- Disorientation (A feeling of losing one's sense of direction).
- Somnolence (Sleeping for unusually long periods or a strong desire for sleep).
- Extrapyramidal reactions (These may include shaking at the hands, slurred speech, anxiety, distress, paranoia etc.).

If you forget to take DOMPERIDONE CIPLA

Do not take a double dose to make up for the forgotten individual doses.

4 . Possible side effects

DOMPERIDONE CIPLA can have side effects.

Not all side effects reported for DOMPERIDONE CIPLA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking DOMPERIDONE CIPLA, please consult your health care provider for advice.

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

- Hypersensitivity (An allergic reaction in response to taking DOMPERIDONE CIPLA).
- Anaphylactic reaction including anaphylactic shock (A life threatening allergic reaction in response to taking DOMPERIDONE CIPLA).
- Rash, pruritis (When the skin becomes red, inflamed and itchy making you want to scratch it constantly).
- Hives (Also known as urticaria, which is swollen, pale, red bumps that appear on the skin suddenly).

These are all very serious side effects. If you have them, you may have had a serious reaction to DOMPERIDONE CIPLA. 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:

- If you go for a liver function test and your result is abnormal.
- Sudden heart problems, which can include an irregular heart rate, chest pain etc.

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

Tell your doctor if you notice the following:

Frequent side effects:

- Depression.

- Dry mouth.
- Breast enlargement.
- Breast tenderness, breast pain.
- A lack of menstruation.
- Irregular menstruation.
- Lack of milk production in breastfeeding women.
- Feeling physically weak or a lack of energy.
- Headache.
- A condition called akathisia which makes it very difficult for you to stay still. You may feel the need to move or fidget all the time.
- Diarrhoea.

Less frequent side effects:

- Hypersensitivity.
- A reduction or loss of sex drive.
- Sleepiness.
- Anxiety (To have a feeling of worry, nervousness or unease about something).
- Discharge of liquid from the breasts.
- Breast swelling.
- A milky discharge from the nipples.

Side effects where the frequency is unknown:

- Feeling agitated.
- Nervousness.
- Convulsion (A sudden, violent, irregular movement of the body).
- Abnormality or impairment of movement.
- An involuntary upward movement of the eyes.
- Difficulty urinating.
- An increased level of the hormone prolactin present in the blood (determined through blood tests).
- Dizziness.

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 or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of DOMPERIDONE CIPLA.

5. How to store DOMPERIDONE CIPLA

Store all medicines out of reach of children.

There are no special storage instructions for DOMPERIDONE CIPLA.

Store in the original package.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

The active substance in DOMPERIDONE CIPLA is domperidone.

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

What DOMPERIDONE CIPLA looks like and contents of the pack

DOMPERIDONE CIPLA are white to off-white, round, flat, bevelled edged tablets, plain on both sides, having peppermint odour.

DOMPERIDONE CIPLA 10 mg orally disintegrating tablets are packed in an Alu-Alu blister pack of 10 tablets each. Such 10 blister strips are packed into one carton together with one leaflet.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR code below.

PLACE HOLDER:

The QR code to be generated and included after approval