Package leaflet: Information for the user

Pantoprazole & Domperidone gastro-resistant Tablets (20 mg + 10 mg)

**PANSA D**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet**

1. What Pansa D is and what it is used for

2. What you need to know before you take Pansa D

3. How to take Pansa D

4. Possible side effects

5. How to store Pansa D

6. Contents of the pack and other information

**1. What Pansa D is and what it is used for**

Pansa D is the combination of Pantoprazole & Domperidone. Pantoprazole is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine. Domperidone as the active ingredient, which belongs to a group of medicines called 'dopamine antagonists'.

Pansa D is used for the treatment of GERD not responding to pantoprazole.

**2. What you need to know before you take Pansa D**

**Do not take Pansa D if you are**

- If you are allergic to pantoprazole, domperidone or to any of the other ingredients listed in the formulation
- If you are allergic to medicines containing other proton pump inhibitors.
- You have black, tarry bowel motions (stools) or notice blood in your bowel motions. This could be a sign of bleeding in the stomach or intestines
- You have a blockage or tear in your intestines
- You have a tumour of the pituitary gland called a prolactinoma.
- have a disorder known as phenylketonuria (a metabolic disorder) orodispersible tablets should not be used as they contain aspartamine
- if you have a moderate or severe liver disease

- if your ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval"
- if you have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure).
- if you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.

Do not take Pansa D tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Pansa D tablet. Do this even if they have applied in the past.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Pansa D

- If you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently, especially when you are taking Pantoprazole as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- If you are on Pantoprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- If you have ever had a skin reaction after treatment with a medicine similar to Pantoprazole that reduces stomach acid.
- If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Pantoprazole. Remember to also mention any other ill-effects like pain in your joints.
- if you are due to have a specific blood test (Chromogranin A).
- if you suffer from liver problems (liver function impairment or failure)
- if you suffer from kidney problems (kidney function impairment or failure).

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 this medicine less often, and your doctor may want to examine you regularly. Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30mg per day. The risk also increases when domperidone is given together with some drugs. Tell your doctor or pharmacist if you are taking drugs to treat infection (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV. Domperidone should be used at the lowest effective dose. While taking domperidone, contact your doctor if you experience heart

rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with domperidone should be stopped.

Adolescents weighing less than 35 kg and children

Pansa D should not be given to adolescents 12 years of age and older weighing less than 35 kg, or in any children less than 12 years of age, as it is not effective in these age groups.

Tell your doctor immediately, before or after taking this medicine, if you notice any of the following

- An unintentional loss of weight
- Vomiting, particularly if repeated
- Vomiting blood; this may appear as dark coffee grounds in your vomit
- You notice blood in your stools; which may be black or tarry in appearance
- Difficulty in swallowing or pain when swallowing
- You look pale and feel weak (anaemia)
- Chest pain, Stomach pain, severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered. If you take Pantoprazole on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

**Other medicines and Pansa D**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because Pantoprazole may influence the effectiveness of other medicines, so tell your doctor if you are taking:

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Pantoprazole treatment because pantoprazole can increase levels of methotrexate in the blood.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose.
- Rifampicin (used to treat infections).
- St John’s wort (Hypericum perforatum) (used to treat mild depression).

Do not take Domperidone tablet if you are taking medicine to treat:

- fungal infections such as azole antifungals, specifically oral ketoconazole, fluconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin,moxifloxacin, pentamidine (these are antibiotics)

- heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil)
- psychoses (e.g., haloperidol, pimozide, sertindole)
- depression (e.g., citalopram, escitalopram)
- gastro-intestinal disorders (e.g., cisapride, dolasetron, prucalopride)
- allergy (e.g., mequitazine, mizolastine)
- malaria (in particular halofantrine)
- AIDS/HIV (protease inhibitors)
- Hepatitis C (e.g., telaprevir)
- cancer (e.g., toremifene, vandetanib, vincamine)
- certain other medicines (e.g., bepridil, diphemanil, methadone)

Before you use Domperidone tablet and apomorphine, your doctor will ensure that you tolerate both medicines when used simultaneously. Ask your doctor or specialist for a personalised advice. Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV. It is important to ask your doctor or pharmacist if Domperidone tablet is safe for you when you are taking any other medicines, including medicines obtained without prescription.

**Pregnancy**

Pantoprazole: There are no adequate and well-controlled studies in pregnant women.

Domperidone: There are limited post-marketing data of its use in pregnant women. A study in rats has shown reproductive toxicity at a high, maternally toxic dose.

Because animal reproduction studies are not always predictive of human response, Pansa D tablet should be used during pregnancy only if clearly needed.

**Lactation**

There is insufficient data on the excretion of pantoprazole in human milk but excretion into human milk has been reported.

Domperidone is excreted in human milk and breast-fed infants receive less than 0.1% of the maternal weight-adjusted dose. Caution should be exercised in case of QTc prolongation risk factor in breast-fed infants.

A decision should be made whether to discontinue breast-feeding or to discontinue/abstain from Pansa D therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the women.

**Driving and using machines**

Pansa D has no or negligible influence on the ability to drive and use machines. If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

**3. How to take Pansa D**

One tablet to be taken 1-3 times a day. The tablets should not be chewed or crushed, and should be swallowed whole 1 hour before a meal with some water.

**Pediatric**

Pansa D tablets are not recommended in children below 12 years of age.

**Hepatic impairment**

• A daily dose of 20 mg pantoprazole should not be exceeded in patients with severe liver impairment.

• Domperidone is contraindicated in moderate or severe hepatic impairment.

Hence, a Pansa D tablet is contraindicated in patients with moderate or severe hepatic impairment.

**Renal impairment**

In subjects with renal insufficiency (creatinine clearance<30 ml/min/1.73m2) the elimination half-life of domperidone was increased from 7.4 to 20.8 hours. Since very little unchanged drug (approx. 1%) is excreted via the kidneys, it is unlikely that the dose of a single administration needs to be adjusted in patients with renal insufficiency. However, on repeated administration, the dosing frequency of Pansa D should be reduced to once or twice daily depending on severity of the impairment.

**If you take more Pansa D than you should**

Consult your doctor or pharmacist. There are no known symptoms of overdose.

**If you forget to take Pansa D**

Do not take a double dose to make up for a forgotten dose. Take your next, normal dose at the usual time.

**If you stop taking Pansa D**

Do not stop taking these tablets without first talking to your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

**Pantoprazole**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

**Serious allergic reactions (frequency rare: may affect up to 1 in 1,000 people)**: swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.

**Serious skin conditions (frequency not known: frequency cannot be estimated from the available data)**: blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme), and sensitivity to light.

**Other serious conditions (frequency not known: frequency cannot be estimated from the available data):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

Other side effects are:

**Common** (may affect up to 1 in 10 people) Benign polyps in the stomach.

**Uncommon** (may affect up to 1 in 100 people) Headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders; fracture in the hip, wrist or spine.

**Rare** (may affect up to 1 in 1,000 people) Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; high fever; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.

**Very Rare** (may affect up to 1 in 10,000 people) Disorientation.

**Not known** (frequency cannot be estimated from the available data) Hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level in blood, decreased magnesium level in blood, feeling of tingling, prickling, pins and needles, burning sensation or numbness, rash, possibly with pain in the joints, inflammation in the large bowel, that causes persistent watery diarrhoea.

Side effects identified through blood tests:

**Uncommon** (may affect up to 1 in 100 people) an increase in liver enzymes.

**Rare** (may affect up to 1 in 1,000 people) an increase in bilirubin; increased fat levels in blood; sharp drop in circulating granular white blood cells, associated with high fever.

**Very Rare** (may affect up to 1 in 10,000 people) a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.

**Domperidone**

**Uncommon** (may affect up to 1 in 100 people): Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm

**Not known** (frequency cannot be estimated from the available data):

- Seizures
- a type of reaction that may occur soon after administration and is recognised by skin rash, itching, shortness of breath, and/or a swollen face.
- a severe hypersensitivity reaction that may occur soon after administration that is characterised by hives, itching, flushing, fainting, and difficulty breathing among other possible symptoms.
- disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heart beat) have been reported; if this happens, you should stop the treatment immediately.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. Domperidone should be used at the lowest effective dose. Stop treatment with Domperidone and contact your doctor immediately if you experience any of the unwanted events described above.

Other unwanted effects that have been observed with Domperidone are listed below:

**Common** (may affect up to 1 in 10 people): Dry mouth

**Uncommon** (may affect up to 1 in 100 people): anxiety, agitation, nervousness, loss of interest in sex or diminished interest in sex, headache, sleepiness, diarrhoea, rash, itchiness, hives, Painful or tender breasts, milk discharge from breasts, a general feeling of weakness, feeling dizzy

**Not known** (frequency cannot be estimated from the available data): Upward movement of the eyes, stopped menstrual periods in women, enlarged breasts in men, inability to urinate, changes in certain laboratory test results, restless legs syndrome (uncomfortable feeling, with an irresistible urge to move your legs, and sometimes arms and other parts of your body).

Some patients who have used Domperidone for conditions and dosages requiring medical oversight have experienced the following unwanted effects: Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breastfeeding, depression, hypersensitivity.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab "Safety Reporting" located on the top right end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

**5. How to store Pansa D**

Store protected from light & moisture at a temperature not exceeding 30°C.

Keep out of reach of children.

Do not use the tablets after the expiry date is stated on the label. Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information**

Each gastro-resistant tablet contains -

Pantoprazole Sodium IP equivalent to Pantoprazole ..... 20 mg

Domperidone Maleate IP equivalent to Domperidone .....10 mg

Excipients .....q.s.

Colours : Yellow Oxide of Iron & Titanium Dioxide IP