Pansped D

For the use of a registered medical practitioner or a hospital or a laboratory only

Abbreviated prescribing information for pansped D

(pantoprazole gastro-resistant and domperidone prolonged –release capsules i.p.)

[please refer the complete prescribing information for details].

Pharmacological properties:

Mechanism of action: ***pantoprazole:*** pantoprazole is a substituted benzimidazole which inhibits the secretion of hydrochloric acid in the stomach by specific blockade of the proton pumps of the parietal cells. Pantoprazole is converted to its active form, a cyclic sulphenamide, in the acidic environment in the parietal cells where it inhibits the h+, k+-atpase enzyme, i. E. The final stage in the production of hydrochloric acid in the stomach. The inhibition is dose-dependent and affects both basal and stimulated acid secretion. In most patients, freedom from heartburn and acid reflux symptoms is achieved in 1 week. Pantoprazole reduces acidity in the stomach and thereby increases gastrin in proportion to the reduction in acidity. The increase in gastrin is reversible. Since pantoprazole binds to the enzyme distal to the receptor level, it can inhibit hydrochloric acid secretion independently of stimulation by other substances (acetylcholine, histamine, and gastrin). The effect is the same whether the active substance is given orally or intravenously. ***Domperidone*****:** is a dopamine antagonist with anti-emetic properties, domperidone does not readily cross the blood-brain barrier. In domperidone users, especially in adults, extrapyramidal side effects are very rare, but domperidone promotes the release of prolactin from the pituitary. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema. Animal studies, together with the low concentrations found in the brain, indicate a predominantly peripheral effect of domperidone on dopamine receptors.

Indications: for gastric ulcer, duodenal ulcer, zollinger-ellison-syndrome and gastro-esophageal reflux diseases.

Dosage and administration: hard gelatin capsule as directed by the physician. Capsule should be taken orally.

Contraindication: hypersensitivity to the active substance or to any of the excipients, prolactin-releasing pituitary tumour (prolactinoma), when stimulation of the gastric motility could be harmful e.g. In patients with gastro-intestinal haemorrhage, mechanical obstruction or perforation, in patients with moderate or severe hepatic impairment, in patients who have known existing prolongation of cardiac conduction intervals, particularly qtc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure, co-administration with qt-prolonging drugs, at the exception of apomorphine, co-administration with potent cyp3a4 inhibitors (regardless of their qt prolonging effects), co-administration with atazanavir.

Warnings & precautions*: pantoprazole*: patients should be instructed to consult a doctor if: they have unintentional weight loss, anaemia, gastrointestinal bleeding, dysphagia, persistent vomiting or vomiting with blood, since it may alleviate symptoms and delay diagnosis of a severe condition. *Gastrointestinal infections caused by bacteria:* decreased gastric acidity, due to any means - including proton pump inhibitors - increases gastric counts of bacteria normally present in the gastrointestinal tract. *Subacute cutaneous lupus erythematosus (scle)*: proton pump inhibitors are associated with very infrequent cases of scle. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping pantoprazole control.*interference with laboratory tests increaed:* chromogranin a (cga) level may

interfere with investigations for neuroendocrine tumours. ***Domperidone:*** *cardiovascular effects:* epidemiological studies showed that domperidone was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. A higher risk was observed in patients older than 60 years, patients taking daily doses greater than 30 mg, and patients concurrently taking qt-prolonging drugs or cyp3a4 inhibitors. *Use with apomorphine* : domperidone is contra-indicated with qt prolonging drugs including apomorphine, unless the benefit of the co-administration with apomorphine outweighs the risks. *Renal impairment*: elimination half-life of domperidone is prolonged in severe renal impairment. The dosing frequency may also need to be reduced depending on the severity of the impairment.

Drug interactions: ***pantoprazole:*** pantoprazole may reduce the absorption of active substances whose bioavailability is dependent on the gastric ph (e.g. Ketoconazole). It has been shown that co-administration of atazanavir 300 mg/ritonavir 100 mg with omeprazole (40 mg once daily) or atazanavir 400 mg with lansoprazole (60 mg single dose) to healthy volunteers resulted in a substantial reduction in the bioavailability of atazanavir. Absorption of atazanavir is ph-dependent. ***Domperidone:*** the main metabolic pathway of domperidone is through cyp3a4. In vitro data suggest that the concomitant use of drugs that significantly inhibit this enzyme may result in increased plasma levels of domperidone. Increased risk of occurrence of qt-interval prolongation, due to pharmacodynamic and/or pharmacokinetic interactions.

ADVERSE REACTIONS*:* common (affects less than 1 in 10 people) benign polyps in the stomach, dry mouth. **Uncommon side effects (may affect up to 1 in 100 people)** headache; dizziness; diarrhoea; feeling sick; vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak, exhausted or generally unwell; sleep disorders; increase in liver enzymes in a blood test; fracture in the hip, wrist or spine, lowering of sexual drive (libido) in men, feeling anxious, feeling drowsy, unusual production of breast milk in men and women, painful or tender breasts, general feeling of weakness. **Rare side effects:** distortion or complete lack of the sense of taste ;disturbances in vision such as blurred vision; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities; depression; increased bilirubin and fat levels in blood (seen in blood test); breast enlargement in males; high fever and a sharp drop in circulating granular white blood cells (seen in blood test) **very rare side effects (may affect up to 1 in 10,000 people):**disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; 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 (seen in blood tests) **frequency not known:** acute kidney injury, hallucination; confusion (especially in patients with a history of these symptoms); decreased level of sodium in blood, decreased level of magnesium in blood, rash, possibly with pain in the joints, disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heart beat), feeling agitated or irritable, feeling more nervous than usual, abnormal eye movements, inability to urinate, breast enlargement in men, in women, menstrual periods may be irregular or stop, a blood test shows changes in the way your liver is working.

Marketed by:

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In/Pansped D 40, 30mg/feb-2022/05/PI

(additional information is available on request)