

PATIENT INFORMATION LEAFLET

Pantoprazole Gastro-resistant and
Domperidone Prolonged-release Capsules IP
(40+30 mg)

QPDOM

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What QPDOM is and what it is used for

QPDOM Capsule is the combination of Pantoprazole Sodium Sesquihydrate Pellets equivalent to Pantoprazole 40 mg (as enteric coated Pellets) and Domperidone Pellets equivalent to Domperidone 30 mg (as prolonged-release pellets). 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 is an antiemetic (anti-sickness) and prokinetic drug. It is used to treat nausea (feeling sick) and vomiting (being sick).

2. What you need to know before you take QPDOM

Do not take QPDOM if:

- ❖ you are allergic to pantoprazole and domperidone or any of the other ingredients of this medicine.
- ❖ 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 (reduced bone density) or if you have been told that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- ❖ you have moderate to severe liver disease, heart disease.
- ❖ you have a tumor of the pituitary gland (prolactinoma).
- ❖ you have a blockage or tear in your intestines.

Do not take QPDOM if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking QPDOM.

Warnings and precautions

Talk to your doctor or pharmacist before taking QPDOM Capsules

Tell your doctor or pharmacist if you:

- ❖ Have osteoporosis (thinning of the bones) due to long periods of inactivity, such as long-term bed rest.
- ❖ Have problems with your kidneys, for example kidney stones.
- ❖ Have higher than normal levels of calcium in your urine (hypercalciuria). If you are unsure your doctor will advise you.
- ❖ Have sarcoidosis (inflammation that produces lumps of cells in various

organs in the body). Your doctor will be able to tell you if you do.

- ❖ Have previously been told by your doctor that you have an intolerance to some sugars.
- ❖ Are taking any other medication, even those you may have bought for yourself without prescription.

Other medicines and QPDOM

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

- ❖ Ketoconazole, itraconazole
- ❖ Warfarin
- ❖ Medicines used to treat HIV-infection, such as atazanavir
- ❖ Methotrexate
- ❖ Fluvoxamine
- ❖ Rifampicin

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)
- ❖ Cancer (e.g., toremifene, vandetanib, vincamine)
- ❖ Certain other medicines (e.g., bepridil, diphepanil, methadone)

Pregnancy and breast-feeding

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. You are breast-feeding. It is best not to take Domperidone tablets if you are breast-feeding. Small amounts of Domperidone have been detected in breast milk. Domperidone may cause unwanted side effects affecting the heart in a breastfed baby. Domperidone should be used during breast feeding only if your physician considers this clearly necessary. Ask your doctor for advice before taking this medicine.

3. How to take QPDOM

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Swallow the capsules whole with a little water. Take capsule before meal without chewing or breaking them and swallow them whole with water.

- ❖ **Adults, elderly and children over 12 years of age** The usual starting dose for adults and elderly people is 1-2 capsules daily. For dosing, contact your doctor or pharmacist.

Children under 12 – Do not give QPDOM Capsules to children under 12 years.

If you take more QPDOM Capsule than you should - You should only take what your doctor recommends. If you take too many capsules contact your doctor or pharmacist if you can do so. If not, go to the nearest hospital casualty department immediately, taking the pack and remaining tablets with you.

If you forget to take QPDOM Capsule - If you forget to take your capsule, take them as soon as possible and then continue to take them as normal. Do not take a double dose to make up for forgotten capsules.

If you stop taking QPDOM Capsule – Always talk to your doctor or pharmacist before you stop taking the caplets.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to take QPDOM Capsule

- ❖ If you forgot to take QPDOM, take it as soon as you remember.
- ❖ However if it is almost time for your next dose, wait until that is due and continue as normal.
- ❖ Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines QPDOM has side effects, although not everybody gets them. Some side effects are more likely to occur than others. Some possible side effects with QPDOM are:

Rare side effect:

- ❖ Disorientation reduction in the number of blood platelets
- ❖ Distortion or complete lack of the sense of taste
- ❖ Disturbances in vision such as blurred
- ❖ Hives
- ❖ Weight Change
- ❖ Pain in joints and muscle
- ❖ Raised body temperature
- ❖ Sharp drop in circulating granular white blood cells
- ❖ Peripheral edema
- ❖ Allergic reactions
- ❖ Depression
- ❖ Breast enlargement in males
- ❖ Increase in bilirubin
- ❖ Increased fat levels in blood

Common side effect:

- ❖ Dry mouth
- ❖ Benign polyps in stomach

Uncommon side effect:

- ❖ Anxiety
- ❖ Loss of interest in sex
- ❖ Sleepiness or headache
- ❖ Diarrhea

- ❖ Rash or Itchiness
- ❖ Painful or tender breasts or discharge from breasts
- ❖ Felling of weakness
- ❖ Dizziness
- ❖ Feeling sick
- ❖ Vomiting bolting and flatulence
- ❖ Constipation
- ❖ Abdominal pain and discomfort
- ❖ Exanthema
- ❖ Eruption
- ❖ Sleep disorder
- ❖ Fracture in the hip
- ❖ Increase in liver enzyme

Serious side effect:

- ❖ Swelling of the hand, feet, ankles, face, lips or throat
- ❖ Difficulty in swallowing or breathing
- ❖ Uncontrolled movements- Irregular eye movement, Unusual movements of tongue
- ❖ Abnormal posture such as a twisted neck
- ❖ Trembling and muscle stiffness
- ❖ Very fast or unusual heartbeat

5. How to store QPDOM

- ❖ Keep this medicine out of the sight and reach of children.
- ❖ Do not use this medicine after the expiry date which is stated on the strip and carton after EXP. The expiry date refers to the last day of that month.
- ❖ QPDOM capsules should be kept in their original strips and outer carton (to protect them from light and moisture).
- ❖ Do not store above 25°C.
- ❖ Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What QPDOM contains

Each hard gelatin capsule contains

Pantoprazole Sodium Sesquihydrate pellets eqvt. to

Pantoprazole 40 mg (as enteric-coated pellets)

Domperidone pellets equivalent to domperidone 30 mg (as prolonged-release pellets)

Approved colours used in capsule shell.

What QPDOM looks like and contents of the pack

QPDOM is hard gelatin capsule of size "2" with "QPDOM" and "Q" logo printed on capsule transparent body and cap respectively.

QPDOM Capsules are supplied in a strip using poly laminated printed aluminium foil on side and plain aluminium foil on other side

Each Strip contains 6 capsules, and 10 such strip are packed in a printed paper carton.



Manufactured by :
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