

PATIENT INFORMATION LEAFLET
RABIFAST DSR 20 mg / 30 mg Capsule
Rabeprazole Domperidone Capsule

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. See section 4.

What is in this leaflet

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

1. WHAT RABIFAST DSR IS AND WHAT IT IS USED FOR

The active ingredients of RABIFAST DSR capsule are Rabeprazole and Domperidone.

Rabeprazole belongs to a group of medicines called Proton Pump Inhibitors (PPIs). It acts by reducing the amount of acid made by the stomach.

Domperidone is a specific blocker of dopamine receptors. It speeds gastrointestinal peristalsis, causes prolactin release, and is used as antiemetic and tool in the study of dopaminergic mechanisms.

RABIFAST DSR capsules are used to treat:

- gastro-esophageal reflux disease (GERD). GERD is commonly referred to as inflammation of the gullet caused by acid and associated with heartburn. Heartburn is a burning feeling rising from the stomach or lower chest up towards the neck.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RABIFAST DSR

Do not use RABIFAST DSR if you

- are allergic (hypersensitive) to rabeprazole sodium, domperidone or any of the other ingredients. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- are pregnant or think that you are pregnant
- are breast-feeding
- have a tumour of the pituitary gland (prolactinoma)
- have a blockage or tear in your intestines
- 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.
- have a moderate or severe liver disease.
- Your ECG (electrocardiogram) shows a heart problem called “prolonged QT corrected interval”.
- have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure).
- You have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.
- You are taking certain medicines (see “Other medicines and RABIFAST DSR”)

Do not take RABIFAST DSR Capsule if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking RABIFAST DSR Capsule.

Warnings and precautions

Talk to your doctor before taking RABIFAST DSR, especially if you

- are allergic to other proton pump inhibitors or “substituted benzimidazoles”.
- have a stomach tumour.
- have or have had any liver or kidney problems.
- are taking a medicine called atazanavir (used to treat HIV).
- have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B12.
- are due to have a specific blood test (Chromogranin A).
- have ever had a skin reaction after treatment with a medicine similar to Rabeprazole 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 RABIFAST DSR. Remember to also mention any other ill-effects like pain in your joints.

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease. The possibility of stomach and oesophageal tumours should be excluded before the treatment is started.

If you take RABIFAST DSR capsule on a long-term basis (longer than one year) your doctor will probably monitor you regularly. You should report any new or different symptoms whenever you see your doctor.

Taking a proton pump inhibitor like rabeprazole, especially over a period of more than one year, may slightly increase your risk of fracture of 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).

Talk to your doctor straight away if you experience severe (watery or bloody) or persistent diarrhoea with symptoms such as fever, abdominal pain or tenderness, as rabeprazole has been associated with a small increase in infectious diarrhoea.

Some abnormal blood and liver enzyme values have been reported during treatment with rabeprazole. Usually, the values become normal when the treatment is discontinued.

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. 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 (see “Other medicines and RABIFAST DSR”).

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.

If you are not sure if any of the above applies to you, consult your doctor or pharmacist before taking RABIFAST DSR capsules.

Children and adolescents

RABIFAST DSR capsules are not recommended for use in children

Other medicines and RABIFAST DSR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is especially important in case you are taking any of the following medicines:

Rabeprazole

- atazanavir (used to treat HIV); Rabeprazole may lower the amount of this type of medicine in your blood and they should not be used together
- ketoconazole or itraconazole (used to treat infections caused by a fungus). Rabeprazole may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose
- methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Rabeprazole treatment.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Rabeprazole.

Domperidone

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

- Fungal infections such as azole anti-fungals, 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)

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV.

apomorphine and Domperidone

Before you use Domperidone and apomorphine, your doctor will ensure that you tolerate both medicines when used simultaneously. Ask your doctor or specialist for a personalised advice. Please refer to the apomorphine leaflet.

It is important to ask your doctor or pharmacist if Domperidone is safe for you when you are taking any other medicines, including medicines obtained without prescription.

Pregnancy and breast-feeding

Do not use RABIFAST DSR capsule if you are pregnant or think you may be pregnant.

Do not use RABIFAST DSR capsule if you are breastfeeding or planning to breast-feed.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Occasionally RABIFAST DSR can cause sleepiness. Therefore, driving and operating machinery should be avoided if you are affected.

3. HOW TO USE RABIFAST DSR

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

Taking this medicine

- Only remove a capsule from the blister strip when it is time to take your medicine.
- Swallow your capsule whole with a drink of water.

- Do not chew or crush the capsule.
- Your doctor will tell you how many capsule to take and how long to take them for. When RABIFAST DSR capsule are taken once daily, it should be taken in the morning before breakfast.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

The recommended dose is: Once capsule once daily in adults

Use in children

RABIFAST DSR capsules are not recommended for use in children.

If you take more RABIFAST DSR than you should

If you have taken more RABIFAST DSR capsules than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take RABIFAST DSR

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual

- If you forget to take your medicine for more than 5 days, talk to your doctor before taking any more medicine
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking RABIFAST DSR

Relief of symptoms will normally occur before the ulcer has completely healed. It is important that you do not stop taking the medicine until told to do so by your doctor.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects are usually mild and improve without you having to stop taking this medicine.

Rabeprazole

If you notice any of the following serious side effects, stop taking RABIFAST DSR capsule and contact a doctor immediately, you may need urgent medical treatment:

- Allergic reactions – the signs may include: sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse.
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat.
- Bruising or bleeding easily.

These side effects are rare (affect fewer than 1 in 1,000 people).

- Sudden onset of severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN))

These side effects are very rare (affect fewer than 1 in 10,000 people).

Other possible side effects:

Common side effects (may affect up to 1 in 10 people):

- cough, sore throat (inflammation of the pharynx), runny nose.
- effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- aches, back pain, non-specific pain.
- weakness or loss of strength, flu like symptoms.
- difficulty sleeping.
- headache, dizziness.
- infection.
- benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people):

- feeling nervous or drowsy.
- sleepiness.
- chest infection (bronchitis).
- painful and blocked sinuses (sinusitis).
- indigestion, dry mouth, belching.
- rash, skin redness (erythema).
- muscle pains, joint pains, leg cramps.
- bladder infection (urinary tract infection).
- chest pain, chills, fever.
- muscle, leg or joint pain.
- change in how your liver is working (which is measured by blood tests).
- fracture of the hip, wrist or spine.

Rare side effects (may affect up to 1 in 1,000 people):

- blood problems such as reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- changes in white blood cells (show in blood tests) which may result in frequent infection.
- allergic reactions including facial swelling, low blood pressure and breathing difficulties.
- loss of appetite (anorexia).
- depression.
- visual disturbance.
- upset stomach or stomach pain, sore mouth, taste disturbance.
- inflammation of the liver, jaundice (yellowing of the skin or eyes).
- itchy rash, sweating, skin blisters.
- kidney inflammation (interstitial nephritis).

- increased weight.

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

- low levels of sodium in the blood which can cause tiredness and confusion, muscle twitching, fits and coma.
- confusion.
- swelling of the feet and ankles.
- enlarged breasts in men.
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease).
- rash, possibly with pain in the joints.
- inflammation of the gut (leading to diarrhoea).
- If you are on Rabeprazole 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.

Do not be concerned by this list of side effects. You may not get any of them.

Domperidone

Stop taking **RABIFAST DSR** and see your doctor or go to a hospital straightaway if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Domperidone.
- You notice any uncontrolled movements. These include irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness. These symptoms should stop once you stop taking Domperidone.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.
- You have a fit (seizure).

Other side effects include:

Common (affects less than 1 in 10 people)

- Dry mouth

Uncommon (affects less than 1 in 100 people)

- Lowering of sexual drive (libido) in men
- Feeling anxious
- Feeling drowsy

- Headaches
- Diarrhoea
- Itchy skin. You may also have a rash
- Unusual production of breast milk in men and women
- Painful or tender breasts
- A general feeling of weakness

Not known (Frequency cannot be estimated from the available data)

- 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.
- 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.

Some patients who have used Domperidone for conditions and dosages requiring longer term medical supervision 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 RABIFAST

- Store in a cool & dry place. Protect from light.
- Keep out of reach of children.
- Capsule should be swallowed whole & not to be opened, chewed or crushed.
- Do not use this medicine after the expiry date which is stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RABIFAST DSR contains

Rabifast DSR

Each hard gelatin capsule contains

Rabeprazole Sodium IP (As gastro-resistant pellets)
.....20 mg

Excipients

.....
.....q.s.

Colours: Red Oxide of Iron & Titanium Dioxide IP

Domperidone IP (As prolonged-release pellets)
.....20 mg

Excipients

.....
.....q.s.

Colours: Sunset Yellow Approved colours used in the capsule shell.