

Patient Information Leaflet (PIL)

Prokinin® 10 mg Film Coated Tablets
Prokinin® 5 mg/5 ml Oral Suspension
Domperidone

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Prokinin is and what it is used for
2. Before you take Prokinin
3. How to take Prokinin
4. Possible side effects
5. How to store Prokinin
6. Further information

1. What Prokinin is and what it is used for
Prokinin is an anti-emetic which can stop you feeling sick. The active ingredient is domperidone.
Prokinin is used to treat:
Adults and Children
The relief of the symptoms of nausea and vomiting.

2. Before you take Prokinin

Do not take this medicine:

- If you have ever had a bad reaction to any of the ingredients.
- If you have a disease of the pituitary gland (prolactinoma).
- If you have ever had heart problems including heart failure, a previous heart attack, angina (chest pains), or heart rhythm disorders including a rapid or slow or irregular heartbeat, without first consulting your doctor.
- If you have an underlying illness affecting the digestive system, for example:
 - A stomach or duodenal ulcer.
 - A blocked or perforated gut.
 - Your bowel motions (stools) are often black, or you notice blood in your bowel motions. This could be a sign of bleeding in the stomach or intestines.
 - You frequently have severe stomach cramps.
- If you have kidney or liver problems.

If any of these apply to you, get advice from a doctor or pharmacist without taking Prokinin.

Important information about some of the ingredients in Prokinin

- If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor before taking Prokinin.
- This medicinal product contains sodium. To be taken into consideration by patients on a controlled sodium dose.
- The oral suspension contains sorbitol and may be unsuitable for patients with sorbitol intolerance.

Taking other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicine, even those not prescribed by a doctor.

If taken with other medicines the effect of Prokinin or the effects of the other medicine may be altered.

Examples of medicines that can affect domperidone are:

- Ketozazole, used to treat fungal infections.
- Ribonavir, used to treat virus infections.
- Erythromycin, used to treat bacterial infections.

If you have any doubts about whether you should take this medicine then talk to your doctor.

If you are pregnant or breast-feeding

- Do not take if you are pregnant or think you might be pregnant.
- It is not known whether this is harmful to the newborn. Therefore breast-feeding is not recommended for mothers who are taking Prokinin.

Driving and using machinery

You may have less control over your movements whilst taking Prokinin. If this happens do not drive or use any tools or machines.

Special warnings about use in travel sickness

This product should not be used to treat travel sickness. Speak to your doctor or pharmacist about suitable treatments.

3. How to take Prokinin

It is recommended to take oral Prokinin before meals. If taken after meals, absorption of the drug is somewhat delayed.

The recommended dose in adults and adolescents weighing 35 kg or more is 10 mg (1 tablet or 10 ml oral suspension) up to three times daily by mouth.

The recommended dose in children and adolescents weighing less than 35 kg is 0.25 mg per kg bodyweight up to three times daily by mouth.

Tablets are unsuitable for use in children weighing less than 35 kg.

Prokinin should not normally be used for longer than one week.

The dose should be reduced for patients with severe kidney problems and reviewed regularly by your doctor.

Your doctor may advise you to take your medicine in a different way, so you should always follow your doctor's advice about how and when to take your medicine and always read the label. If you feel that the effect of Prokinin is too strong or too weak, talk to your doctor or pharmacist.

If anyone takes too much

If anyone takes too many Prokinin, contact a doctor or your nearest Accident and Emergency department (Casualty) taking this leaflet and pack with you.

If you forget to take the medicine

You should only take this medicine as required following the dosage instructions above carefully. If you forget to take a dose, take the next dose when needed as long as you do not take more than 4 tablets in any 24 hour period. Do not take a double dose.

4. Possible side effects

Prokinin can have side effects, like all medicines, although these don't affect everyone and are usually mild.

If you experience any of the following, stop using the medicine and seek immediate medical help:

- Fits or seizures.
- Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm.

Allergic reactions Signs of allergy include rash (such as hives), itching, shortness of breath, wheezing and/or swollen face or neck, flushing or fainting. **Very rarely (less than 1 in 10,000 people)**

- Heart rhythm disorders.

If you experience any of the following, stop using the medicine and talk to your doctor:

Common (less than 1 in 10 people)

- Dry mouth.

Uncommon (less than 1 in 100 people)

- Anxiety.
- Loss of interest in sex or diminished interest in sex.
- Sleepiness or headache.
- Diarrhea.
- Rash or itchiness.
- Painful or tender breasts.
- Milk discharge from breasts.
- A general feeling of weakness.
- Stop in menstrual periods.

Other side effects which occur but it is unknown how often:

- Hives.
- Agitation or Nervousness.
- Eye movement disorder.
- Inability to urinate.
- Swollen breasts (even in men).

Changes in certain laboratory test results. If you have a blood test to check your liver function tell your doctor or nurse that you are taking Prokinin. 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 in adults and children.

Some patients who have been prescribed domperidone for conditions and dosages requiring medical oversight have experienced the following unwanted effects: flatulence; swollen or enlarged breasts; unusual discharge from breasts; irregular menstrual periods in women; difficulty breast-feeding; depression; and hypersensitivity.

If you experience any side effects not included in this leaflet or are not sure about anything, talk to your doctor or pharmacist.

5. How to store Prokinin

Keep out of reach of children.

Store below 30°C.

Prokinin Oral Suspension:

After opening, it should be used within three months. Close the bottle tightly after opening, and store it in the original pack.

Do not use beyond the expiry date or if the product shows any sign of deterioration.

6. Further Information

What Prokinin contains:

Prokinin Tablets:

Each film coated tablet contains: 10 mg domperidone. Excipients: Cellulose, sodium lauryl sulphate, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, HPMC, polyethyleneglycol, simethicone, talc, and E171.

Prokinin Oral Suspension:

Each 5 ml contains: 5 mg domperidone. Excipients: Microcrystalline cellulose, carboxymethyl cellulose sodium, methylparaben, propylparaben, sorbitol, polyoxyl 40 hydrogenated castor oil, saccharin sodium, lemon flavor, and simethicone.

Presentations:

Prokinin Oral Suspension: Bottle of 180 ml.

Prokinin Tablets: Packs of 30 Film Coated Tablets.

Hospital packs are available.

To report any side effect(s):

• Saudi Arabia:
National Pharmacovigilance and Drug Safety Center (NPC)

Fax: +966-11-205-7862

Call NPC at +966-11-2038222

Ext: 2317-2358-2353-2354-2334-2340

Toll free phone: 8002490000

E-mail: npc.drug@sfdc.gov.sa

Website: www.sfdc.gov.sa/npc

• Other GCC States:

Please contact the relevant competent authority.

® is a trademark.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to medicines is dangerous for you.
 - Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are experts in medicine, its benefits and risks.
 - Do not try yourself interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.

This patient information leaflet is approved by the Saudi Food and Drug Authority.



Manufactured by:
TABUK PHARMACEUTICAL MANUFACTURING COMPANY,
P.O. Box 2633, TABUK-SAUDI ARABIA.

1443 H
0445001