

PROPULSID[®] is also provided as blue tablets, debossed "Janssen" and P/20, containing the equivalent of 20 mg cisapride in blister packages of 100 (NDC 50458-440-01) and in unit of use bottles of 60 (NDC 50458-440-06).

PROPULSID[®] Suspension is provided as a bright pink homogeneous suspension containing the equivalent of 1 mg/mL of cisapride in 16 oz. unit of use bottles containing 450 mL (NDC 50458-450-45).

Unit of use bottles should be dispensed as an intact unit. The Medication Guide should be dispensed with the product. Store at 15°-25°C (59°-77°F). Protect the tablets from moisture. The 20 mg tablets should also be protected from light.

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JANSSEN PHARMACEUTICA

Titusville, New Jersey 08560

7502617

U.S. Patent No. 4,962,115

Revised May 1999, January 2000

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MEDICATION GUIDE

IMPORTANT: READ COMPLETELY BEFORE USE. Do not take PROPULSID[®] if you have a medical condition or take a drug listed in this Medication Guide in the section "Who Should Not Take PROPULSID[®]?"

MEDICATION GUIDE

Brand Name: PROPULSID[®] (pro-pul-sid)

Generic Name: cisapride

Available as: Tablets and Suspension (liquid form)

What is the Most Important Information I Should Know About PROPULSID[®] (cisapride)?

PROPULSID[®] may cause serious irregular heartbeats that may cause death. Taking PROPULSID[®] together with certain other medicines or if you have certain medical conditions increases the chance that you will have irregular heartbeats. PROPULSID[®] should never be taken with these other medicines or if you have these conditions. A list of these medicines and these medical conditions is in the section "Who Should Not Take PROPULSID[®]?". If you faint or feel faint, become dizzy or have irregular heartbeats while using PROPULSID[®], stop taking PROPULSID[®] and get medical help right away.

What is PROPULSID[®] (cisapride)?

PROPULSID[®] is a medicine approved only to treat the symptoms of nighttime heartburn in adults. Nocturnal, or nighttime, heartburn is a common symptom of a medical condition called gastroesophageal reflux disease (GERD). It occurs when stomach contents wash back, or "reflux," into the esophagus (a muscular tube that carries food from the mouth to the stomach). Reflux is very common at nighttime because stomach contents can easily wash backwards when you are lying down. Usually, physicians recommend that patients with nighttime heartburn make simple lifestyle changes and use antacids or acid-reducing agents to relieve their symptoms. (See the section "What Else Can I Do for Nighttime Heartburn?" for more details.) These other lifestyle changes and medicines should be tried first because of the risk of serious, and sometimes fatal, irregular heartbeats associated with the use of PROPULSID[®].

Who Should Not Take PROPULSID[®] (cisapride)?

Some patients who have taken certain medicines together with PROPULSID[®] have experienced serious problems such as fainting, dizziness and irregular heartbeats. These problems can cause death. Medications that should never be taken with PROPULSID[®] include:

<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Name)</u>
Anti-allergy:	promethazine (Phenergan [®])
Anti-angina: (for heart pain)	bepridil (Vascor [®])
Antiarrhythmics: (for irregular heart rhythm)	quinidine (such as Quinidex [®] , Cardioquin [®] , Quinaglute [®]) procainamide (Procanbid [®]) sotalol (Betapace [®])
Antibiotics:	erythromycin (such as E.E.S. [®] , E-Mycin [®] , Ilotycin [®] , Pediazole [®]) clarithromycin (Biaxin [®]), troleandomycin (TAO [®]) sparfloxacin (Zagam [®])
Antidepressants:	amitriptyline (Elavil [®]) maprotiline (Ludiomil [®]) nefazodone (Serzone [®])
Antifungals:	fluconazole (Diflucan [®]) itraconazole (Sporanox [®]) oral ketoconazole (Nizoral [®])
Anti-nausea:	prochlorperazine (Compazine [®]) promethazine (Phenergan [®])
Antipsychotics:	sertindole prochlorperazine (Compazine [®])
Protease Inhibitors:	indinavir (Crixivan [®]) ritonavir (Norvir [®])

- This is not a complete list of medications that you should not take. Therefore, tell your doctor about all other prescriptions and nonprescription drugs you are taking, including herbal supplements. While taking PROPULSID[®], do not start a new medicine without first consulting your doctor or pharmacist.

Also, you should not take PROPULSID[®] if you have any of these conditions:

- a history of irregular heartbeats
- an abnormal electrocardiogram (ECG or EKG)
- heart disease
- kidney disease
- lung disease
- low blood levels of potassium, calcium or magnesium
- an eating disorder (such as bulimia or anorexia)
- your body has suddenly lost a lot of water
- persistent vomiting
- Tell your doctor if you have any type of medical condition, especially a heart condition or kidney or lung disease. Be sure your doctor knows about both your personal and family medical history before you take PROPULSID[®].
- If you have not tried other medicines to relieve your nighttime heartburn, tell your doctor before using PROPULSID[®].

- The safety and effectiveness of PROPULSID[®] in children younger than 16 years have not been demonstrated for any use. Serious adverse events, including death, have been reported in infants and children while being treated with PROPULSID[®], although there is no clear evidence that PROPULSID[®] caused them.

How Should I Take PROPULSID[®] (cisapride)?

- Take PROPULSID[®] exactly as your doctor prescribes it.
- Never take more than the recommended dose of PROPULSID[®]. Always take your medicine for as long as the doctor has prescribed it, even if you are beginning to feel better right away.
- If you forget to take a dose, do not take the missed dose. Take the next dose at the regularly scheduled time. Never take more than your prescribed dose at any one time to make up for the missed dose.
- PROPULSID[®] does not work for everyone. If you do not get relief of your nighttime heartburn, talk to your doctor about whether to stop using PROPULSID[®].

What Should I Avoid While Taking PROPULSID[®] (cisapride)?

- Never take PROPULSID[®] with the medications listed in the above section Who Should Not Take PROPULSID[®] (cisapride)?
- Do not take prescription or non-prescription medicines while taking PROPULSID[®] without checking first with your doctor.
- Do not drink grapefruit juice at any time while you are on PROPULSID[®] therapy. Drinking grapefruit juice while you are on PROPULSID[®] therapy may cause the same kinds of serious irregular heartbeats as taking PROPULSID[®] with the wrong medicines.
- Tell your doctor if you are pregnant or nursing. Your doctor will talk to you about whether you should take PROPULSID[®] while pregnant or nursing, based on the benefits and risks.

What are the Possible Side Effects of PROPULSID[®] (cisapride)?

- PROPULSID[®] may cause serious irregular heartbeats that may cause death.

Stop taking PROPULSID[®] and call your doctor right away if you

- faint or feel faint
- become dizzy
- have irregular heartbeats or pulse
- develop any unusual symptoms

These may be signs of a serious side effect.

- PROPULSID's[®] most common side effects are headache, diarrhea, stomach pain, nausea, constipation and a runny nose. Other side effects have been reported less often. Be sure to ask your doctor or pharmacist about the side effects of any medicine that you are taking, including PROPULSID[®].
- PROPULSID[®] may cause you to become more drowsy than normal if you drink alcohol or take medicines called benzodiazepines (used to reduce anxiety).

What Else Can I do for Nighttime Heartburn?

- Stop smoking or reduce the number of cigarettes you smoke.
- Elevate the head of your bed when you sleep.
- Avoid eating large meals or eating just before bedtime.
- Do not lie down right after eating.
- If you are overweight or your doctor recommends it, try to lose weight.

- Avoid fatty foods and foods containing chocolate, caffeine or citrus.
- Avoid alcoholic drinks.

All of these lifestyle changes will help to restore your body to a more normal way of functioning.

General Information

This leaflet provides a summary of information about PROPULSID[®]. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you need to report problems associated with the use of PROPULSID[®], contact your doctor. If you have additional questions or concerns, or want more information about PROPULSID[®], contact your doctor or pharmacist. You can also call the Janssen One-to-One[™] Customer Action Center toll-free at 1-800-526-7736 for more information. Your pharmacist also has a longer leaflet about PROPULSID[®] that is written for health professionals that you can ask to read. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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7515202

U.S. Patent No. 4,962,115

May 1999, January 2000

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Revised: 10/2006

Distributed by: Janssen Pharmaceutica