

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PROMETRIUM® (100 mg progestin oral capsules, Organon Std.)

Read this carefully before you start taking **PROMETRIUM®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PROMETRIUM®**.

Serious Warnings and Precautions

In postmenopausal women taking estrogen with progestin, there is an increased risk of:

- Heart attack
- Stroke (bleeding or blood clot in the brain),
- Breast cancer,
- Pulmonary emboli (blood clots in the lungs),
- Deep vein thrombosis (blood clots in the deep veins of the leg or arm). And
- Dementia (in women 65 years or older)

In postmenopausal women taking estrogen-alone who had prior surgery to remove the uterus (called a hysterectomy), there is an increased risk of:

- Stroke (bleeding or blood clot in the brain), and
- Deep vein thrombosis (blood clots in the deep veins of the leg or arm)

Therefore, you should highly consider the following:

- Estrogens with or without progestins should not be used for the prevention of heart disease, stroke, or dementia.
- Estrogens with or without progestins should be used at the lowest effective dose and for the shortest period of time possible. Regular medical follow-up is advised.

What is PROMETRIUM® used for?

PROMETRIUM is used with estrogen replacement therapy to help treat symptoms of menopause. It helps reduce the risk of:

- endometrial hyperplasia (thickening of the uterus lining)
- uterine cancer

PROMETRIUM is intended for women with an intact uterus (has not been removed by surgery).

How does PROMETRIUM® work?

The active ingredient in PROMETRIUM® capsules is progesterone, a natural female hormone. In women of childbearing age, progesterone plays a role in the monthly shedding of the inner lining of the uterus (endometrium) and the menstrual bleeding that follows. PROMETRIUM helps protect the inner lining of the uterus from overgrowth caused by estrogen therapy during and after menopause.

What are the ingredients in PROMETRIUM®?

Medicinal ingredients: progesterone

Non-medicinal ingredients: gelatin, glycerin, soya lecithin (may contain traces of medium chain triglycerides), sunflower oil, titanium dioxide.

PROMETRIUM® comes in the following dosage forms:

Capsules. Each capsule contains 100 mg (milligrams) of progesterone.

Do not use PROMETRIUM® if you:

- Have an allergic or an unusual reaction to progesterone, soya, peanut or to any of the ingredients in PROMETRIUM®;
- Have liver disease;
- Have or have had hormone dependent cancers, like cancer of the breast or uterus;
- Have overgrowth of the lining of the uterus;
- Have undiagnosed or unexpected vaginal bleeding;
- Are pregnant or suspect you may be pregnant;
- Have a history of heart disease (including heart attack) or stroke;
- Have or have had blood clotting problems or disorders;
- Have porphyria (a disorder that affects how your body makes hemoglobin).
- Have partially or completely lost vision due to blood vessel disease of the eye.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PROMETRIUM®. Talk about any health conditions or problems you may have, including if you:

- have a history of liver disease, liver tumors, or jaundice (yellowing of the eyes and/or skin) or itching related to estrogen use or during pregnancy;
- have a personal history of breast disease (including breast lumps) and/or breast biopsies, abnormal mammograms, or a family history of breast cancer);
- have experienced undiagnosed or abnormal vaginal bleeding;
- have a history of uterine fibroids or endometriosis;
- have been diagnosed with lupus;
- have been diagnosed with hearing loss due to otosclerosis;
- have been diagnosed with gallstones;

- have been told that you have a condition called hereditary angioedema or if you have had episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage), or digestive tract
- have a history of heart conditions;
- have a personal or family history of blood clots or a personal history of active thrombophlebitis (inflammation of the veins);
- are breastfeeding or planning to breastfeed;
- smoke;
- have a history of high blood pressure;
- have a history of kidney disease, epilepsy (seizures) or asthma;
- have a history of bone disease (this includes certain metabolic conditions or cancers that can affect blood levels of calcium and phosphorus);
- have been diagnosed with diabetes;
- have a history of high cholesterol or high triglycerides;
- have a history of migraine headaches;
- have a history of depression;
- have had a hysterectomy (surgical removal of the uterus).

Other warnings you should know about:

Breast Cancer

- Estrogens with or without progestins should not be taken by women who have a personal history of breast cancer.
- There is an increased risk of breast cancer in post-menopausal women taking combined estrogen plus progestin.
- You may also have an increased risk of breast cancer if you have:
 - a family history of breast cancer or have had breast lumps, breast biopsies or abnormal mammograms (breast x-rays);
 - never had a baby before or had your first full-term pregnancy at an older age;
 - you are overweight;
 - you started menstruating at an early age.

Women should have a mammogram before starting HRT and at regular intervals during treatment as recommended by their Health Care Professional.

Regular breast examinations by a Health Care Professional and regular breast self-examinations are recommended for all women. You should review technique for breast self-examination with your Health Care Professional.

Ovarian cancer

In some studies, the use of estrogen-alone and estrogen plus progestin therapies for 5 or more years has been associated with an increased risk of ovarian cancer.

Stroke and Heart Disease

There is increased risk of stroke and coronary heart disease in post-menopausal women taking combined estrogen plus progestin.

Abnormal Blood Clotting

There is an increased risk of blood clots in the lungs and large veins in post-menopausal women taking combined estrogen plus progestin.

You should discuss risk factors for blood clots with your Health Care Professional since blood clots can be life-threatening or cause serious disability. The risk of blood clots also increases with:

- age,
- family history of blood clots,
- smokers,
- patients that are severely overweight.

The risk of blood clots is also temporarily increased if you are immobilized for long periods of time and following major surgery.

Dementia

The Women's Health Initiative Memory Study (WHIMS) showed an increased risk of dementia (loss of memory and intellectual function) in postmenopausal women age 65 and over taking oral combined estrogen plus progestin.

Driving and Operating Machinery

PROMETRIUM® may cause some people to feel dizzy or sleepy, 1-4 hours after ingestion of the capsules. This is more likely if PROMETRIUM is taken with food. Do not drive or do anything requiring alertness until you know how PROMETRIUM affects you.

Medical Testing

Your Health Care Professional will need to order medical tests before and during your treatment. This will help determine if it is safe for you to continue taking PROMETRIUM. These tests include:

- Blood pressure.
- Breast and pelvic exam.
- Pap smear.
- Mammogram.
- Blood glucose.
- Calcium.
- Triglycerides.
- Cholesterol.
- Liver function test.

You should schedule a follow-up with your Health Care Professional within 3-6 months after starting PROMETRIUM. You should schedule an appointment with your Health Care professional at least once a year while you are taking PROMETRIUM. You should regularly talk with your Health Care Professional about whether you still need treatment with HRT.

Vaginal Bleeding

A few days after completing a PROMETRIUM® course of 3 capsules daily, the inner lining of the uterus will usually shed. This is accompanied by vaginal bleeding (resembling a normal monthly period). With a dosage of 2 capsules daily, many women will not have such vaginal bleedings, although the lining of the uterus will also be protected against overgrowth.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PROMETRIUM®:

- anticonvulsant medicines used to prevent seizures, such as phenobarbital, carbamazepine, phenytoin
- antiviral drugs, used to treat viral infections, such as ritonavir and efavirenz
- antifungal drugs, used to treat fungal infections, such as fluconazole, itraconazole, ketoconazole, voriconazole
- bosentan, used to treat high blood pressure
- rifampicin and rifabutin, antibiotics used to treat bacterial infections
- sedatives, such as barbiturates and meprobamate
- tacrolimus, used in organ transplants
- topiramate, used to treat epilepsy and migraines
- some herbal products, such as St. John's wort, used to treat depression

PROMETRIUM may interfere with certain medical tests. This may continue for 2-4 weeks after you stop taking PROMETRIUM. Tell your Health Care Professional that you are taking PROMETRIUM when they order any tests for you.

How to take PROMETRIUM®:

- Follow the instructions given by your Health Care Professional.
- Capsules of PROMETRIUM should be taken by mouth and swallowed whole with a glass of water.
- Do not crush, do not pierce the PROMETRIUM capsules.
- Do not take with food. If you are taking PROMETRIUM in the morning, wait 2 hours after breakfast before taking your dose.

Usual adult dose:

Your Health Care Professional will adjust your dose based on how much estrogen you are taking.

200 mg daily: Take two capsules (200 mg) in the evening before bed. This dose should be taken for the last 14 days of your estrogen treatment each cycle. This means days 8 to 21 for a 28 day cycle or day 12 to 25 on a 30 day cycle.

300 mg daily: Take one capsule (100 mg) in the morning and two capsules (200 mg) in the evening before bed. This dose should be taken for the last 12-14 days of your estrogen treatment each cycle.

Overdose:

If you take too much PROMETRIUM® (progesterone), you may experience the following symptoms: nausea, vomiting, sleepiness, dizziness, depressive mood, tiredness, acne and hairiness.

If you think you, or a person you are caring for, have taken too much PROMETRIUM, contact a healthcare professional, hospital emergency department, or regional poison control center immediately, even if there are no symptoms.

Missed Dose:

If you are taking 2 capsules a day (total dose at bedtime) and you forget to take this dose, you should take one capsule the following morning and continue taking the rest of the capsules as prescribed.

If you are taking 3 capsules a day and you forget to take a morning or evening dose, you should not take the missed dose.

What are possible side effects from using PROMETRIUM®?

These are not all the possible side effects you may feel when taking PROMETRIUM®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects of PROMETRIUM:

- breast tenderness/swelling/pain;
- dizziness or vertigo;
- fatigue (tiredness);
- genital bleeding or spotting (minor vaginal bleeding) in between the normal periods (mainly during the first two months);
- headaches or depressive mood;
- irregular menstrual periods;
- lightheadedness (feeling faint);
- nausea (urge to vomit), cramps;
- sleepiness, insomnia;

Side effects observed in women taking progestins in general:

- darkening of skin in patches;
- rash with or without itching;
- swelling, bloating from water retention;

Other side effects that have been observed with estrogen and progestin combinations in general, but not necessarily with PROMETRIUM® treatment are:

- acne;
- changes in appetite and body weight;
- change in sexual drive;
- inflammation of the bladder;
- increase in blood pressure;
- irritability;
- loss of hair, hairiness;
- menstrual cramps;
- nervousness;
- overgrowth of the lining of the uterus;

- pain during sexual intercourse;
- palpitations (unpleasant sensation of irregular and/or forceful beating of the heart);
- pain in the joints and muscles, usually lasting only 3-6 weeks;
- pain on urination or difficulty urinating;
- premenstrual syndrome (PMS);
- skin rash, tender red lumps or nodules or other skin reactions;
- vaginal itching/discharge;
- intolerance to contact lenses.

During your first 2-4 months of HRT, you may experience minor unscheduled vaginal bleeding (at times other than when you would expect a normal period). This is a normal response of your body as it adjusts to the return of estrogen and progesterone to the levels that were seen before menopause. Should unscheduled vaginal bleeding persist, you should consult your Health Care Professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Abdominal pain, Abdominal distension, Nausea	√		
UNCOMMON			
Jaundice: Yellowing of the skin or eyes, dark urine, light coloured stool, itching all over your body			√
Unexpected vaginal bleeding Abnormal withdrawal bleeding		√	
Mood disorder: Agitation, Anxiety, Apathy, Depression, Disorientation, Mood swings, Nervousness			√
UNKNOWN			
Breast abnormalities (including breast cancer): Breast lump		√	
Deep vein thrombosis (blood clot in the deep veins of the leg or arm): pain or swelling in the leg/inflamed vein			√
Heart attack, heart disease: Crushing chest pain or chest heaviness, jaw, left arm, between the shoulder blades or upper abdomen, shortness of breath, dizziness, fatigue, lightheadedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat, lack of			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
appetite, nausea, swelling in ankles, legs and feet, cough, fluid retention			
Pulmonary embolism (blood clot in the lung): sharp pain in the chest, coughing blood or sudden shortness of breath			√
Severe allergic reaction: hives, itchiness, skin redness, swelling, wheezing, increase heart rate and difficulty breathing			√
Stroke (bleeding or blood clot in the brain): Sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech or weakness or numbness as per in an arm or leg			√
Sudden partial or complete loss of vision			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

The capsules should be stored at controlled room temperature between 15°C and 30°C (59°F and 86°F). Protect from light. Keep in a safe place out of the reach of children and pets.

If you want more information about PROMETRIUM®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <http://hc-sc.gc.ca/index-eng.php> or the Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

Last revised: JUL 17, 2025

© 2025 Organon Canada Inc. All rights reserved.