

PATIENT INFORMATION

Prochieve® 8%

(progesterone gel)

For Vaginal Use Only

FOR PROGESTERONE SUPPLEMENTATION OR REPLACEMENT AS PART OF AN ASSISTED REPRODUCTIVE TECHNOLOGY (“ART”) TREATMENT FOR INFERTILE WOMEN WITH PROGESTERONE DEFICIENCY

Please read this information carefully before you start to use Prochieve® and each time your prescription is renewed, in case anything has changed. This leaflet does not take the place of discussions with your doctor. If you still have any questions, ask your doctor or health-care provider.

What Prochieve® is

Prochieve® is a specially formulated gel that you insert in your vagina. It contains the natural female hormone called progesterone. Prochieve® 8% is used as part of a program for women who are undergoing fertility treatment.

Understanding the role of Prochieve® in your infertility treatment

Progesterone is one of the hormones essential for maintaining a pregnancy. If you are undergoing ART treatment and your doctor has determined your body does not produce enough progesterone on its own, Prochieve® may be prescribed to provide the progesterone you need.

The progesterone in Prochieve® will help prepare the lining of your uterus so that it is ready to receive and nourish a fertilized egg. If pregnancy occurs, Prochieve® may be supplemented for 10-12 weeks until production of progesterone by the placenta is adequate.

When you should not use Prochieve®

- *If you are allergic to progesterone, progesterone-like drugs, or any of the inactive ingredients in the gel (ask a pharmacist if you are not sure about the inactive ingredients in Prochieve®).*
- *If you have unusual vaginal bleeding which has not been evaluated by a doctor.*
- *If you have a liver disease.*
- *If you have known or suspected cancer of the breast or genital organs.*
- *If you have a miscarriage and your physician suspects some tissue is still in the uterus.*
- *If you have or have had blood clots in the legs, lungs, eyes, or elsewhere.*

Risks of Prochieve®

- *Risk to the fetus.* Birth defects have been reported in the offspring of women who were using Prochieve® during early pregnancy. These included an abdominal wall defect and a cleft palate. A causal association has been neither confirmed nor refuted. You should check with your doctor about the risks to your unborn child of any medication used during pregnancy.
- *Blood clots and related health problems.* Blood clots have been reported with the use of estrogens and progestational drugs (alone or in combination). If blood clots do form in your bloodstream, they can cut off the blood supply to vital organs, causing serious problems. These problems may include a stroke (by cutting off blood to part of the brain), a heart attack (by cutting off blood to part of the heart), a pulmonary embolus (by cutting off blood to part of the lungs), or other problems. Any of these conditions may cause death or serious long-term disability. Call your doctor immediately if you suspect you have any of these conditions. He or she may advise you to stop using this drug.

PRECAUTIONS

Be alert for unusual signs and symptoms. If any of these warning signals (or any other unusual symptoms) happen while you are using Prochieve®, call your doctor immediately:

- Abnormal bleeding from the vagina.
- Pains in the calves or chest, a sudden shortness of breath or coughing blood indicating possible clots in the legs, heart, or lungs.
- Severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg indicating possible clots in the brain or eye.
- Breast lumps, which could be associated with fibrocystic disorders, fibroadenoma, or breast cancer. (Ask your doctor or health-care provider to show you how to examine your breasts monthly.)
- Yellowing of the skin and/or white of the eyes indicating possible liver problems.

You should also notify your doctor if you experience depression, worsening of your diabetic condition, or fluid retention.

Possible side effects of Prochieve®

In addition to the risks listed above, the following side effects have been reported with Prochieve® used either for progesterone supplementation or for replacement as part of an ART treatment for infertile women with progesterone deficiency. Consult your doctor if you experience any of the side effects mentioned below, or other side effects.

SIDE EFFECTS REPORTED AT A FREQUENCY OF 5% OR GREATER

- abdominal pain; perineal pain (the perineum is the area between the vagina and the rectum)
- headache
- constipation; diarrhea; nausea
- joint pain
- depression; decreased libido; nervousness; sleepiness*

- breast enlargement
- excessive urination at night

SIDE EFFECTS REPORTED AT A FREQUENCY RANGING FROM 1% TO 5%

- allergy; bloating; cramps; fatigue; pain
- dizziness*
- vomiting
- mood swings
- breast pain
- difficult or painful intercourse; genital itching; genital yeast infection; vaginal discharge
- urinary tract infection

SIDE EFFECTS REPORTED AT A FREQUENCY OF LESS THAN 1%

- fever; flu-like symptoms
- water retention†
- gastrointestinal discomfort; gas; abdominal swelling
- back pain; leg pain
- insomnia
- sinusitis; upper respiratory tract infection
- asthma
- acne; itching
- painful or difficult urination; frequent urination

*If you experience dizziness or sleepiness, do not drive or operate machinery.

†This may worsen some conditions such as asthma, epilepsy, migraine, heart disease, or kidney disease.

How Prochieve® works

Prochieve® has been formulated to be administered through the vagina. The moisturizing gel in Prochieve® forms a coating on the walls of the vagina which allows for absorption of progesterone through the vaginal tissue. Small, white globules may appear as a vaginal discharge possibly due to gel accumulation, even several days after usage. Prochieve® contains no irritating perfumes or dyes.

Other information

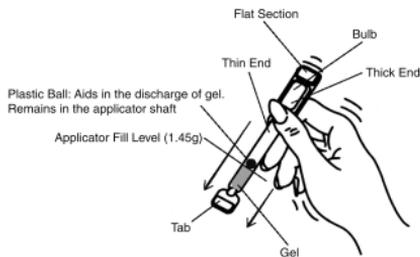
1. Your doctor has prescribed this drug for you and you alone. Do not give this drug to anyone else.
2. This medication was prescribed for your particular medical condition. Do not use it for another condition.
3. Keep this and all drugs out of the reach of children.

How to use Prochieve®

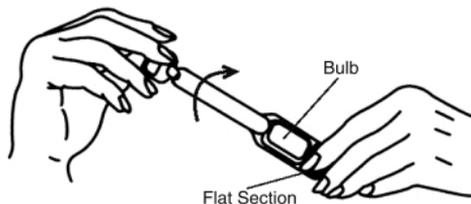
The dosage is one application of the 8% gel (90 mg of progesterone) vaginally, daily or twice daily as directed by your doctor. If you become pregnant, your doctor may decide to continue treatment for up to 10 to 12 weeks.

Prochieve® is to be applied directly from the specially designed sealed applicator into the vagina. The applicator is designed to deliver a premeasured dose of Prochieve®. A small amount of gel will be left in the tube after usage. Do not be concerned because you will still be receiving the appropriate, measured dosage.

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1. Remove the applicator from the sealed wrapper. **DO NOT** remove the twist-off tab at this time. *For use at altitudes above 2500 feet, see special instructions below.*
 2. Hold the applicator between the thumb and forefinger along the seam on the sides of the bulb. Shake down vigorously 3 to 4 times (like a thermometer) to ensure that the contents are at the thin end of the applicator.
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3. Hold the applicator by the flat section of the bulb. Twist off the tab at the thin end and throw away. **DO NOT** squeeze the bulb while twisting the tab. This could force some gel to be released before it is inserted.



Twist off completely - Do not pull off

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4. The applicator may be inserted into the vagina while you are in a sitting position or when lying on your back with your knees bent. Gently insert the thin end well into the vagina.

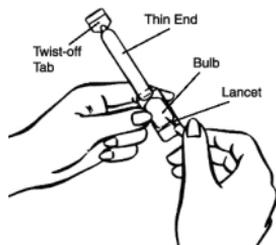


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5. Squeeze the bulb of the applicator to deposit the gel into the vagina. Remove the applicator and throw it away in a waste container. Do not be concerned if a small amount of gel is left in the applicator. You will still be receiving the appropriate, measured dosage.



SPECIAL INSTRUCTIONS FOR USE AT ALTITUDES ABOVE 2500 FEET

1. Remove the applicator from the sealed wrapper. **DO NOT** remove the twist-off tab at this time. *Hold the applicator on both sides of the bulb, as shown. Using a lancet or a stick pin, make a single puncture in the flat part of the bulb. This will relieve the difference in air pressure between the inside and outside of the applicator caused by high altitudes. It will not affect the amount of gel administered. You will still be receiving the appropriate, measured dosage.*



2. See Step 2 above.

3. See Step 3 above.

4. See Step 4 above.

5. *Place your thumb or finger over the puncture that you made in the bulb of the applicator. Squeeze the bulb of the applicator to deposit the gel into the vagina. Remove the applicator and throw it away in a waste container. Do not be concerned if a small amount of gel is left in the applicator. You will still be receiving the appropriate, measured dosage.*



Prochieve® coats the vaginal lining to provide long-lasting release of progesterone. Small, white globules may appear as a vaginal discharge possibly due to gel accumulation, even several days after usage. It is not unusual, but if you are concerned, discuss this with your doctor.

If you forget a dose of Prochieve®, use it as soon as you remember, but do not use more than the recommended daily dose. Prochieve® should not be used at the same time that you are using other vaginal therapy.

This leaflet provides the most important information about Prochieve®. If you want to read more, ask your doctor or pharmacist about the professional leaflet. You may need their help to understand some of the information.

How Supplied

Prochieve® is available as 8% gel (90 mg of progesterone).

Each box of the 8% gel contains either six or eighteen single use, disposable vaginal applicators with a twist-off tab. Each applicator is wrapped and sealed in a foil overwrap.

Prochieve® should be stored at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

Do not use Prochieve® after the expiration date which is printed on the box.