

# PROMETRIUM 200mg Vaginal Soft Capsules

Progesterone (200mg)

## What is in this leaflet

1. What Prometrium is used for
2. How Prometrium works
3. Before you use Prometrium
4. How to use Prometrium
5. While you are using it
6. Side Effects
7. Storage and Disposal of Prometrium
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

## What Prometrium is used for

PROMETRIUM is used for:

- Women who need extra progesterone while undergoing fertility treatment (e.g. ART)

If you are having fertility treatment and your doctor has determined your body does not produce enough progesterone your doctor may prescribe PROMETRIUM.

The progesterone will help prepare your uterus (womb) to receive and maintain a fertilised egg.

Once pregnancy occurs PROMETRIUM may be used until production of progesterone by the placenta is adequate.

- Prevention of preterm birth in women with singleton pregnancy who have a short cervix (midtrimester sonographic cervix  $\leq 25$  mm) and/or a history of spontaneous preterm birth. There is limited evidence supporting the use of progesterone with twin/multiple pregnancies. There is insufficient evidence to recommend the use of progesterone in women with preterm labour or 'other' risk factors for preterm birth.

- Reducing the risk of miscarriage in women with bleeding in the current pregnancy and a history of three or more previous miscarriages. The benefit of this medicine was shown to be limited to women who have had three or more previous miscarriages. However, your doctor may consider it appropriate to use in women with less than three miscarriages, who have a reduced chance of future pregnancy. Other known causes of potential miscarriage should be ruled out before starting treatment.

Your doctor may have prescribed PROMETRIUM for another purpose. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

## How does Prometrium work

PROMETRIUM contains the active ingredient micronised progesterone.

PROMETRIUM is provided as a soft capsule to be inserted deep into the vagina and contains the natural female hormone progesterone. Progesterone is a hormone essential for maintaining pregnancy.

## Before you use Prometrium

### - When you must not use it

Always check the ingredients to make sure you can use this medicine.

Do not use PROMETRIUM if:

- you are allergic to progesterone, or any of the ingredients listed at the end of this leaflet.
- you have or have had any of the following conditions:
  - Unusual vaginal bleeding that has not been evaluated by your doctors;
  - Known missed abortions or ectopic pregnancy;
  - Severe liver problems;
  - Known or suspected cancer of the breast or genital tract;
  - Blood clots (thrombophlebitis or thromboembolic disorder), such as inflammation of a vein, deep vein blood clotting (thrombosis) or a blood clot that travelled to the lungs (pulmonary embolism);
  - Bleeding on the brain;
  - Porphyria disorder (a blood disease).

### - Before you start to use it

Check with your doctor if you:

- have or have had any medical conditions, especially the following:
  - Epilepsy
  - Migraine
  - High blood pressure
  - Asthma
  - Heart, liver or kidney diseases
  - Diabetes
  - History of depression

- Tell your doctor or pharmacist if you have allergies to:
  - Any other medicines

- Soya (PROMETRIUM contains soya lecithin which may cause hypersensitivity reactions)

- Any other substances, such as foods, preservatives or dyes

If you have not told your doctor or pharmacist about any of the above, tell them before you use PROMETRIUM.

- If you think you have miscarried, you should speak to your doctor as you will need to stop using PROMETRIUM.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section "side effects"

PROMETRIUM is not suitable for use as a contraceptive.

## *Pregnancy and breastfeeding*

During fertility treatment PROMETRIUM should only be used during the first three months of pregnancy, unless your doctor has recommended otherwise.

For treatment to reduce the risk of miscarriage in women with bleeding in the current pregnancy PROMETRIUM should be initiated at the first sign of vaginal bleeding during the first trimester and should continue at least until the 16th week of pregnancy.

For the prevention of preterm birth PROMETRIUM may be prescribed by your Doctor during the second trimester (16 – 24 weeks gestation) and should be continued to the end of the 36th week of your pregnancy or until delivery.

Do not use PROMETRIUM if you are breast-feeding.

## *Children and adolescents*

Do not give PROMETRIUM to a child of any age. PROMETRIUM has not been evaluated in adolescents with childbearing potential.

## - Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

# PROMETRIUM 200mg Vaginal Soft Capsules

## Progesterone (200mg)

Some medicines may interfere with PROMETRIUM and affect how it works or how these medicines work. These include:

- Carbamazepine, Phenobarbital and Phenytoin (medicines for epilepsy)
- Rifampicin
- Phenylbutazone
- Spironolactone
- Griseofulvin
- Some antibiotics including Ampicillins and Tetracyclines
- Bromocriptine
- Cyclosporin
- Ketoconazole

These medicines may be affected by PROMETRIUM or may affect how well they work. You may need different amounts of your medicine or you may need to use different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PROMETRIUM.

## How to take Prometrium

### -How much to take

Your doctor will tell you how many capsules you need to use each day.

- For supplementation during Assisted Reproductive Technology, the recommended dosage is 600 mg/day, in three divided doses from the day of embryo transfer until at least the 7th week of pregnancy and not later than the 12th week of pregnancy.

- For treatment to reduce the risk of miscarriage in women with bleeding in the current pregnancy, the usual dose is 400 mg twice daily from the first sign of vaginal bleeding until at least the 16th week of pregnancy.

- For the prevention of preterm birth the usual dose is 200 mg/day recommended at bedtime, during the second trimester (16-24 weeks gestation) and should be continued until the end of the 36th week of your pregnancy or until delivery.

### - When to use it

PROMETRIUM is intended to be inserted into the vagina.

- Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

- PROMETRIUM should not be used at the same time as other vaginal preparations.

### - How long to use it

Do not stop using PROMETRIUM or lower the dosage without checking with your doctor.

### - If you forget to use it

PROMETRIUM should be used as instructed by your doctor for the recommended timeframes for each use.

If you miss a dose, use it as soon as you remember, and then go back to using your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and go back to using your medicine when you are meant to.

Do not use a double dose to make up for the dose you missed.

### - If you use too much (overdose)

If you think that you or anyone else may have used too much PROMETRIUM, you may need urgent medical attention.

You should immediately:

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose with PROMETRIUM include feeling dizzy or feeling tired.

## While you are using it

### - Things you must do

PROMETRIUM contains soya lecithin. If you are allergic to soya do not use PROMETRIUM.

### Things you should do

Call your doctor straight away if you:

- Experience swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Hives

You may have had a very serious reaction to PROMETRIUM and may need urgent medical attention or hospitalization.

Remind any doctor, dentist or pharmacist you visit that you are using PROMETRIUM.

### - Things you must not do

Prometrium is not suitable to be used as contraceptive pill.

Do not give Prometrium away to others.

- Do not stop using this medicine or lower the dosage without checking with your doctor or pharmacist.
- PROMETRIUM should not be used at the same time as other vaginal preparations

### - Things to be careful of

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how PROMETRIUM affects you.

PROMETRIUM may cause drowsiness or dizziness in some people. Make sure you know how you react to PROMETRIUM before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

#### **Drinking alcohol**

Tell your doctor if you drink alcohol. Alcohol may increase the effect of PROMETRIUM

#### **Side effects**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

| Less serious side effects                                                                                                               | What to do                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Side effects such as: <ul style="list-style-type: none"> <li>• Burning</li> <li>• Local itching</li> <li>• Vaginal disorders</li> </ul> | Speak to your doctor if you have any of these less serious side effects and they worry you. |

#### Serious side effects

| serious side effects                                                                                                  | What to do                                                                    |
|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| Side effects such as: <ul style="list-style-type: none"> <li>• Swelling of the face, lips, mouth or throat</li> </ul> | Call your doctor straight away, or go straight to the Emergency Department at |

# PROMETRIUM 200mg Vaginal Soft Capsules

Progesterone (200mg)

|                                                                |                                                                        |
|----------------------------------------------------------------|------------------------------------------------------------------------|
| which may cause difficulty swallowing or breathing.<br>• Hives | your nearest hospital if you notice any of these serious side effects. |
|----------------------------------------------------------------|------------------------------------------------------------------------|

Inactive ingredients:  
Sunflower oil, soybean lecithin, gelatin, glycerol, purified water and titanium dioxide.

Systemic side effects of tiredness and dizziness observed with the oral form have not been reported at the recommended dosages for vaginal use. Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Other side effects not listed here may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of Prometrium

### - Storage

Store below 30 Celcius. Do not refrigerate.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

### - Disposal

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date

## Product Description

### - How it looks like

PROMETRIUM 200 is an ovoid, slightly yellow soft capsule, containing a whitish oily suspension.

PROMETRIUM 200 is supplied in blister strips packaged in an outer carton. Each carton contains 7 (trade or starter pack), 14, 15, 21, 28, 30, 42, 45, 56, 84 or 90\* capsules.

\* Not all pack sizes may be marketed

### - Ingredients

Active Ingredient:  
Micronized progesterone.

### - MAL Number

MAL24066005ACZ

### Manufacturers

Cyndeia Pharma S.L.  
Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31-42110 Olvega, (Soria), Spain

### Product Registration Holder

EP Plus Group Sdn. Bhd.  
Block C-3-1, Plaza Mont Kiara, No. 2, Jalan Kiara, Mont Kiara, 50480 Kuala Lumpur, Malaysia

### Date of Revision:

05/05/2025

### Serial No.:

NPRA (R1/1) 12072024/133

# PROMETRIUM 200mg Vaginal Soft Capsules

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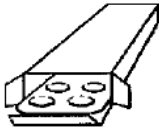
## Prometrium Vaginal administration

### Method

1. Wash your hands and vagina before insertion.



2. Remove the soft capsules from the packaging.



3. Choose the position that is most comfortable for you:

(a) Lie on your back with your knees bent, and legs slightly apart

a



(b) Squatting

b



(c) Standing with one leg up

c



4. Gently insert the soft capsule into the vagina.



5. Slowly insert the capsule as deep as possible into your vagina, with the help of your fingers.



Note: insert the capsules one by one when more than one capsules are required. Sanitary pad can be used to protect your underwear from oily ingredient.