PATIENT INFORMATION LEAFLET

PROGESTOGEL®
gel, 10mg/g; tube containing 80g gel with dose applicator in the box

1. Besins Manufacturing Belgium;
2. Laboratoires Besins International;
1. Groot Bijgaardenstraat 128, 1620 Drogenbos, Belgija
2. 13, rue Perier, 92120 Montrouge, Francuska
MA Holder: Sodimed d.o.o.
Address: Milorada Šapčanina 2, Beograd
PROGESTOGEL® 10 mg/g; gel progesteron

Read all of this leaflet carefully before using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should 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 becomes serious or you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist on this.

In this leaflet you will read:
1. What is PROGESTOGEL and what it is used for
2. Before using PROGESTOGEL
3. How to use PROGESTOGEL
4. Possible side effects
5. How to store PROGESTOGEL
6. Additional information
1. WHAT IS PROGESTOGEL AND WHAT IT IS USED FOR
Progestogel contains natural physiological progestagen (progesterone) that is used for pre-menstrual breast pain (essential pre-menstrual mastodynia) provided that there are no pathological changes in the breast tissue.

Progestogel is not indicated for male patients.

2. BEFORE USING PROGESTOGEL

Warn your doctor if you are taking other medicines, having any chronic disease, other metabolism disorder, have hypersensitivity to medicines or have had any allergic reactions to medicines.

Do not use Progestogel:
- If you are allergic (hypersensitive) to progesterone or any other excipient of Progestogel (see section 6.1.)
- If you have or you had hormone-dependent tumour (e.g. Progesterone receptor positive breast cancer)

Take special care with PROGESTOGEL:
Before initiating a therapy with medicine Progestogel there should be a physical examination to diagnose potentially existing hormone dependent tumours, e.g. breast cancer.

Special attention should be paid to hygiene of breasts and hands after applying the gel.

This medicine is for external use and should not be swollen.

This treatment is not contraceptive.

The risk of side effects after direct contact to another person should not be excluded, although it has not be specifically studied or highlighted.

Using PROGESTOGEL with other medicinal products

Warn your doctor if you are taking or have took recently other medicines, including medicines delivered without prescription.

Using PROGESTOGEL with food and beverages

Not applicable.

Using PROGESTOGEL in pregnancy and breastfeeding
It is not recommended to use Progestogel during pregnancy or breastfeeding. If you have any questions ask your doctor.

**Driving or using machines**

Effects on the ability to drive or to operate machines are not known.

**Important information about some of the ingredients of PROGESTOGEL**

Medicine contains the excipient polyoxyl hydrogenated castor oil which may cause skin reactions.

**3. HOW TO USE PROGESTOGEL**

For external use.

Therapy should be used from 10th – 25th day of the cycle. Daily apply 5 g of gel (2.5g on each breast).

Squeeze out the gel evenly from the tube inside the groove on the dose applicator.

After bath, apply on each breast 2.5g of gel using dose applicator, and massage gently until gel penetrates the skin.

Medicine Progestogel can be used during longer period of time, provided that medical examinations are recommended every three months.

The maximum daily dose is 5 g.

If you consider that Progestogel affects your organism too strong or too weak, consult with your doctor or pharmacist.

If you use more PROGESTOGEL than you should:

If you use too much PROGESTOGEL, immediately contact your doctor or pharmacist.

If you forget to use PROGESTOGEL:

If you forget a dose, do not double the dose to make up for the forgotten dose. Follow the treatment as prescribed.

If you suddenly stop using PROGESTOGEL

Not applicable.

**4. POSSIBLE SIDE EFFECTS**
Like all medicines, PROGESTOGEL can have side effects, but they don't have to appear to all persons. Most commonly can be observed an advance (1-2 days) of menstrual bleeding, without any changes in the bleeding flow. Isolated cases of hypersensitivity or skin irritations have been observed due to presence of alcohol in gel.

*If you notice any side effect not stated here, please inform your doctor or pharmacist.*

### 5. HOW TO STORE PROGESTOGEL

*Keep PROGESTOGEL out of reach of children!*

#### Shelf life

3 years in original packaging

Shelf life after first opening is 30 days in storing conditions on temperature up to 25° C.

#### Storage

*Unused medicine and material for throwing should be disposed in accordance with applicable regulations of the Republic of Serbia.*

Drugs should not be thrown in sewers or household waste. Ask your pharmacist how to remove drugs that you are no longer needed. These measures help to keep the environment.

### 6. ADDITIONAL INFORMATION

#### What contains PROGESTOGEL

100 g gel contains 1 g of progesterone.

Other excipients are: oktildodekanol, carbomer 980, macrogolglycerol hydroksistearate, trolamine, 96% ethanol, purified water

#### How PROGESTOGEL looks like and content of packaging

Colorless or little opalescent gel, smells on alcohol and without presence of crystals.

80 g of gel in tube with dose applicator in box.

Inner packaging is sealed Al tube which is coated on the inside with the layer of epoxyphenol and closed with white HDPE closure.

In the packaging there is graduated applicator for dosing made from polystyrene marked with labels for dosing: 2x1,25 g, total 2,5g.

#### MA Holder

Sodimed d.o.o. Milorada Šapčanina 2, Beograd

#### Manufacturer

Laboratoires Besins International, 13, rue Périer, 92120 Montrouge, Francuska and

Besins Manufacturing Belgium, Groot Bijgaardenstraat 128, 1620 Drogenbos, Belgija
This leaflet is last approved

June 2010

Medicine delivery:

Delivered on medical prescription

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