

PACKAGE LEAFLET: INFORMATION FOR THE USER

BLISSEL® 50 micrograms/g, vaginal gel

Estriol

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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1. WHAT BLISSEL IS AND WHAT IT IS USED FOR

BLISSEL contains estriol, a female hormone which is identical to a hormone naturally produced by the body called oestrogen. Estriol helps maintain the cells that cover the vagina (mucosa) elastic and more resistant to friction and decreases the risk of occurrence of infection.

BLISSEL is used in the treatment of vaginal dryness, which could be due to a lack of oestrogens after menopause.

2. BEFORE YOU USE BLISSEL

Do not use BLISSEL

- if you suffer, have suffered or suspect that you may suffer from breast or uterine cancer
- if you are or believe you may be pregnant
- if you have abnormal vaginal haemorrhaging
- if you suffer from abnormal growth of the endometrium (endometrial hyperplasia)
- if you suffer or have previously suffered blood clots in the veins of the legs (deep venous thrombosis) or in the lungs (pulmonary embolism)
- if you suffer or have recently suffered heart problems such as angina pectoris or heart attack
- if you suffer from an acute liver disease or have previously suffered from any liver disease and it has not recovered
- if you are allergic (hypersensitive) to oestriol or to any of the other ingredients of BLISSEL
- if you suffer from porphyria (rare metabolic disease)

If any of the previously mentioned circumstances apply, **do not use** this medicine.

Take special care with BLISSEL

This medicine is administered inserting an applicator in the vagina. This may cause discomfort or pain in women with severe vaginal atrophy (narrowing or inflammation of the vagina walls).

Medical examinations

Before treatment with BLISSEL, your doctor should ask about you and your family's medical history. Your doctor may decide to examine your breasts or your stomach and may do an internal examination. They will only do this if it is necessary or if you have any special concerns.

Once you have started using BLISSEL, you must see your doctor for regular check-ups (**at least once a year**). At these check-ups, your doctor may discuss the need to continue using BLISSEL.

Please inform your doctor if you have ever had any of the following diseases/conditions, which in rare occasions may reappear or worsen during treatment with BLISSEL: any heart or circulation disease, excess cholesterol or other fats in the blood, changes in the breast, endometriosis (abnormal growth of the layer covering the inside of the uterus, outside of the uterus), benign uterus tumour (myoma), high blood pressure, diabetes, stones in the gallbladder, migraine or severe headache, a rare immune disease called Systemic Lupus Erythematosus (SLE), epilepsy (seizures), asthma, otosclerosis (deafness caused by hardening of ear tissue), kidney disease.

Reasons to consult your doctor immediately

- jaundice (yellow colouring of the white of the eyes and the skin) or liver disorders
- sudden increase in blood pressure
- if you suffer from migraine or severe headache for the first time
- pregnancy
- if any of the circumstances described in the section “Do not use BLISSEL” occur.

If any of the situations described above occur, your doctor may need to interrupt the treatment and provide you with an alternative.

Treatment with medicines that contain higher doses of oestrogen which may increase blood oestrogen levels (such as tablets or patches) increase the risk of abnormal endometrium growth (hyperplasia of the endometrium), certain types of cancer such as breast and endometrial cancer and blood clots in the veins. Since BLISSEL is a topical treatment vaginal gel and contains a very low estriol dose, the risk of these diseases occurring is very low. How if you are concerned about these risks, consult your doctor.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Since BLISSEL contains a very low estriol dose and is a topical treatment, it is not expected to affect or be affected by the use of other medicines.

Pregnancy and breast-feeding

Do not use BLISSEL if you are pregnant.

If you become pregnant during treatment, tell your doctor immediately and do not use BLISSEL.

You should not use BLISSEL while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

BLISSEL does not affect the ability to drive and use machines.

Important information about some of the ingredients of BLISSEL

BLISSEL may produce allergic reactions (possibly delayed) as it contains sodium methyl parahydroxybenzoate (E-219) and sodium propyl parahydroxybenzoate (E-217).

Do not use this medicine if you are allergic to any of its ingredients.

3. HOW TO USE BLISSEL

Always use BLISSEL exactly as your doctor has told you.

The normal dose over the first three weeks of treatment is one application daily, preferably at bedtime. After 3 weeks of use, the discomfort should have decreased and the dose should be reduced. You may only need an application twice a week.

How to apply the gel

Inside the cardboard box, you will find a 10g tube of BLISSEL and a blister with 10 disposable tubes (cannula) engraved with a fill mark and a reusable plunger.

Use the applicator to introduce the gel in the vagina (it is recommended to apply it before going to bed).

If you use more BLISSEL than you should

Do not worry if you apply too much gel or if someone ingests a little gel accidentally. However, consult your doctor or pharmacist.

You may be in pain and in some women, there may be vaginal haemorrhaging after a few days.

If you forget to use BLISSEL

Apply the forgotten dose when you remember, unless more than 12 hours have passed by. In that case, simply omit the forgotten dose. **Do not take a double dose to make up for a forgotten dose.**

If you have any any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BLISSEL can cause side effects, although not everybody gets them.

Inform your doctor immediately if any of the situations described in the section “BEFORE YOU USE BLISSEL”, such as vaginal bleeding. Your doctor may suspend the treatment and provide you with another alternative.

Vaginal irritation or itching may occur in the beginning of treatment. In the majority of patients, these side effects disappear with continuous use. Inform your doctor in case of vaginal bleeding or if any of the following side effects worsen or continue.

Common side effects (occur in less than 1 out of 10 patients):

Itching, irritation within or around the vagina.

Uncommon side effects (occur in less than 1 out 100 patients):

Lower abdominal pain, skin irritation, vaginal rash, headache, candidiasis (vaginal infection).

The following very rare side effects may appear when medicines that contain much higher doses of oestrogen, which may increase oestrogen levels in blood (such as tablets or patches) are used:

- Certain types of tumours such as endometrial or breast cancer
- Blood clots in veins
- Heart attacks and stroke
- Gallbladder disease
- Skin disorders such as rashes or red spots on the skin
- Dementia (brain disease)

Since BLISSEL is a vaginal gel for topical treatment and contains a very low dose of estriol, the risk of appearance of these side effects is very low.

- **If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet**

5. HOW TO STORE BLISSEL

Keep out of the reach and sight of children.

Do not use BLISSEL after the expiry date which is stated on the carton and the label.

Do not store above 25°C.

Medicines should not be disposed via wastewater or household waste. Take the packaging and medicines no longer required to the pharmacy. Ask your pharmacist how to dispose of packaging and medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What BLISSEL contains

The active substance is estriol.

The applicator filled to the line corresponds to a dose of 1g of vaginal gel.

Each gram of gel contains 50 micrograms of estriol.

The other ingredients are: Glycerol (E 422), sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), polycarbophil, carbopol, sodium hydroxide, hydrochloric acid, purified water.

What BLISSEL looks like and contents of the pack

This medicine is a colourless, transparent or slightly translucent vaginal gel that contains an aluminium tube of 10g and one blister with 10 disposable cannula with a fill line and a reusable plunger.

Marketing Authorisation

Holder and Manufacturer:

ITALFARMACO, S.A.

C/ San Rafael, 3

28108 Alcobendas (Madrid)

Spain

Distributed by:

VERSALYA PHARMA S.L. (Italfarmaco Group)

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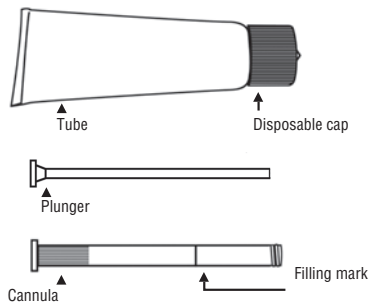
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Spain

This leaflet was last approved in September 2013.

The following instructions explain how the gel should be used.

You can see all the components of the tube and the applicator in the following picture.



- 1 Unscrew the top of the tube, turn the top upside down and use the sharp tip to break the seal in the neck of the tube.



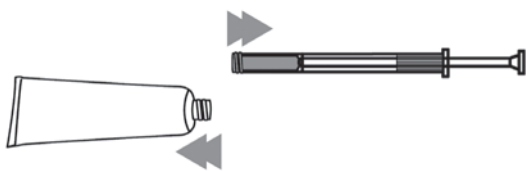
- 2 Take a cannula and the plunger. Introduce the white plunger through the cannula. Screw the cannula to the end of the tube.



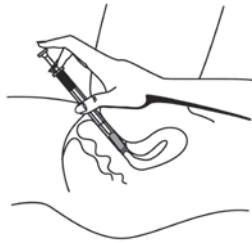
- 3 Press the tube to fill the applicator with gel up to the fill line.



- 4 Unscrew the cannula from the tube and place the top again on the tube.



- 5 To apply the gel, lie down, introduce the tip of the applicator deep into the vagina and slowly push the plunger down.



- 6 After use, take out the plunger from the cannula, throw away the cannula and clean the plunger thoroughly with water for use again in the next application.

