Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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. See section 4.

What is in this leaflet

1. What Blissel is and what it is used for
2. What you need to know before you use Blissel
3. How to use Blissel
4. Possible side effects
5. How to store Blissel
6. Contents of the pack and other information

1. What Blissel is and what it is used for

Blissel contains estriol, a female hormone that is identical to a hormone that your body makes naturally called oestrogen.

Blissel is used: For vaginal problems caused by having too little ‘oestrogen’

Shortage of oestrogens may cause the vaginal wall to become thin and dry. So sexual intercourse may become painful and you may get vaginal infections. These problems can be relieved by using medicines like Blissel which contain oestrogen. It may take several days or weeks before you notice an improvement.

Blissel is used for the treatment of vaginal dryness, which is due to lack of oestrogen after menopause.

2. What you need to know before you use Blissel

As well as benefits, HRT (Harmone Replacement Therapy) has some risks that you need to consider when you're deciding whether to start taking it, or whether to carry on taking it.

Before you start taking HRT

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 for you or you have any special concerns.

- Tell your doctor if you have any medical problems or illnesses.
Regular check-ups

Once you have started on HRT, see your doctor for regular check-ups. At these check-ups, your doctor may discuss the benefits and risks of continuing to take HRT.

Do not use Blissel

- If you have or have ever had breast cancer, or if you are suspected of having it;
- If you have cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it;
- If you have any unexplained vaginal bleeding;
- If you have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated;
- If you have or have ever had a blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism);
- If you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency);
- If you have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina;
- If you have or have ever had a liver disease and your liver function tests have not returned to normal;
- If you have a rare blood problem called “porphyria” which is passed down in families (inherited);
- If you are allergic (hypersensitive) to Estriol or any of the other ingredients of Blissel (listed in section 6 Further information);

If any of the above conditions appear for the first time while taking Blissel, stop taking it at once and consult your doctor immediately.

Warnings and precautions

The medicine is given by inserting an applicator into the vagina. This may cause discomfort or soreness in women who have severe vaginal atrophy (thinning or inflammation of the vaginal walls).

Please tell your doctor if you have or have had any of the following disease/conditions, that in rare cases can return or become worse during treatment with Blissel:

- any disease of the heart or circulation
- too much cholesterol or other fatty substances in the blood
- changes in your breast
- endometriosis (abnormal growth of the inner lining of your womb outside the womb)
- benign tissue lump in your womb (myoma)
- high blood pressure
- diabetes
- gallstones
- migraine or severe headache
- a rare disease of the immune system called systemic lupus erythematosus (SLE)
- epilepsy (fits)
- asthma
- otosclerosis (deafness caused by thickened ear tissue)
- kidney disease
Reasons to contact your doctor immediately

- you get jaundice (your eyes and skin go yellow) or problems with your liver function
- a sudden increase in blood pressure
- if you get migraine or severe headache, for the first time
- you become pregnant
- if anything under the heading “Do not use Blissel” occurs.

If any of the above occurs, your doctor may need to stop treatment and give you an alternative.

Treatment with higher dose oestrogen preparations that can raise your blood levels of oestrogen (such as tablets or stick on patches) increases the risk for abnormal growth of the lining of your womb (endometrial hyperplasia), certain types of cancer such as breast and endometrial cancer and blood clots in the veins. Blissel is a vaginal gel for local treatment and contains a very low dose of estriol, therefore your risk of developing these conditions is very low. Nevertheless, if you are concerned about these risks, you should discuss it with your doctor.

Other medicines and Blissel

Blissel contains a low dose of estriol and is for local treatment, therefore it is not expected to affect or be affected by taking other medicines.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You should not use Blissel if you are pregnant.

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

You should not use Blissel during breast-feeding.

Driving and using machines

Blissel has no effect on your ability to drive and use machines.

Blissel contains

Sodium methyl parahydroxybenzoate (E 219) and sodium propyl parahydroxybenzoate (E 217). They may cause allergic reactions (possibly delayed).

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

3. How to use Blissel

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for the first 3 weeks of treatment is one applicator-dose per day, preferably before going to bed. After 3 weeks of use, your discomfort should have decreased and the dose should be lowered. You may only need one dose twice a week.

Use the applicator to insert the gel in the vagina (it is recommended before going to bed).
The following instructions explain how the gel should be used.

In the picture below you can see different elements of the tube and the applicator (plunger and cannula).

1. Remove the tube cap, turn it upside down and use the sharp point to pierce the seal on the neck of the tube. Do not use if seal is broken.

2. Take out a cannula and the plunger. Insert the white plunger all the way into the cannula. Screw the cannula on the neck of tube.

3. Squeeze the tube to fill the applicator with the gel up to the filling mark. The plunger will stop at the mark.
4. Unscrew the cannula from the tube and replace the cap on the tube.

5. To apply the gel, lie down, insert the end of the applicator deep into the vagina and slowly push the plunger all the way down.

6. After use,

Pack size of 10g – 1 Blister containing 10 disposable tubes (cannulas) and a reusable plunger.
Pack size of 30g – 3 Blisters containing 30 disposable tubes (cannulas) and a reusable plunger.
Pull the plunger out of the cannula, dispose of the cannula and rinse the plunger well with warm and clean water so it can be reused for the next application.
Pack size of 10g – Bag containing 1 reusable tube (cannula) and a reusable plunger.
Pack size of 30g – Bag containing 1 reusable tube (cannula) and a reusable plunger.
Pull the plunger out of the cannula. Rinse both cannula and plunger well with warm and clean water so it can be reused for the next application.

If you use more Blissel than you should
If too much gel is applied at any time or someone has swallowed some gel accidentally, there is no need to worry. However, you should consult a doctor for advice. You might feel sick or be sick and some women may have some vaginal bleeding after a few days.

If you forget to use Blissel
Do not use a double dose to make up for a forgotten dose.
Apply the missed dose when you remember, unless you are more than 12 hours late. If you are more than 12 hours late just skip the missed dose.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
4. **Possible side effects**

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

**Tell your doctor immediately** if any of the conditions that are listed in the section “What you need to know before you use Blissel” occur, such as vaginal bleeding. Your doctor may need to stop treatment and give you an alternative.

At the beginning of treatment local irritation or itching may occur. In most patients these side effects go away with continued use. Tell your doctor if vaginal bleeding occurs, or if any of the following side effects become troublesome or continue.

**Common side effects (may affect up to 1 in 10 people):**
- Itching, local irritation in or around the vagina

**Uncommon side effects (may affect up to 1 in 100 people):**
- Low abdominal pain, skin irritation, genital rash, headache, Candidiasis (vaginal ‘thrush’)

**Other very rare side effects (may affect up to 1 in 10,000 people):** may occur when higher dose oestrogen preparations that can raise blood levels of oestrogen (such as tablets or stick on patches) are taken for a long time.

- breast cancer;
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer);
- blood clots in the veins of the legs or lungs (venous thromboembolism);
- heart disease;
- stroke;
- probable memory loss;

For more information about these side effects, see Section 2.

As Blissel is a vaginal gel for local treatment and contains a very low dose of estriol, your risk of developing these side effects is very low.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. **How to store Blissel**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
6. Contents of the pack and other information

What Blissel contains
The active substance is estriol.
One applicator filled to the mark delivers a dose of 1 g vaginal gel that contains 50 micrograms estriol.
The other ingredients are: Glycerol (E422), sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), polycarbophil, carbopol, sodium hydroxide, hydrochloric acid, purified water.

What Blissel looks like and content of the pack
This medicinal product is presented as a colourless, clear to slightly translucent vaginal gel, pack size of 1 aluminium tube 10 g or 30 g.

- **Pack size of 10 g – Blister containing 10 disposable tubes (cannulas) and a reusable plunger.**
  Cardboard box containing 10 g of Blissel and one blister containing 10 disposable tubes (cannulas) with a filling mark and a reusable plunger.

- **Pack size of 10 g – Bag containing 1 reusable tube (cannula) and a reusable plunger.**
  Cardboard box containing 10 g of Blissel and one bag containing 1 reusable tube (cannula) with a filling mark and a reusable plunger.

- **Pack size of 30 g - 3 Blisters each-containing 10 disposable tubes (cannulas) and a reusable plunger.**
  Cardboard box containing 30 g of Blissel and three blisters each-containing 10 disposable tubes (cannulas) with a filling mark and a reusable plunger.

- **Pack size of 30 g – Bag containing 1 reusable tube (cannula) and a reusable plunger.**
  Cardboard box containing 30 g of Blissel and one bag containing 1 reusable tube (cannula) with a filling mark and a reusable plunger.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

**Marketing Authorisation Holder**
ITALFARMACO S.A.
San Rafael, 3 - 28108 Alcobendas
(Madrid)- Spain

**Distributor**
Flynn Pharma Limited
Hertlands House, Primett Road,
Stevenage,
SG1 3 EE.

Manufacturer responsible for batch release
This medicinal product is authorized in the Member States of the EEA under the following names:

ES: Blissel 50 microgramos/g gel vaginal
SU: Blissel 50 mikrogram/g vaginal gel
FR: Blissel 50 microgrammes/g gel vaginal
IT: Blissel 50 microgrammi/g gel vaginale
PO: Blissel 50 microgramas/g gel vaginal
EL: Blissel 50 μικρογραμμάρια/g κολπική γέλη
BE: Blissel 50 microgrammes/g gel vaginal
DK: Gelisse 50 mikrogram/g vaginalgel
FI: Blissel 50 mikrog/g emätingeeli
IE: Blissel 50 micrograms/g vaginal gel
NL: Blissel 50 microgram/g gel voor vaginaal gebruik
NO: Gelisse 50 mikrogram/g vaginalgel
UK: Blissel 50 micrograms/g vaginal gel

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