

BP Gonadotropin

Powder for solution for injection **5 000 IU + solvent 1 ml**
Gonadotropin, chorionic

Read all of this leaflet carefully before you start taking 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 BP Gonadotropin is and what it is used for
2. What you need to know before you take BP Gonadotropin
3. How to use BP Gonadotropin
4. Possible side effects
5. How to store BP Gonadotropin
6. Contents of the pack and other information

1. What BP Gonadotropin is and what it is used for

BP Gonadotropin belongs to a group of medicines called gonadotrophins (sex hormones). It controls the release of eggs from the ovary in women and controls production of the male hormone, testosterone in men.

Women

In female infertility it can be used to cause women to ovulate (ovulation induction). BP Gonadotropin is also used along with other fertility drugs, to help produce eggs in medically assisted reproduction programs. (IVF treatment).

Men

In men it is used to help treat delayed puberty, undescended testes or oligospermia (low sperm count).

2. What you need to know before you use BP Gonadotropin

Do not use BP Gonadotropin if you:

- are allergic (hypersensitive) to chorionic gonadotropin or any of the other ingredients of BP Gonadotropin.
- have cancer (especially a hormone-dependent cancer of the breast, ovaries, womb or the testes) of uterus in the female and prostate tumor in males.
- suffer from malformations of the sexual organs incompatible with pregnancy
- suffer from fibroids in the uterus that are incompatible with pregnancy
- have recently had unexpected vaginal bleeding

Do not use BP Gonadotropin if you have any of the conditions listed above. If any of these conditions apply to you, please tell your doctor before starting to use this medicine.

Tell your doctor before you use BP Gonadotropin if you suffer from or have suffered in the past from any of the following conditions:

- Men with
 - heart problems
 - kidney problems
 - high blood pressure
 - epilepsy
 - migraine

as their worsening or recurrence may occasionally be induced as a result of increased production of androgens (male sex hormones).

Treatment with gonadotrophins causes an increase in the production of androgens (male sex hormones).

- abnormalities of the sexual organs. Before treatment with BP Gonadotropin your doctor should have checked that your sexual organs are normal.
- in women patients: your doctor should have checked how your ovaries are working before starting treatment with BP Gonadotropin. Extra supervision may be necessary in some cases.

BP Gonadotropin should be used carefully when treating **boys who have not reached puberty**. This is because it can cause early sexual development and may result in final adult height not being reached.

Fertility treatment

Close supervision of female patients undergoing fertility treatment is extremely important to avoid the rare complication of hyperstimulation of the ovaries. The side effect may be felt as pain in the stomach.

If you are troubled with stomach pains, contact your doctor straight away.

This warning is particularly important with respect to patients with polycystic ovarian disease. Regular monitoring of the response to gonadotropin-treatment helps your doctor to prevent excessive ovarian stimulation.

If treatment with BP Gonadotropin results in pregnancy, there is an increased chance of having twins or multiple pregnancies. Multiple pregnancies carry an increased risk for both the mother and her babies around the time of birth. There is also an increased chance of a miscarriage, or a pregnancy outside the womb (an ectopic pregnancy).

In addition, multiple pregnancies and characteristics of patients undergoing infertility treatment (eg, woman's age, sperm characteristics) may be associated with an increased risk of congenital malformations.

BP Gonadotropin may be used for luteal phase support but should not be used later during pregnancy.

If you have risk factors for having a **blood clot** (for example being overweight, or if blood clots run in your family), the chance of having a blood clot may be increased during IVF treatment.

Being pregnant increases the chance of having a blood clot.

BP Gonadotropin has no effect on fat metabolism, fat distribution or appetite.

The presence of a thyroid, adrenal or pituitary illness which is not being treated should be ruled out before using BP Gonadotropin.

BP Gonadotropin and other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Interactions of BP Gonadotropin with other drugs have not been evaluated; therefore, interactions with commonly used drugs cannot be excluded.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking any medicine.

BP Gonadotropin may be used for luteal phase support but should not be used later during pregnancy.

Breast-feeding

BP Gonadotropin must not be used during lactation.

Driving and using machines

As far as is known, BP Gonadotropin has no effect on alertness and concentration.

This medicinal product contains less than 1 mmol sodium (23 mg) per daily dose, i.e. essentially 'sodium-free'.

3. How to use BP Gonadotropin

Always use BP Gonadotropin exactly as your doctor has told you. You should check with your doctor if you are not sure. Your doctor will decide on the dose of BP Gonadotropin to be given.

Dosage

Dosage in females:

- Ovulation induction in subfertility due to anovulation or impaired follicle-ripening

Usually, one injection of 5000-10000 IU BP Gonadotropin to complete treatment with an FSH-containing preparation.

- Preparation of follicles for puncture in controlled ovarian hyperstimulation programs

Usually, one injection of 5000-10000 IU BP Gonadotropin to complete treatment with an FSH-containing preparation.

- Luteal phase support

Two to three repeat injections of 1000 to 3000 IU each may be given within nine days following ovulation or embryo transfer (for example on day 3, 6 and 9 after ovulation induction).

Dosage in males:

In male patients, injections are given several times a week for some weeks or months, depending on the problem. Because the development of sperm cells takes about 74 days, treatment should be continued for at least three months before any improvement can be expected.

- Hypogonadotropic hypogonadism

1000-2000 IU BP Gonadotropin, two to three times per week. If the main complaint is subfertility, BP Gonadotropin may be given with an additional follitropin (FSH)-containing preparation two to three times a week. This treatment should be continued for at least three months before any improvement in spermatogenesis can be expected. During this treatment testosterone replacement therapy should be suspended. Once achieved, the improvement may sometimes be maintained by hCG alone.

- Delayed puberty associated with insufficient gonadotropic pituitary function

1500 IU two to three times a week for at least six months.

- Preoperative preparation of ectopic testes

500 IU 2 or 3 times weekly for 1 to 2 months before operation

- Cryptorchidism, not due to anatomical obstruction

- under 2 years of age: 250 IU twice weekly for six weeks,
- under 6 years of age: 500-1000 IU twice weekly for six weeks,
- over 6 years of age: 1500 IU twice weekly for six weeks.

If necessary, this treatment can be repeated.

If you have the impression that the effect of BP Gonadotropin is too strong or too weak, talk to your doctor immediately.

How are the injections given?

Prior to use, the dry powder should be dissolved with the solvent contained in the ampoule.

This medicine can be injected into muscles in the buttock, upper leg or upper arm, or immediately under the skin (for example in the abdominal wall). Only to be injected by a doctor or a nurse.

If you use more BP Gonadotropin than you should

As BP Gonadotropin is only to be given by a doctor or a nurse, it is unlikely that you will be given too much, however too high a dose of BP Gonadotropin may cause hyperstimulation of the ovaries. This may be noticed as pain in the abdomen.

If you are troubled by stomach pains, tell your doctor immediately.

If you accidentally use too much BP Gonadotropin, contact your doctor or pharmacist immediately.

The toxicity of BP Gonadotropin is very low.

If you forget to use BP Gonadotropin

If you forget to use a dose do not take a double dose to make up for a missed dose.

Talk to your doctor.

If you stop taking BP Gonadotropin

Do not stop taking BP Gonadotropin unless your doctor tells you to. Your doctor will advise you if you need to stop using BP Gonadotropin for any reason.

If you have any further questions on how to take BP Gonadotropin, ask your doctor or pharmacist.

4. Possible side effects

Contact your doctor immediately if you are a woman and experience:

Swelling of abdomen or chest due to fluid retention, weight gain, severe pain in the abdomen, feeling sick (nausea), diarrhea, or painful breasts, also if it occurs a few days after you receive your last injection, since it could be a sign of unwanted overstimulation of the ovaries (OHSS).

Very rarely, thrombosis can occur without unwanted ovarian hyperstimulation.

Like all medicines, BP Gonadotropin can cause side effects, although not everybody gets them. Injection site reactions such as bruising, pain, redness, swelling and itching have been reported.

Occasionally, allergic reactions that have been reported mainly involve pain and rash at the injection site. In rare cases, generalized reactions such as rash and fever may occur.

If you are a man

In men, there may be accumulation of fluid in the tissues, manifested by swelling of the ankles or feet, and occasionally, breast enlargement. This may be caused by increased androgen production following BP Gonadotropin treatment. If any of these signs occur, notify your doctor immediately.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store BP Gonadotropin

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

Store in refrigerator (2 °C - 8 °C), in original package.

Do not freeze.

Do not use this medicine after the expiry date which is stated on the ampoule label and carton.

The expiry date refers to the last day of that month.

Do not use BP Gonadotropin if you notice that the reconstituted solution contains particles or if the solution is not clear.

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 BP Gonadotropin contains

Each vial of powder contains 5000 IU of the active ingredient Chorionic Gonadotropin.

The other ingredients are:

- carmellose sodium,
- mannitol,
- sodium dihydrogen phosphate, anhydrous
- disodium hydrogen phosphate, anhydrous.

Each ampoule (1 ml) of solvent contains sodium chloride 9 mg, water for injections.

What BP Gonadotropin looks like and contents of the pack

- Colorless injection vial with a rubber stopper, sealed with a FLIP-OFF combi cap, containing white or off-white lyophilized powder or porous mass.
- Colorless glass ampoule with a break system OPC (One point Cut) or break ring, containing clear and colorless solution.

1 vial of Powder, 1 ampoule with solvent and a leaflet are packed in an outer carton.

Manufactured by:

SC Balkan Pharmaceuticals SRL
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mun. Chisinau, Republic of Moldova

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