

PACKAGE LEAFLET

Package leaflet: Information for the user

CHORAPUR 1500 IU powder and solvent for solution for injection CHORAPUR 5000 IU powder and solvent for solution for injection

Chorionic gonadotrophin

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 nurse.
- 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 nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What CHORAPUR is and what it is used for
2. What you need to know before you use CHORAPUR
3. How to use CHORAPUR
4. Possible side effects
5. How to store CHORAPUR
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1. What CHORAPUR is and what it is used for

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

CHORAPUR contains the active ingredient human chorionic gonadotrophin (hCG) (a protein hormone) which is extracted and purified from the urine of pregnant women. The gonadotrophins play a vital role in fertility and reproduction.

In Women

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

In Men

CHORAPUR is used in men to help treat low sperm count. CHORAPUR is used either alone or in combination with other gonadotrophins (hMG, FSH). CHORAPUR is also used in men before a stimulation treatment to assess the function of the testes where the reproductive organs are not working correctly due to a lack of sex hormones.

In Children

CHORAPUR is used in children to treat delayed puberty or in children whose testicles have not or not completely descended into the scrotum .

2. What you need to know before you use CHORAPUR

Do not use CHORAPUR:

- if you are allergic to chorionic gonadotrophin or any of the other ingredients of this medicine (listed in section 6).

- if you have tumours in the brain or pituitary gland.
- if you have ovarian cysts or enlarged ovaries (unless caused by polycystic ovarian disease).
- if you have bleeding from the vagina where the cause is not known.
- if you have been diagnosed with cancer in the ovaries, uterus or breasts.
- if you had an ectopic pregnancy within the last three months.
- if you are suffering from severe phlebitis (inflammation of the veins) or blood clots in the veins (active thromboembolic disorders).
- if you suffer from ovarian hyperstimulation syndrome (OHSS – over stimulation of the ovaries).
- if a normal pregnancy is not naturally possible, e.g. in the case of ovarian failure, malformations of sexual organs incompatible with pregnancy or fibroids, or if you have experienced an early menopause.
- if you have known or suspected sex hormone dependent tumours, e.g. prostate cancer or (male) breast cancer.
- if it is known that the cause of undescended testicle cannot be treated by hormones (inguinal hernia, condition after surgery in the inguinal region, abnormal position of testicle).

Warnings and precautions

Talk to your doctor or nurse before using CHORAPUR.

Please inform your doctor if you have or have had any of the following conditions as they may be aggravated by the use of CHORAPUR:

- heart disease
- kidney disease
- epilepsy
- migraine-like headache

Treatment with CHORAPUR may increase the risk of thrombosis. A thrombosis is the formation of a blood clot in a blood vessel, mostly in the leg veins or the lung. Pregnancy itself may also increase the risk of thrombosis. Before starting treatment with CHORAPUR, please inform your doctor if:

- you know that you have an increased risk of thrombosis
- you or a close relative of yours already had a thrombosis
- you are overweight

Prior to the treatment, your or your partner's infertility and possible reasons why a pregnancy may not be possible are to be identified. You should be examined thoroughly in order to exclude any changes of the reproductive organs or hormonal disorders which are not connected with the gonads (e.g. disorders of the thyroid, adrenal or pituitary glands).

During the treatment, close supervision by your doctor is very important. Usually, regular ultrasound examinations and blood sampling are performed. This is particularly important, since treatment with CHORAPUR increases your risk of ovarian hyperstimulation syndrome (OHSS) (see also section 4 „Possible side effects“). This occurs when the egg sacs (ovaries) overreact to the treatment and form too many follicles. Usually, OHSS resolves itself during a menstruation period. OHSS may be more severe and more protracted if pregnancy occurs. Therefore, it is recommended that your doctor monitors you for at least two weeks after hCG administration.

Symptoms of mild or moderate OHSS are:

- Pain or discomfort in the abdomen
- Swelling in the abdomen
- Nausea
- Vomiting
- Diarrhoea
- Weight gain

In severe cases of OHSS additional symptoms may occur such as:

- Difficulty in breathing
- Decreased urination

In very rare cases complications like twisting of egg sacs (ovaries) and blood clots in veins or arteries may occur with severe cases of OHSS.

Talk to your doctor straight away, even if the symptoms develop some days after the last injection has been given. These can be signs of high levels of activity in the ovaries which might become severe.

If these symptoms become severe, the infertility treatment should be stopped and you should receive treatment in hospital.

Keeping your recommended dose and careful monitoring of your treatment will reduce your risk of getting these symptoms.

Patients with polycystic ovarian disease have an increased risk of getting OHSS.

Pregnancies achieved by using gonadotrophin therapy are more likely to be twin or multiple pregnancies than normal pregnancies.

The number of miscarriage both in patients who cannot form enough egg cells or even none at all and in women who undergo medically assisted reproductive programmes, such as IVF, is higher than in the average population but comparable to the miscarriage rate of women with other fertility disorders.

Women with pre-damaged fallopian tubes have a slightly increased risk of ectopic pregnancy.

The frequency of malformations after pregnancy treatment can be slightly higher than with natural conception. This can be related to a number of preconditions in the parents (e.g. mother's age, sperm quality) and to an increased occurrence of multiple pregnancies.

Your doctor will perform special supervision during treatment if you suffer from a clinically significant illness in which pregnancy could worsen your condition.

CHORAPUR may lead to a false positive pregnancy test for up to 10 days following administration.

The use of CHORAPUR may lead to positive results in drug tests. The use of CHORAPUR for doping purposes can result in hazard of your health.

Children

CHORAPUR should be used with caution in prepubertal boys to avoid bone problems or premature puberty. Skeletal development should be monitored regularly.

Other medicines and CHORAPUR

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

Interactions with other medicinal products are unknown.

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 for advice before taking this medicine.

CHORAPUR is indicated for the treatment of infertility (see section “What CHORAPUR is and what it is used for” above).

CHORAPUR should not be used during pregnancy and breast-feeding.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. It is expected that CHORAPUR has no influence on the ability to drive and use machines.

CHORAPUR contains sodium

CHORAPUR contains sodium, but less than 1 mmol (23 mg) sodium per ml solvent, i.e. it is nearly „sodium-free“.

3. How to use CHORAPUR

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Method of administration:

This medicine will be given as an injection into the muscle by a doctor experienced in the treatment of fertility problems.

CHORAPUR 1500 IU

Treatment with CHORAPUR should be performed by a doctor experienced in the treatment of fertility problems.

In male patients the recommended dose is 1 vial twice a week (corresponding to 3000 IU per week). Because the development of sperm cells takes about 74 days, treatment should be continued for at least 3 months before any improvement can be expected. During this treatment your doctor will monitor your testosterone levels. It may be necessary to increase the dose.

If the response to CHORAPUR alone is not sufficient, your doctor may decide to give you another medicine at the same time as CHORAPUR. Once an improvement has been achieved using a combination of these medicines, it may then in some cases be maintained by using CHORAPUR alone.

Use in children

Treatment of undescended testes should finish when the child is 1 year of age.

The recommended dose is 250 IU/dose (0.17 ml of the 1500 IU vial). This medicine will be administered twice a week for 5 weeks in young infants.

CHORAPUR 5000 IU

Treatment with CHORAPUR should be performed by a doctor experienced in the treatment of fertility problems.

For triggering ovulation and stimulation of the ovaries:

The recommended dose is 1 vial (5000 IU) or 2 vials (10000 IU). Administration should be performed 24 to 48 hours after optimal stimulation of the ovaries is achieved.

If CHORAPUR is used for ovulation induction following stimulation of the ovaries, it is recommended to have sexual intercourse on the day of and the day after injection.

For assessment of the function of the testes in cases where the reproductive organs are not working correctly due to a lack of sex hormones:

The recommended dose is 1 vial (5000 IU) once.

Use in children

In boys with delayed puberty:

The recommended dose is 1 vial (5000 IU) per week over a period of 3 months.

In the absence of one or both testes:

The recommended dose is 1 vial (5000 IU) once.

If you use more CHORAPUR than you should

No cases of overdose have been reported. However, it is possible that an overdose can cause an ovarian hyperstimulation syndrome (OHSS), see section 2 “What you need to know before you use CHORAPUR”.

If you forget to use CHORAPUR

Do not take a double dose to make up for a forgotten dose. Talk to your doctor.

If you stop using CHORAPUR

Talk to your doctor.

4. Possible side effects

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

Hormones used in the treatment of infertility such as CHORAPUR may cause high levels of activity in the ovaries leading to a disease called ovarian hyperstimulation syndrome (OHSS). Symptoms may include: pain in the abdomen, swelling of the abdomen, nausea, vomiting, diarrhoea and weight gain. In cases of severe OHSS, accumulation of fluid in abdomen, pelvis and/or chest cavity, difficulty in breathing, decreased urination may also occur. Formation of blood clots in blood vessels (thromboembolism) and twisting of ovaries (ovarian torsion) have been reported as rare complications in cases of severe OHSS. If you experience any of these symptoms contact your doctor immediately, even if they develop some days after the last injection has been given.

Allergic (hypersensitivity) reactions may occur with the use of CHORAPUR. Symptoms may include: rash, itching, swelling of the throat and difficulty in breathing. If you experience any of these symptoms, contact your doctor immediately.

The assessment of the side effects is based on the following grades of frequency:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

Very common

- Enlargement of male mammary glands (gynaecomastia)
- Headache
- Reactions and pain at the injection site

Common

- Nausea, abdominal pain, vomiting
- Mild to moderate ovarian hyperstimulation syndrome (OHSS), breast swelling, pain in testis
- Hot flush (only seen in men)
- Rash (exanthema), inflammation of the sebaceous glands (acne vulgaris)

Uncommon

- Diarrhoea
- Impaired excretion of salts and water
- Severe ovarian hyperstimulation syndrome (OHSS)
- Depression, irritability, restlessness

Not known:

- Hypersensitivity (allergic) reactions
- Formation of blood clots in blood vessels
- Swelling of the abdomen
- Rash, hives, itching

- Breast tenderness and breast pain
- Fever, tiredness (fatigue), weakness (asthenia)

Increase in size of penis and erections and prostate growth have been observed.

Additional side effects in children

Occasionally, minor emotional changes in boys similar to those at the beginning of puberty may occur during treatment (pubertal behaviour).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

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

[*For the printed material, please refer to the guidance of the annotated QRD template.]

5. How to store CHORAPUR

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 outer carton.

This medicinal product does not require any special storage conditions. Do not freeze. Store in the original container in order to protect from light.

The powder should only be dissolved with the solvent provided in the package.

The solution for injection must be used immediately after the preparation.

Do not use this medicine if you notice any particles or if the solution is not clear.

The solution must not be mixed with other products.

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 CHORAPUR contains

- The active substance is highly purified human chorionic gonadotrophin (hCG).
- The other ingredients in the powder are lactose monohydrate and sodium hydroxide.
- The ingredients in the solvent are sodium chloride, hydrochloric acid 10% and water for injections.

What CHORAPUR looks like and contents of the pack

CHORAPUR is a powder and solvent for solution for injection, 1500 IU and 5000 IU.

Appearance of the powder: white lyophilised cake.

Appearance of the solvent: clear colourless solution.

CHORAPUR 1500 IU and 5000 IU are supplied in packs of 1, 3 or 5 powder vials with the corresponding number of solvent ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Ferring Pharmaceuticals Ltd
Drayton Hall
Church Road
West Drayton
UB7 7PS

Manufacturer:
Ferring GmbH,
Wittland 11, D-24109 Kiel, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

{Name of the Member State} {Name of the medicinal product}
{Name of the Member State} {Name of the medicinal product}

This leaflet was last revised in 03/2016.

The following information is intended for healthcare professionals only:

Method of administration

- CHORAPUR must be administered intramuscularly immediately after reconstitution
- Attach a reconstitution needle to the syringe.
- Withdraw the entire content of the ampoule with solvent and inject the total contents into the vial containing the powder. The powder should dissolve quickly to a clear solution. If not, roll the vial gently between the fingers (hands) until the solution is clear. Shaking should be avoided.
- The reconstituted solution contains 1500 IU or 5000 IU per ml.
- Depending on the required dose, withdraw the appropriate amount of reconstituted solution from the vial into the syringe, change to an injection (hypodermic) needle and administer immediately.