

Package leaflet: Information for the user

finasteride cinfa 1 mg film-coated tablets

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

1. What finasteride cinfa is and what it is used for

finasteride cinfa contains the drug substance Finasteride.

finasteride cinfa is to be used solely by men.

finasteride cinfa is used to treat male pattern hair loss (also known as androgenetic alopecia) in men aged 18 to 41 years. If, after reading this patient information leaflet, you have any questions on male pattern hair loss, consult your doctor.

Male pattern hair loss is a common disorder that is believed to be caused by a combination of genetic factors and one hormone in particular, called dihydrotestosterone (DHT). DHT contributes to shortening the growth stage of the hair and makes the hair thinner.

In the scalp, finasteride cinfa specifically decreases the levels of DHT by blocking an enzyme (5-alpha-reductase type II) that converts testosterone into DHT. Only men with mild to moderate, but not complete, hair loss can expect to benefit from using finasteride cinfa. In many men treated with finasteride cinfa for 5 years, the progression of hair loss was slower, and in at least half of these men, hair growth improved in some way.

2. What you need to know before you take finasteride cinfa

Do not take finasteride cinfa

- if you are a woman (because this medicinal product is for men, see the section on Pregnancy). Clinical trials have shown that finasteride cinfa is not effective in women with hair loss.
- if you are allergic to Finasteride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Talk to your doctor or pharmacist before taking finasteride cinfa.

Effects on prostate-specific antigen (PSA)

In blood tests, finasteride cinfa can affect a test called PSA (prostate-specific antigen) for detecting prostate cancer. If you have had a PSA test, you must inform your doctor or pharmacist that you are taking finasteride cinfa, because it reduces PSA levels.

Effects on fertility

Infertility has been reported in men taking Finasteride for a long time and who had other risk factors that could affect fertility. Semen quality has been reported to return to normal or improve after suspending treatment with Finasteride. No long-term clinical studies have been performed on the effect of Finasteride on male fertility.

Breast cancer

See section 4.

Mood alterations and depression

Mood alterations, such as depressed moods, depression and, less commonly, suicidal ideation have been reported in patients treated with finasteride cinfa 1mg. If you experience any of these symptoms, stop taking finasteride cinfa 1mg and consult your doctor as soon as possible.

Children and adolescents

finasteride cinfa must not be administered to children. No data are available that prove the efficacy and safety of Finasteride in children under the age of 18 years.

Other medicines and finasteride cinfa

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

finasteride cinfa with food and drink

finasteride cinfa can be taken with or without food.

Pregnancy, breast-feeding and fertility

finasteride cinfa is intended for the treatment of male pattern hair loss exclusively in men. For the effects on male fertility, see section 2.

- **Women cannot use finasteride cinfa due to the risk in pregnancy.**
- **Women who are or might be pregnant must not touch crushed or broken tablets of finasteride cinfa.**
- If a pregnant woman with a male foetus absorbs the active substance of finasteride cinfa after ingesting it orally or through the skin, her son could be born with abnormalities of the sexual organs.
- If a pregnant woman comes into contact with the active substance of finasteride cinfa, she must consult her doctor.
- finasteride cinfa tablets are coated to avoid contact with the active substance during normal handling.

Check with your doctor if you are not sure.

Driving and using machines

No data are available that show that finasteride cinfa affects the ability to drive and use machines.

This medicine contains lactose. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

This medicine contains less than 1 mmol of sodium (23 mg) per dose unit; that is, it is essentially “sodium-free”.

3. How to take finasteride cinsa

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

The recommended dose is one tablet a day. The tablets can be taken with or without food.

Your doctor will help you to determine whether finasteride cinsa has the desired results in your case. It is important to take finasteride cinsa for as long as your doctor tells you to. Finasteride cinsa only acts in the long term if its administration is maintained.

If you take more finasteride cinsa than you should

If you take too many tablets by mistake, consult a doctor immediately. Finasteride cinsa will not act faster or better if you take more than one tablet per day.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately or call the Toxicology Information Service, telephone 91.562.04.20, specifying the medicine and the amount ingested. It is recommendable to take the package and the leaflet of the medicine to the healthcare provider.

If you forget to take finasteride cinsa

- If you forget a dose, skip the forgotten dose.
- Continue with the usual regime of one tablet once a day.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking finasteride cinsa

To see the effect, it may be necessary to take the medicine for 3 to 6 months. It is important that you try to take finasteride cinsa for as long as your doctor tells you to. If you stop taking finasteride cinsa, you will probably lose the hair you have gained during the 9 to 12 months after stopping the treatment.

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. In general, the adverse effects have been transitory with continued treatment or have disappeared when the treatment stopped.

Stop taking finasteride cinsa and inform your doctor immediately if you present any of the following symptoms: swelling of the lips, face, tongue and throat; difficulty swallowing; lumps under the skin (wheals) and difficulty breathing.

Inform your doctor immediately of any changes in breast tissue, such as lumps, pain, growth or secretion of the nipple, as these may be signs of a serious disease, such as breast cancer.

Uncommon: may affect up to 1 in 100 people

- decreased sex drive
- difficulty achieving an erection
- problems with ejaculation, including a reduction in the amount of semen ejaculated
- depression.

Unknown frequency: cannot be estimated from the available data

- allergic reactions, including rash and itching
- sensitivity and increased size of the breasts
- testicular pain
- accelerated heartbeat
- lasting difficulty in achieving an erection after stopping the treatment
- lasting decrease in sex drive after stopping the treatment
- lasting problems with ejaculation after stopping the treatment
- male infertility and/or poor semen quality
- elevated liver enzymes.
- anxiety.

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 the Spanish Pharmacovigilance System of Medicinal Products for Human Use: www.notificaram.es/. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store finasteride cinfa

Keep this medicine out of the sight and reach of children. This medicinal product requires no special storage conditions.

Do not use this medicine after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

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 finasteride cinfa contains

- The active substance is Finasteride. Each tablet contains 1 mg of Finasteride.
- The other ingredients are:

Tablet core: lactose monohydrate, maize starch, sodium carboxymethyl potato starch, anhydrous colloidal silica, sodium docusate benzoate, magnesium stearate.

Coating: hydroxypropyl methylcellulose, titanium dioxide (E-171), polyethylene glycol 6000, brown iron oxide (E-172) and red iron oxide (E-172).

What finasteride cinfa looks like and contents of the pack

- The tablets are red, film-coated, cylindrical and scored.
- The tablets are available in blister packs in boxes of 28 or 98 tablets. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Laboratorios Cinfa, S.A.

Carretera Olaz-Chipi, 10 Polígono Industrial Areta

31620 Huarte (Navarra) – Spain

This leaflet was last revised in: August 2018

Detailed information on this medicine is available on the website of the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS - The Spanish Agency of Medicines and Medical Devices) <http://www.aemps.gob.es/>.

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What is in this leaflet

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1. What finasteride cinfa is and what it is used for

Finasteride cinfa is an 5-alpha reductase inhibitor that reduces enlarged prostate size.

Your doctor has prescribed finasteride cinfa to you because you suffer from a condition called benign prostatic hyperplasia (BPH). Your prostate, a gland located near the urinary bladder that produces a liquid that transports sperm, has increased in size and hinders the expulsion of urine.

finasteride cinfa reduces the size of the enlarged prostate and relieves the urinary symptoms: frequent need to urinate, pain on urinating, weak urine stream, sensation that the bladder has not been emptied completely. finasteride cinfa reduces the need for a surgical operation.

2. What you need to know before you take finasteride cinfa

Do not take finasteride cinfa:

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

The disorder for which finasteride cinfa is prescribed occurs only in men, so it should not be taken by women or children.

Warnings and precautions

Talk to your doctor or pharmacist before taking finasteride cinfa.

Tell your doctor about your current and past medical problems and any allergies you suffer.

finasteride cinfa is solely for the treatment of BPH in men. Women must not use finasteride cinfa when they are or may be pregnant, and they should not be exposed to finasteride cinfa by handling crushed or broken tablets. If the active substance of finasteride cinfa is absorbed after oral use or through the skin by a woman who is pregnant with a male foetus, he can be born with anomalies in his sexual organs. If the pregnant woman was in contact with the active substance of finasteride cinfa, she must consult her doctor. finasteride cinfa tablets are coated and this will prevent contact with the active substance during normal handling, provided that the tablets are not crushed or broken. Check with your doctor if you are not sure.

If your sexual partner is or may be pregnant, you must avoid exposing her to your semen as this could contain minimal quantities of the medicine.

BPH develops over a long time. Sometimes symptoms improve quickly, but you may have to take finasteride cinfa for at least six months to see whether the symptoms improve. Even if you do not notice any improvement or change in the symptoms, therapy with finasteride cinfa can reduce the risk of urinary retention and, therefore, the need for surgery. You should visit your doctor regularly for monitoring and evaluation of your progress.

Although BPH is not a cancer and does not cause cancer, both conditions can exist simultaneously. Only a doctor can evaluate the symptoms and their possible causes.

finasteride cinfa can reduce the levels of prostate-specific antigen (PSA is a substance in the body that increases when the prostate grows and can cause obstruction). If you have had a PSA test, tell your doctor that you are taking finasteride cinfa.

Children and adolescents

finasteride cinfa is not indicated in children.

Mood alterations and depression

Mood alterations, such as depressed moods, depression and, less commonly, suicidal ideation have been reported in patients treated with finasteride cinfa 5 mg. If you experience any of these symptoms, consult your doctor as soon as possible.

Other medicines and finasteride cinfa

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

Finasteride does not usually cause interactions with other medicines.

finasteride cinfa with food and drink

Take one tablet of Finasteride cinfa daily, with or without food.

Pregnancy and breast-feeding

Finasteride cinfa for use exclusively in men. finasteride cinfa is not indicated for women.

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 taking this medicine.

Driving and using machines

Finasteride cinfa should not affect your ability to drive or handle machines.

Finasteride cinfa contains lactose

This medicine contains lactose. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

Finasteride cinfa contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per dose unit; that is, it is essentially “sodium-free”.

3. How to take finasteride cinfa

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

Remember to take your medicine.

The standard dose is one tablet of finasteride cinfa a day.

Method of administration:

Finasteride cinfa is a medicine that is taken orally, with or without food.

Remember that your prostate took many years to grow large enough to cause symptoms. finasteride cinfa will only be able to treat your symptoms and control the disease if you continue taking it on a long-term basis.

Your doctor can prescribe finasteride cinfa in conjunction with another medicine, called doxazosin, to help you control your BPH better.

If you have the impression that the effect of finasteride cinfa is too strong or too weak, talk to your doctor or pharmacist.

If you take more finasteride cinfa than you should

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately or call the Toxicology Information Service, telephone: 91 562 04 20, stating the medicine taken and how much.

If you forget to take finasteride cinfa

If you forget to take a dose, do not take an additional dose; just take the next tablet as usual.

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

These are uncommon and do not occur in most cases. The side effects due to finasteride cinfa include:

Immune system disorders

Unknown frequency (cannot be estimated from the available data): allergic reactions such as swelling of the lips, tongue, throat and face.

Psychiatric disorders

Common (may affect up to 1 in 10 patients): reduced sexual desire.

Unknown frequency (cannot be estimated from the available data): depression, reduced sexual desire that continues after suspending the medication, anxiety.

Cardiac disorders

Unknown frequency (cannot be estimated from the available data): irregular heartbeat.

Hepatobiliary disorders

Unknown frequency (cannot be estimated from the available data): elevated liver enzymes.

Skin and subcutaneous tissue disorders

Uncommon (may affect up to 1 in 100 patients): skin rash

Unknown frequency (cannot be estimated from the available data): itching, hives.

Reproductive system and breast disorders

Common (may affect up to 1 in 10 patients): impotence (inability to achieve an erection).

Uncommon (may affect up to 1 in 100 patients): swelling and increased breast sensitivity and ejaculation problems.

Unknown frequency (cannot be estimated from the available data): pain in the testes, inability to have an erection that continues after suspending the medication; problems with ejaculation that continue after suspending the medication, male infertility or poor semen quality. Improved semen quality has been reported after suspending the medication.

Investigations

Common (may affect up to 1 in 10 patients): decreased amount of semen on ejaculation. This reduction in the amount of semen does not appear to affect normal sexual function.

Inform your doctor immediately of any changes in breast tissue, such as lumps, pain, growth or secretion of the nipple, as these may be signs of a serious disease, such as breast cancer.

In some cases, these adverse events disappeared despite the fact the patient continued taking Finasteride. When the symptoms persisted, they generally disappeared when Finasteride was discontinued.

Stop taking finasteride cifa and contact your doctor immediately if you experience any of the following symptoms (angioedema): swelling of the face, tongue or throat; difficulty swallowing; wheals and difficulty breathing.

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 the Spanish Pharmacovigilance System for Medicines for Human Use: <https://www.notificaram.es>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store finasteride cinfa

No special storage conditions are required.

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 container after “EXP”. The expiry date refers to the last day of that month.

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 finasteride cinfa contains

- The active substance is Finasteride. Each tablet contains 5 mg of Finasteride.
- The other ingredients are:
Tablet core: lactose monohydrate, sodium carboxymethyl potato starch (type A), maize starch, anhydrous colloidal silica, sodium docusate benzoate and magnesium stearate, Tablet coating: macrogol 6000, titanium dioxide (E 171), hypromellose and indigo carmine dye (E-132).

What finasteride cinfa looks like and contents of the pack

finasteride cinfa 5 mg tablets are light blue, cylindrical, biconvex tablets that are smooth on both sides. Each pack contains 28 or 500 (clinical pack) tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta
31620 Huarte (Navarra) – Spain

Manufacturer

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