Editor's note: This English translation was done by a third party. The original report can be accessed here.

### **Product information**

## Information for patients

Read this package insert carefully before taking or using this medicine. This medication has been given to you personally on medical prescription. Do not give it to other people, even if they seem to have the same symptoms as you. Indeed, this drug could harm their health.

Keep this package insert so that you can read it later if necessary.

Sandoz finasteride 5 Sandoz Pharmacieurica/s AG

### What is Sandoz finasteride 5 and when should it be used?

Sandoz finasteride 5 is a medicine for the treatment of a benign form of prostate enlargement (benign prostatic hyperplasia: BPH). Sandoz finasteride 5 should only be taken when prescribed by a doctor.

## What should be considered apart from the treatment?

Benign prostatic enlargement is a common disease that increases in frequency with age and develops slowly over many years. During the progressive increase in the volume of the prostate can occur disorders when urinating, as well as problems with the level of the bladder. Typical of this state: hesitation or delay at the start of urinating, dripping after urinating, decrease in the force of the urinary stream, single or repeated interruptions in the flow of urine while urinating, feeling of incomplete emptying of the bladder, pain and burning when urinating, need to push to start urinating. wet clothes, urgent need to urinate and frequent urination, day and night. Repeated urinary tract infections, kidney failure, and acute urinary retention and resulting surgical procedures are known complications of untreated benign prostate enlargement.

Sandoz finasteride 5 influences the cause of pathological prostate growth. It can reduce the volume of the enlarged prostate and therefore improve the abovementioned disorders. Benign prostatic hyperplasia develops over several years, which is why the shrinkage of the enlarged prostate normally requires long-term therapy with Sandoz finasteride 5. However, in some cases, a rapid improvement in symptoms has been observed. Regardless of whether your symptoms improve or change, therapy with Sandoz finasteride 5 may reduce the risk of sudden urinary retention or surgery.

Follow your doctor's recommendations. When Sandoz finasteride 5 is discontinued, the prostate may again enlarge and symptoms of benign prostatic rheumatoid arthritis may reappear. Visit your doctor for regular checkups. Sandoz finasteride 5 may affect the results of a blood test, PSA test. If a PSA test is done, tell your doctor that you are taking Sandoz finasteride 5.

# When should Sandoz finasteride 5 not be taken?

Finasteride Sandoz 5 should not be used in case of allergy to any component of the drug.

Sandoz finasteride 5 should not be used by women or children.

## What precautions should I take while taking Sandoz finasteride 5?

Tell your doctor about all your current or past medical problems, as well as any known allergies.

If you observe changes in the breast tissue such as, for example, lumps, pain, enlargement of the breast or discharge of fluid from the nipple, you should inform your doctor immediately. These symptoms may possibly indicate the presence of a sore disease such as breast cancer.

There have been reports of male infertility and/or poor sperm quality in men treated with Sandoz finasteride 5. Improvement in sperm quality after discontinuation of Sandoz finasteride 5 has been reported.

Women of childbearing age should avoid contact with Sandoz finasteride 5 by handling broken film-coated tablets, due to possible absorption of the active ingredient during pregnancy and the potential risk of malformations of the external organs of children of the male sex resulting. Since Sandoz finasteride 5 tablets are film-coated, normal handling makes contact with the active ingredient impossible if the film-coated tablets are crushed or broken.

Sandoz finasteride 5 usually does not interact with other drugs. However, you should always tell your doctor about all medicines you are taking or plan to take, even those you have obtained without a prescription. Please tell your doctor or pharmacist if:

- —you suffer from another disease,
- —you are allergic or
- —you are already taking other medicines (or already using other medicines for external use) (even self-medication!).

## Can Sandoz finasteride 5 be taken during pregnancy or breastfeeding?

Sandoz finasteride 5 does not sleep to be taken by women.

#### How to use Sandoz finasteride 5?

The usual dosage of Sandoz finasteride 5 is one film-coated tablet per day, regardless of meals.

Take Sandoz finasteride 5 once a day as prescribed. If you have forgotten to take your daily dose, do not take an extra dose. Simply continue the usual dosage of one film tablet per day.

Tell your doctor immediately if you have swallowed too many dandruff tablets at once.

Do not change the present dosage on your own. Speak to your doctor or pharmacist if you feel that the effectiveness of the medicine is too weak or, on the contrary, too strong (see also "What else should you pay attention to?").

### What side effects can Sandoz finasteride 5 cause?

Taking Sandoz finasteride 5 may cause the following side effects:

Undesirable effects have been observed frequently, the cause of which is perhaps, probably or surely related to the drug. These were impotence, decreased libido (sexual arousal) and decreased ejaculate volume.

These undesirable effects disappeared in a few cases while taking finasteride. If symptoms persisted, these were usually reversible upon discontinuation of treatment. Occasional cases of side effects including ejaculation disorder, breast pressure tenderness and/or breast enlargement and rash have been reported.

Rare cases of side effects including testicular pain or allergic reactions such as itching, hives, swelling of the lips, tongue, throat and face have been reported.

If you notice any changes in your breast tissue such as lumps, pain or discharge of fluid from the nipple in your home, you should inform your doctor immediately (see "What precautions to take when taking Sandoz finasteride 5?").

Very rarely, cases of breast cancer in men have been reported.

### Individual cases:

- —blood in semen;
- —continuation of inability to have an erection after discontinuation of drug administration;
- —persistence of ejaculation problems after stopping the administration of the drug;
- —decrease in libido (sexual arousal) persisting after discontinuation of drug administration; and
- —depression has been reported.

Also, if you notice any side effects not mentioned in this package insert, please inform your doctor or pharmacist.

## What else should you pay attention to?

This medicine must not be used beyond the date appearing after the word "EXP" on the container.

## **Notes on Storage**

Store in the original packaging, at room temperature (15-25 celcius) and out of the reach of children.

## Additional remarks

For more information, consult your doctor or pharmacist, who have detailed information for professionals.

#### What does Sandoz finasteride 5 contain?

One pellicule tablet of Sandoz finasteride 5 contains 5 mg of the active substance finasteride.

Blue dye: Indigotine (E 132) and other excipients.

## **Authorization number**

57890 (SwissMedic)

# Where do you get Sandoz finasteride 5? What packaging do you have available on the market?

In pharmacies, only on medical prescription.

Sandoz finasteride 5 is available in packs of 30 and 100 film-coated tablets.

## **Authorization holder**

Sandoz Pharmaceuticals SA, Risch; place of residence: Rotkreuz

This package insert was last checked in December 2019 by the Medicines Control Authority (SwissMedic).