Package leaflet: Information for the user

Finasteride Ascend 5 mg film-coated tablets
finasteride

This medicine is for use in men only

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.

In this leaflet:

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

1. What Finasteride Ascend is and what it is used for

Finasteride Ascend contains medicine called finasteride. This belongs to group of medicines called '5α-reductase inhibitors'. Finasteride Ascend shrinks the prostate gland in men when it is swollen. The prostate gland is found underneath the bladder (but only in men). It produces the fluid found in semen. A swollen prostate gland can lead to a condition called'benign prostatic hyperplasia' or BPH.

What is BPH?
If you have BPH it means that your prostate gland is swollen.
It can press on the tube that urine passes through, on its way out of your body.
This can lead to problems such as:
- feeling like you need to pass urine more often, especially at night
- feeling that you must pass urine right away
- finding it difficult to start passing urine
- when you pass urine the flow of urine is weak
- when you pass urine the flow stops and starts
- feeling that you cannot empty your bladder completely

In some men, BPH can lead to more serious problems, such as:
- urinary tract infections
- a sudden inability to pass urine
- the need for surgery

What else should you know about BPH?
- BPH is **not** cancer and does not lead to cancer, but the two conditions can be present at the same time.
- Before you start Finasteride Ascend, your doctor will do some simple tests to check whether you have prostate cancer.

Talk to your doctor if you have any questions about this.

2. What you need to know before you take Finasteride Ascend

Do not take Finasteride Ascend
- if you are a woman (because this medicine is for men)
- if you are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine (listed in section 6).

Do not take Finasteride Ascend if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Finasteride Ascend if:
- your partner is pregnant or planning to become pregnant. You should use a condom or other barrier method of contraception when taking Finasteride Ascend. This is because your semen could contain a tiny amount of the drug and may affect the normal development of the baby's sex organs.
- you are going to have a blood test called PSA. This is because Finasteride Ascend can affect the results of this test.

If you are not sure, talk to your doctor or pharmacist before taking Finasteride Ascend.

Mood alterations and depression
Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride Ascend. If you experience any of these symptoms contact your doctor for further medical advice as soon as possible.

Children
Finasteride Ascend should not be used in children.

Taking other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Finasteride Ascend does not usually affect other medicines.

Taking Finasteride Ascend with food and drink
Finasteride Ascend can be taken with or without food.

Pregnancy and breast feeding
- Finasteride Ascend should not be taken by women.
- Do not touch crushed or broken Finasteride Ascend tablets if you are a woman who is pregnant or planning to become pregnant (whole tablets are coated to stop contact with the medicine during normal use). This is because this medicine may affect the normal development of the baby's sex organs.
- If a woman who is pregnant comes into contact with crushed or broken Finasteride Ascend tablets, speak to your doctor.

Driving and using machines
Finasteride Ascend is not likely to affect you being able to drive, use tools or machines.

Finasteride Ascend contains
Lactose. This is a type of sugar. If you have ever been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor or pharmacist before taking this medicine.

Finasteride Ascend contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Finasteride Ascend

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

Taking this medicine
- The usual dose is one tablet each day.
- Take this medicine by mouth.
- Your doctor may prescribe Finasteride Ascend along with another medicine (called doxazosin) to help control your BPH.

If you take more Finasteride Ascend than you should
If you take too many tablets by mistake, contact your doctor immediately.

Alkem Laboratories Limited			
Product: Finasteride Tablets 5 mg		Market: UK	
Itemcode: PTXXXX	Version No: 00	Superseed No: NA	Mfg Location: Baddi
Pantone No.: Black			Pack Size:
Component: Insert	Style: folded	Substrate:	
Change Part No: NA		Pharmacode:	Barcode: NA
Reason for Issue: New artwork			Change Control No:
Date of Initiation: 27-03-2025			Final approval of artwork:
Modification Date: 06-07-2026			

If you forget to take Finasteride Ascend
- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Finasteride Ascend
Your condition may show an early improvement after taking Finasteride Ascend. However, it may take at least six months for the full effect to develop. It is important to keep taking Finasteride Ascend for as long as your doctor tells you, even if you do not feel any benefit straight away. 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. The following side effects may happen with this medicine:

Allergic reactions
Stop using Finasteride Ascend and immediately contact a doctor if you experience any of the following symptoms:
- Swelling of face, lips, tongue or throat, difficulty swallowing and breathing difficulties (angioedema)
- Skin rashes, itching, or lumps under your skin (hives).

Other side effects may include:
- You may be unable to have an erection (impotence)
- You may have less desire to have sex
- You may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function.

These side effects above may disappear after a while if you continue taking Finasteride Ascend. If not, they usually resolve after stopping Finasteride Ascend. Other side effects reported in some men are:
- Breast swelling or tenderness
- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working, which can be shown by a blood test
- Pain in your testicles
- Blood in semen
- An inability to have an erection which may continue after stopping the medication
- Male infertility and/or poor quality of semen. Improvement in the quality of the semen has been reported after stopping medication
- Depression
- Decrease in sex drive that may continue after stopping the medication
- Problems with ejaculation that may continue after stopping the medication
- Anxiety
- Suicidal thoughts (Frequency: not known)

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement or nipple discharge as these may be signs of a serious condition, such as breast cancer. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist. It will help if you make a note of what happened, when it started and how long it lasted.

What else should you know about Finasteride Ascend?

Finasteride Ascend (finasteride) is not licensed to treat prostate cancer. Information collected for a clinical trial in men taking finasteride for 7 years showed:
- The number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing.
- The number of men who had a high score in a tumour grading system was higher in some of those taking finasteride compared to those taking nothing.
- The effect of long-term use of finasteride on tumours of this kind is not known.

If you would like further information about the tumour grading system or this trial, please talk to your doctor.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finasteride Ascend

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage condition. Keep them in the original package.

Do not use Finasteride Ascend after the expiry date which is stated on the carton after the letters 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 to protect the environment.

6. Contents of the pack and other information

What Finasteride Ascend contains
- The active substance is finasteride. Each tablet contains 5 mg finasteride.
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, lauroyl macrogolglycerides, magnesium stearate.

The tablet coating material contains: hypromellose, titanium dioxide (E171), macrogol and FD&C Blue (E132).

What Finasteride Ascend looks like and the content of the pack
Blue, 7 mm round, biconvex, film-coated tablets, marked "F5" on one side and plain on other side.

Finasteride Ascend tablets are supplied in pack sizes:
PVC/PVDC Alu blister - 10, 14, 20, 28, 30, 50, 60, 90, 98, 100 or 120 tablets
Not all pack sizes may be marketed.

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