

Aindeem 1mg Film-coated Tablets

Finasteride

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:

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- 1 What Aindeem is and what it is used for**

Aindeem contains the active substance finasteride which belongs to a group of medicines called Type II '5-alpha reductase inhibitors'.
Aindeem is used to treat early forms of male pattern hair loss (also called androgenetic alopecia).

- 2 What you need to know before you take Aindeem**

Do not take Aindeem if you

- are **allergic** to finasteride or any of the other ingredients of this medicine (listed in section 6).
- are a **woman** (because this medicine is for men).
- are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).

Warnings and precautions

Talk to your doctor or pharmacist before taking Aindeem if you

- notice any **changes in your breast tissue** such as **lumps, pain, enlargement** of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer. You should promptly report to your doctor if you notice any of these changes.
- need to have a blood test called "**PSA**" (**prostate-specific antigen**). Make sure you tell your doctor or pharmacist first since finasteride may alter the results of the test.

Mood alterations and depression

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with finasteride 1mg. If you experience any of these symptoms stop taking finasteride 1mg and contact your doctor for further medical advice as soon as possible.

Children

Aindeem should not be used in children.

Other medicines and Aindeem

Aindeem can normally be taken with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Do not take Aindeem if you are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).

Aindeem with food

Aindeem can be taken with or without food.

Pregnancy and breastfeeding

- Aindeem should **not** be taken by women.
- **Women who are pregnant or may become pregnant should not handle broken or crushed Aindeem tablets.** If finasteride is absorbed through the skin or taken by mouth by a woman pregnant with a male foetus, the child may be born with malformed genital organs. The tablets are film-coated, which prevents contact with finasteride provided the tablets are not broken or crushed.

If you think a pregnant woman has come into contact with finasteride, you should consult a doctor.

Driving and using machines

There is no evidence to suggest that Aindeem affects the ability to drive or use machines.

Aindeem contains lactose monohydrate

Aindeem contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

Using other medicine for male pattern hair loss with Aindeem

No information is available about the use of Aindeem with minoxidil, another type of medicine for male pattern hair loss which is applied to the head.

- 3 How to take Aindeem**

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 (1mg finasteride) daily.

- The tablet should be swallowed whole and should not be broken or crushed.
- Aindeem may be taken with or without food.
- Aindeem will not work faster or better if you take it more than once a day.

If you stop taking Aindeem

It may take 3 to 6 months for the full effect to develop. It is important to keep taking Aindeem for as long as your doctor tells you. If you stop taking Aindeem, you are likely to lose the hair you have gained within 9-12 months.

If you take more Aindeem than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

If you forget to take Aindeem

Do not take a double dose to make up for a forgotten tablet. Just take the next one when it is due.

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.

Stop taking Aindeem and immediately contact a doctor if you experience any of the following symptoms of an allergic reaction:

- Skin rashes, itching, or lumps under your skin (hives)
- (angioedema) swelling of lips, face, tongue or throat
- Difficulty swallowing
- Breathing difficulties

You should promptly report to your doctor any changes in the breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

Other possible side effects

Uncommon (affects 1 to 10 users in 1,000):

- inability to develop or maintain an erection (impotence)
- problems with ejaculation (such as reduced amount of ejaculatory fluid)
- less desire to have sex
- depression.

Not known (frequency cannot be estimated from the available data):

- awareness of your heart beating (palpitation)
- increase of liver enzymes (as seen in blood tests)
- testicular pain
- infertility
- persistent difficulty having an erection after discontinuation of treatment
- persistent decrease in sex drive that may continue after discontinuation of treatment
- persistent problems with ejaculation after discontinuation of treatment, for example a decrease in the amount of semen released during sex.

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 Website: www.mhra.gov.uk/yellowcard.

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

5 How to store Aindeem

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 blister, carton or bottle after 'EXP'. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions. 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 Aindeem contains

- The active substance is finasteride. Each film-coated tablet contains 1mg finasteride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, lauroyl macroglycerides, sodium starch glycollate – Type A, magnesium stearate, hypromellose, titanium dioxide (E171), yellow and red iron oxide (E172), and macrogol 6000.

What Aindeem looks like and contents of the pack

Aindeem 1mg film-coated tablets are round, biconvex reddish-brown tablets, with the markings 'F1'

They are supplied in: Blister packs containing 28 and 84 tablets

Marketing Authorisation Holder

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer

Actavis hf
Reykjavíkurvegur 78
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Actavis Group PTC ehf.
Reykjavíkurvegur 76-78
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