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

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 it 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.

3. How to take Aindeem

The recommended dose is one tablet (1mg finasteride) daily.

Finasteride is usually taken on a daily basis. You can take it with or without food, but should be taken at the same time each day. This will help you to remember to take it regularly.

4. Possible side effects

In addition to the possible side effects listed in section 4, people taking finasteride may have a higher risk of the rare but serious condition prostate cancer.

5. How to store Aindeem

Aindeem can be taken with or without food.

6. Contents of the pack and other information

Aindeem is a medicine for oral use. The tablets are film-coated, which prevents contact with other substances in your body. They should be swallowed whole and not chewed or crushed.

6.1 Package and leaflet

Aindeem tablets come in boxes of 30 and 90 tablets. Each box contains an informative leaflet for the patient which is an essential source of information.

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 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 scalp.

Aindeem can normally be taken with other medicines.

Aindeem should not be used in children.

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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.

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 (blisters)
- (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
- anxiety.

Possible side effects

With Aindeem contains
- The active substance is finasteride. Each film-coated tablet contains 1 mg finasteride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, lauryl macrogolglycerides, sodium starch glycolate – 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

Manucrator
Actavis hf
Reykjavíkurveggur 78
IS-220 Hafnarfjörður
Iceland
or
Actavis Group PTC ehf
Reykjavíkurveggur 76-78
IS-220 Hafnarfjörður
Iceland

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If you would like a leaflet with larger text, please contact 01271 385257.