NEW ZEALAND CONSUMER MEDICINE INFORMATION

REGEN
Finasteride Film-coated Tablet 1 mg

What is in this leaflet

This leaflet answers some common questions about ReGen. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ReGen against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ReGen is used for

ReGen is used to treat men with male pattern hair loss to increase hair growth on the scalp and to prevent further hair loss.

Male pattern hair loss (also known as androgenetic alopecia) is a common condition in which men experience thinning of hair on the scalp. This often results in a receding hair line and/or balding on the top of the head. These changes typically start to occur in some men in their twenties and become more common with age. Once hair loss has occurred over a long period of time, the hair may be permanently lost.

Male pattern hair loss is thought to be caused by a combination of family history (heredity) and production of a particular male hormone called dihydrotestosterone (DHT). Men with male pattern hair loss have more of the hormone (DHT) in the balding part of their scalp than in other parts, resulting in increased hair loss.

ReGen contains the active ingredient finasteride. It works by lowering the levels of DHT in the scalp, thus helping to reverse the balding process.

ReGen does not affect hair on other parts of the body.

Men with mild to moderate, but not complete, hair loss can expect to benefit from the use of ReGen.

ReGen is for use by men only. It is not effective in the treatment of hair loss in women (androgenetic alopecia).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor’s prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take ReGen

When you must not take it:

Do not take ReGen if you have an allergy to:

- any medicine containing finasteride.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give ReGen to women or children.

Do not handle broken or crushed tablets or handle tablets with wet hands if you are pregnant or may be pregnant.

If the active ingredient in ReGen is absorbed after swallowing a tablet or through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the sex organs.

Whole tablets are coated to prevent contact with the active ingredient during normal handling, provided that the tablets have not been crushed or broken.

If a pregnant woman swallows ReGen, handles crushed or broken tablets, or handles tablets with wet hands, her doctor must be consulted immediately.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions.

If you have not told your doctor about any of the above, tell him/her before you start taking ReGen.
Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work. However, ReGen has not been shown to interfere with other medicines.

How to take ReGen
Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take
Take one tablet once each day. ReGen will not work faster or better if you take it more than once a day.

How to take it
Swallow the tablet whole with a full glass of water.

When to take it
Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it
Continue taking ReGen for as long as your doctor prescribes it. Male pattern hair loss is a condition that develops over a long period of time. It takes time for new hair to grow, so you will not see immediate results taking ReGen. In general, daily use for 3 months or more may be necessary before you notice increased hair growth or prevention of further loss.

If you forget to take it
If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.
Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.
If you are not sure what to do, ask your doctor or pharmacist.
If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you stop taking it
Continued use is recommended. If you stop taking the tablets your hair loss is likely to resume.

If you take too much (overdose)
Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ReGen. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using ReGen

Things you must do
If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ReGen.
Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must not do
Do not take ReGen to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects
Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ReGen. This medicine helps most men with male pattern hair loss, but it may have unwanted side effects in a few men. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:
• difficulty in achieving an erection that continued after stopping the medication
• problems with ejaculation that continue after stopping medication
• less desire for sex that continued after stopping the medicine
• decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function)
• male infertility and/or poor quality or semen (improvement in the quality of semen has been reported after stopping the medication).

It is important to understand that, in clinical trials, these unwanted effects disappeared in men who stopped taking the medication, as well as in many men who continued treatment.

Tell your doctor immediately if you notice any of the following:
• breast swelling and/or tenderness
• breast lumps, pain or discharge from the nipples
• skin rash, itchiness
• hives or nettle rash (pinkish, itchy swellings on the skin)
• testicle pain
• blood in your sperm
• depression (feelings of severe sadness and unworthiness).

The above list includes serious side effects that may require medical attention. These side effects are uncommon.

In rare cases, male breast cancer has been reported.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:
• swelling of the lips, tongue, throat or face.

These may be symptoms of a serious allergic reaction to ReGen which may cause difficulty in swallowing or breathing. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some men.

After using ReGen

Storage
Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ReGen or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal
If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like
ReGen is a brown, round, biconvex film-coated tablet, 7.6 mm in diameter.

It is supplied in a blister pack of 28 tablets.

Ingredients
ReGen contains 1 mg of finasteride as the active ingredient.

It also contains:
• lactose monohydrate
• pregelatinised maize starch
• microcrystalline cellulose
• sodium starch glycollate
• povidone
• docusate sodium
• magnesium stearate
• hydroxypropyl methyl cellulose
• hydroxypropyl cellulose
• titanium dioxide (E171)
• talc
• yellow iron oxide (E172)
• red iron oxide (E172).

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more
Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine
Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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05 July 2019
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