PACKAGE LEAFLET

Package leaflet: Information for the patient

Finjuve 2.275 mg/mL cutaneous spray, solution
finasteride

Read all of this leaflet carefully before you start using 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 experience 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 Finjuve is and what it is used for
2. What you need to know before you use Finjuve
3. How to use Finjuve
4. Possible side effects
5. How to store Finjuve
6. Contents of the pack and other information

1. What Finjuve is and what it is used for

Finjuve contains the active substance finasteride. It is administered to the skin of the bald scalp using a spray applicator consisting of a bottle with a pump and cone.

Finjuve is used for the treatment of mild to moderate male pattern hair loss (also known as androgenetic alopecia). Finjuve increases hair growth on the scalp and prevents further hair loss in men. Finjuve is only for use by men from 18 to 41 years of age.

Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a particular hormone, dihydrotestosterone (DHT). In male pattern hair loss, the balding scalp contains increased amounts of DHT. This hormone is thought to contribute to shortening the length of time that the hair grows and to thinning of the hair. As the hair follicles become smaller (miniaturised), balding becomes apparent. Finjuve lowers the level of DHT in the scalp. This helps to reverse the balding process, leading to an increased hair growth and prevention of further hair loss.

2. What you need to know before you use Finjuve

Do not use Finjuve
- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman and are or may become pregnant.

Warnings and precautions
Talk to your doctor or pharmacist before using Finjuve.

Possible transfer of Finjuve
This medicine may cause a male baby to be born with abnormalities of the sex organs if the active ingredient finasteride is absorbed through the skin of a pregnant woman. Avoid any contact between the treated area and a woman who is or may become pregnant. You should also tell her to avoid touching surfaces exposed to Finjuve. If contact with Finjuve occurs, the woman concerned should wash the affected body part quickly and thoroughly.

Children and adolescents must not come into contact with Finjuve. If contact with Finjuve occurs, the child or adolescent concerned should wash the affected body part quickly and thoroughly.

Effects on Prostate-Specific Antigen (PSA)
If you have a prostate-specific antigen (PSA) blood test done for prostate cancer screening, tell your doctor that you are using Finjuve as it may affect interpretation of the results.

Effect on male hormone dihydrotestosterone (DHT)
Finjuve makes the concentration of the male hormone DHT in blood go down and commonly even to below normal values. However, this occurs less frequently and also the decrease is lower than with finasteride tablets. Side effects of a sexual nature that are known for finasteride tablets may also occur with Finjuve but are less likely (see section 4). Therefore, adhere to the dose that your doctor has prescribed for you. Do not use more than 4 sprays daily.

Breast cancer
Although breast cancer has not occurred in men treated with Finjuve in clinical studies, it has been reported during treatment with finasteride tablets. If you experience any changes in your breast tissue such as lumps, pain, enlargement or nipple discharge, contact your doctor as soon as possible.

Mood alteration and depression
Although mood alteration has not been observed in patients treated with Finjuve in clinical studies, it has been reported during treatment with finasteride tablets. If you experience symptoms such as low mood, depression or suicidal thoughts, contact your doctor for advice as soon as possible.

Children and adolescents
Finjuve should not be used by children or adolescents. There are no data demonstrating efficacy or safety of finasteride for children under the age of 18 years.

Other medicines and Finjuve
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Do not apply Finjuve if you are using other topical products, such as cosmetics, sunscreens or other medicines, in the same area.

Pregnancy
Finjuve must not be used by women.

Women who are or may become pregnant must avoid contact with the treated scalp or surfaces exposed to Finjuve. See section “Possible transfer of Finjuve” above. If direct contact with this medicine occurs, the woman should wash the affected body part quickly and thoroughly and ask her doctor for advice.

Driving and using machines
Finjuve has no influence on the ability to drive and use machines.

Finjuve contains ethanol
This medicine contains 25 mg ethanol (96 per cent) in each spray which is equivalent to 0.5 mg/microlitre (55 per cent). It may cause burning sensation on damaged skin.

3. How to use Finjuve

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

Depending on how much of your scalp is bald, your doctor will prescribe between 1 and 4 sprays daily to be used on separate areas. Do not use more than 4 sprays daily.

Finjuve is for cutaneous use. It is only to be used on the scalp.

Finjuve is composed of two separate parts: a bottle with a pump attached and a cone. These components require assembly before first use. Before first application read the entire handling instructions below.

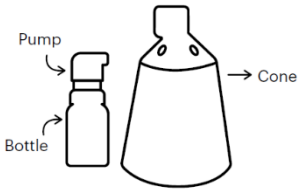
Ensure hair and scalp are fully dry prior to application. Apply Finjuve on the scalp only by yourself. If more than one spray is prescribed, apply these to areas that do not overlap. Do not apply the solution to areas of the body other than the scalp. Once applied, leave Finjuve in place for at least 6 hours.

Finjuve can be transferred through contact with fabrics, hands or other surfaces and objects. Avoid contact between the treated scalp and pillows, helmets, hats etc until the solution has dried.

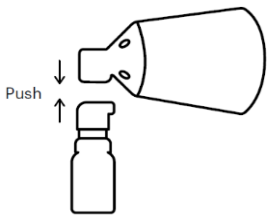
Finjuve can transfer from your body to others if they touch your treated scalp or other exposed surfaces. If contact with Finjuve occurs, the person should wash the affected body part quickly and thoroughly.

Store Finjuve in a safe and secure location out of the reach of children. Advise family members or others with access to the storage location of the contact precautions.

Components and assembly of the spray applicator

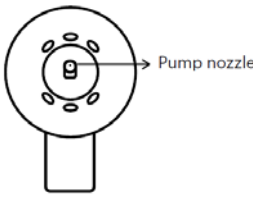


Assembly of the spray applicator



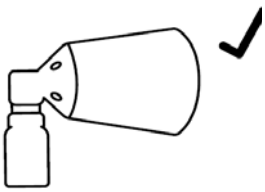
A Align and press

Align the cone with the pump button and firmly press into place.



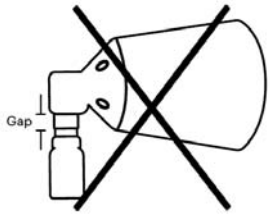
B Correct assembly

The spray applicator is correctly assembled when you hear a click after pressing, the pump spray nozzle is located in the centre position of the cone.



C Correct assembly

and the bottom of the pump button is lined up with the bottom of the cone without any gap.

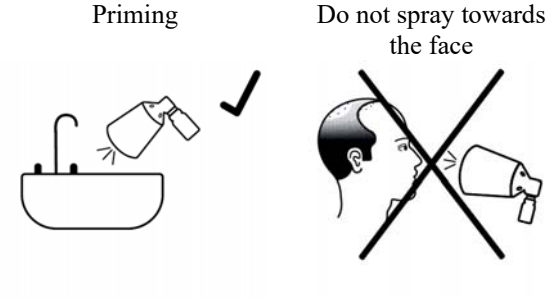


D Incorrect, gap. Realign and press again

If you do not hear a click during assembly or you can see a gap between the bottom of the pump button and the cone, realign the components and press into place again.

Priming the pump

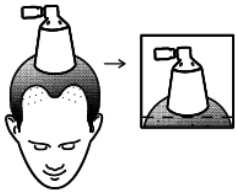
- After assembly of the spray applicator the pump must be primed for the first use. If the spray applicator has not been used for 2 weeks or longer, the pump will need priming again. There is no need to reprime at each use.
- To prime the pump for the first time, fully press the pump four times with your thumb or index finger, directing the sprayed solution into a sink. Then rinse the sink with water. To reprime the pump after non-use for 2 weeks or longer fully press the pump one time only.
- Do not spray Finjuve towards your face.
- If solution is released during assembly or priming, clean surfaces where it may have been deposited.



Dose application

- Depending on the size of the bald area on your scalp, your doctor will prescribe between 1 and 4 sprays daily.
- There is no need to shake the bottle before use.
- Hold the spray applicator with the cone flat against the scalp to avoid dispersion of the solution in the air.
- Fully press the pump once for one spray.
- Move the cone to different areas of your scalp to apply any further doses according to the number of sprays prescribed by your doctor. Do not overlap and treat areas that have already been sprayed.
- After use, do not remove the cone from the pump. Put the spray applicator back in the box.
- Once applied, do not wash Finjuve off for at least 6 hours.

Cone flat against scalp



Move cone to the next area which does not overlap



Ensure that Finjuve does not come into contact with your hands or any other parts of the body. Wash immediately and thoroughly any part of the body exposed other than your scalp.

If the cone becomes dirty, wipe it with a clean dry tissue. Safely throw away the used tissue and wash your hands thoroughly.

Dose and treatment days per dose

The bottle contains up to 180 sprays. The number of days of treatment depends on the prescribed dose, 1 to 4 sprays per day. Do not use the bottle beyond 180 sprays, because any remaining solution in the bottle may not give a full dose, which could limit the effect of your treatment.

Sprays per day	Days of treatment
1	180
2	90
3	60
4	45

- The prescribed dose and resulting number of treatment days until the product is used up will be written on the box by the pharmacist.
- On the date you start treatment with Finjuve make a note in your calendar of the prescribed dose (1 to 4 sprays) and calculate when a new bottle is needed. Contact your doctor before your supply runs out so there is no break in your treatment.

If you use more Finjuve than you should
If you apply more Finjuve than recommended, talk to your doctor. Finjuve will not work faster or better if you apply it more than once a day, but side effects may be more likely.

If you forget to use Finjuve
If you forget to apply Finjuve, do not apply a double dose to make up for the forgotten application. Continue to use at the dose recommended by your doctor.

If you stop using Finjuve
It may take 3 months for the treatment effect to develop. It is important to keep using Finjuve for as long as your doctor tells you. If you stop applying Finjuve, you are likely to lose the hair you have gained.

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.

Common (may affect up to 1 in 10 people)
- Itching or redness of the scalp

- Very common (may affect more than 1 in 10 people)Decrease of a male hormones (dihydrotestosterone) in blood

Other side effects known to occur with oral finasteride may also be possible with Finjuve. This includes:
- Allergic (hypersensitivity) reactions including skin rash, itching, swelling around the mouth (angioedema)
- Depressed mood
- Anxiety
- Awareness of heart beats (palpitations)
- Increase in liver enzymes
- Breast tenderness and enlargement
- Pain in the testicles
- Blood in the ejaculate (haematospermia)
- Impaired sexual desire
- Difficulties with erection
- Ejaculation disorder including decreased amount of ejaculate
- Infertility

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finjuve

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 box and the bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Finjuve contains alcohol and is therefore flammable. Avoid spraying the medicine near open flames or while smoking.

Do not use Finjuve for longer than 6 months after first opening the bottle.

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 Finjuve contains
- The active substance is finasteride. Each mL solution contains 2.275 mg of finasteride. Each spray delivers 50 microlitres, which contain 114 micrograms of finasteride.
- The other ingredients are: ethanol (96 per cent), purified water, propylene glycol, hydroxypropyl chitosan.

What Finjuve looks like and contents of the pack
Finjuve is a colourless, clear and slightly viscous cutaneous spray solution.

Pack sizes:
1 bottle (corresponding to 180 sprays) with a snap-on mechanical spray pump and 1 separate cone.
3 bottles (corresponding to 3 x 180 sprays) with a snap-on mechanical spray pump and 3 separate cones.

Before first use attach the cone to the pump of the bottle, as described in section 3.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
[To be completed nationally]

This medicine is authorised in the Member States of the EEA under the following names:

Country	**Trade names**
Germany	Finjuve für Männer 2,275 mg/ml Spray zur Anwendung auf der Haut (Kopfhaut), Lösung
Bulgaria	Финюве за мъже 2,275 mg/ml спрей за кожа, разтвор Finjuve for men 2.275 mg/ml cutaneous spray, solution
Czech Republic	Fynzur 2.275 mg/ml kožní sprej, roztok
Greece	Fynzur for men 2.275 mg/ml cutaneous spray, solution
Hungary	Fynzur 2,275 mg/ml külsőleges oldatos spray
Ireland	Finjuve 2,275 mg/ml cutaneous spray, solution
Italy	CARETOPIC 2.275 mg/ml spray cutaneo, soluzione
Luxembourg	Finjuve für Männer 2,275 mg/ml Spray zur Anwendung auf der Haut (Kopfhaut), Lösung
Poland	Finjuve, 2,275 mg/ml, aerozol na skórę, roztwór
Portugal	Finasterida Cantabria 2.275 mg/ml Solução para Pulverização Cutânea
Romania	Finjuve pentru bărbați 2,275 mg/ml spray cutanat, soluție
Slovakia	Finjuve pre mužov 2,275 mg/ml dermálny roztokový sprej
Spain	Alocare 2,275 mg/ml Solución para pulverización cutánea

This leaflet was last revised in {MM/YYYY}.