

### Patient information leaflet

#### Nano-D microemulsion (Dutasteride 0.03%)

**Do not swallow. For external use only**

Read instructions carefully. Use only as directed.

This nano-emulsion contains 0.03% Dutasteride which is a Type 2 and Type 1 '5-Alpha reductase inhibitor'. It is scientifically shown and used off label to treat hair loss. It is not licensed to treat hair loss. (It is licenced as 0.5mg capsules to treat enlarged prostate).

It is used off label to treat male pattern hair loss. In the scalp, Dutasteride lowers the levels of DHT (dihydrotestosterone) by blocking the enzymes (Type 2 and 1 alpha reductase) that converts testosterone to DHT which contributes to the shortening of the growth phase of hair. Only men with mild to moderate but not complete hair loss can expect some benefit from treatment with Dutasteride. (Finasteride only blocks type 2 alpha reductase enzyme where as Dutasteride blocks type 1 & 2 alpha reductase enzyme)

#### Do not use this solution if you:

- are allergic to Dutasteride, or any other ingredients in the solution (ask the pharmacist)
- are a woman (as this solution is for men)
- are already taking Finasteride or dutasteride tablets, used for a prostate problem called benign prostatic hyperplasia.

#### Warnings and precautions

Talk to your doctor or pharmacist if you:

- notice any changes in your breast tissue such as lumps, pain, enlargement of breast tissue or nipple discharge as they may be signs of a serious condition, such as breast cancer
- need to have a blood test called "PSA" (prostate-specific antigen). Make sure you tell your doctor or pharmacist first as Finasteride may alter the results of this test. Also:

Do not use more than the recommended dose. Your hair will NOT re-grow any more quickly and you have an increased chance of getting side effects. If forgotten, just apply when your next dose is due.

Do not apply to areas of the body other than the scalp.

Avoid contact with the eyes, mouth, broken skin and sensitive areas. If the solution is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water.

Accidental ingestion may cause serious unwanted cardiac events. Therefore keep this product out of the reach of children.

Get accurately the required dose into the dosing syringe given. Tilt the head back and release the liquid in

#### Mood alteration and depression

Mood alterations such as depressed mood, depression, anxiety and, less frequently suicidal thoughts have been reported in some patients treated with Dutasteride oral capsules. If you experience any of these, you must stop Dutasteride and contact your doctor.

#### Pregnancy and breastfeeding

Dutasteride should not be used by women.

Use a condom during sexual intercourse.

Women who are pregnant or may become pregnant should not handle this solution. If Dutasteride is absorbed through the skin by a woman pregnant with a male foetus, the child may be born with malformed genital organs.

If you think a pregnant woman has come into contact with Dutasteride, you should consult a doctor. If trying for a baby, stop 6 months before trying.

There is no evidence to suggest that Dutasteride affects ability to drive or use machines. Dutasteride should not be used in children.

Dutasteride can react with other medications. Tell your doctor or pharmacist if you are taking, have recently taken or are planning to take other medicines.

To be used as directed by your prescriber or pharmacist.

It may take 3 to 6 months for the full effect to develop. It is important to keep using Dutasteride 0.03% nano-emulsion for as long as your prescriber tell you. If you stop using it, you are likely to lose your hair you have gained within 9-12 months.

Application of Dutasteride 0.03% nano-emulsion

Do not apply to any other area apart from the scalp.

Read instructions carefully.

Use 1ml dose THREE times a WEEK or as directed by the prescriber.

Apply 1ml of the emulsion to the dry scalp in the evening. (The evening dose should be applied 1-2 hours before bedtime). Otherwise, use as directed by the prescriber.

When using the solution dispensed from the Hairology Centre for the first time, for the first week, start by using a 0.5ml dose, then on week 2, increase to 0.7ml dose, then on week 3 and onwards, increase to a 1ml maintenance dose as directed by the prescriber.

- blood in semen

drops on to different areas by gently tapping the plunger of the syringe. Make sure each drop of the solution coming out of the syringe is tiny to prevent excessive dripping on to the forehead. No application is required around the back and sides of the head.

Spread the emulsion with the tip of the syringe. If needed, you can gently massage the emulsion with your finger tip and let it absorb into the scalp.

Do not use more than 1ml dose

Do not use more than THREE TIMES a WEEK

If you forget your dose, do not use twice the dose to make up for the missed dose. If forgotten, just apply when your next dose is due.

Clean the syringe after each use by rinsing with clean water.

Wash your hands thoroughly with warm soapy water.

While using this medication, it is recommended that you gently wash your scalp/hair regularly, at least twice a week.

#### **Possible side effects**

Although this is applied on the scalp with lower chances of adverse effects, like all medicines, this medicine can cause side effects, although not everyone gets them.

Stop using this solution 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)
- Swelling of lips, face, tongue or throat (angioedema)
- Breathing difficulties.

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

#### **Other possible side effects:**

Localized itching, redness, irritated skin, dryness, flakey skin, contact dermatitis

**Dutasteride side effects** (topical solution has lower incidence of side effects than tablets)

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

Not known (frequency cannot be estimated from available data)

- awareness of your heart beating (palpitations)
- increase in liver enzymes

- testicular pain

- infertility

- persistent difficulty in having an erection, sex drive and problems with ejaculation after discontinuation of treatment

- anxiety.

Getting all listed side effects is unlikely and any that occur usually wear off after stopping use of the medication.

At the start of use, for some patients, Dutasteride can cause temporary initial hair shedding for the first 1-2 months. This is normal for all hair loss treatments as some hairs in their final resting stage of their growth cycle are shed and replaced by new hair growth from beneath.

Also contains Oleic acid, Tween 20 denatured ethanol, purified water.

It is your duty to inform us of any change to your health or medication/vitamins/supplements you take.

Like all medicines, overusing this can be dangerous and it being regulated, we have to ensure that the correct dose is being used. Therefore, request for early supply before the due date may be declined resulting in sub-optimal treatment.

#### **Storage:**

Do not refrigerate and store this medication at room temperature between 18-25 degrees centigrade and protect from sunlight.

Keep container tightly closed.

Keep away from heat/sparks/open flames/hot surfaces - No smoking.

Do not use this medication after its expiry date.

If you notice any problems with your product you must inform us within 48 hours.

Please take care of your medication, as this prescription medication cannot be replaced due to patient mishandling or expiring (past its expiry date) by not being used.

Androgenetic alopecia is a continuing condition that requires ongoing treatment and inconsistent use could lead to substandard results.

Dutasteride 0.03% nano-emulsion is available unlicensed if prescribed for special use according to a patient's need.

All solutions (unlicensed) at the Hairology Centre are prepared extemporaneously and formulated, with all elements licensed and approved by the MHRA.

The Hairology pharmacy is thoroughly regulated by the General Pharmaceutical Council whose officers inspect and monitor compliance to all standards.

Keep all medicines out of reach of children.