Shampoo

Hair Therapy Shampoo Reconstruction and Thickening.

Introduced by HUSSSH®

TECHNICAL INFORMATION PACK Version 0.05

Science dive and drugs edition

HUSSSH Therapy Shampoo for Hair Loss

Finasteride/Minoxidil vs Natural Oil Extracts from plants and fruits - The Science

Licensed Brug Broducts Combination Bruge Not Licensed

Clinical Studies/Reports Yes No Yes	
Chemicals 100% 98% 2%	
Side Effects Many Many None	
Effective Yes Yes Yes	王
Male use Yes Yes Yes	SSSH
Female use No No Yes	2
High strength No Yes Not needed	THE STATE OF THE S
MINOXIDIL MHRA warning Yes Yes No	The second second
MHRA licensed Yes No Yes	•
Safety assured Yes No Yes	
Long term use No No Yes	
Environmental impact Yes Yes No	

(Notes)

Unlicensed/not licensed drugs - are products that the MHRA have not granted licenses for and that are prescribed by GPs that consider no other products are applicable to treat the patient. The pharmacy is obliged to dispense the product if they can locate it either in another country with the same quality and compliance standards as the UK or there is a company in the UK that can compound the product.

Licensed Drugs – these are products that have detailed clinical studies and human trials that prove they work and are safe for humans to use. The dossiers for such products are very very large and thorough. The dossier includes a great many pages of data and reports from the public and private sector.

(bibliography). This would be the correct definition of "clinically proven".

Long term use – it is not recommended that drug chemicals are continuously used unless they are life critical e.g. blood pressure, chemotherapy, breathing. Environmental impact – every drug product must have an impact risk assessment report to describe how the chemicals are broken down in the natural environment, if they are and how the chemicals impact such things as the quality of water supply, fauna and flora and animals. These risks are assessed in accordance with what governments have laid out as acceptable or unacceptable risks to the natural world. The reports HUSSSH has seen show that the long-term effects of Finasteride and Minoxidil need more work to better assess the impacts. Natural derived products readily absorb back into the environment with no long term negative impacts.

The Myth Biotin Supplements are Needed for Hair Loss Recovery

The term Biotin is a generalisation to describe a Vitamin B complex. Otherwise also called Vitamin B7 and Vitamin H.

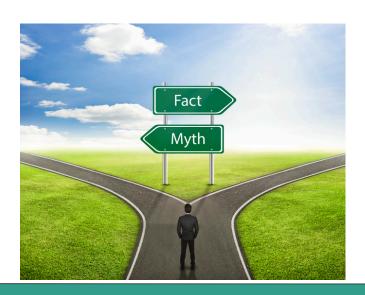
A deficiency in this vitamin is rare in people with a normal balance diet including eggs, liver, cereals, vegetables, rice. Dietary professionals recommend 30 micro grams a day maintains good health. In the western world it is estimated that average intake is well in excess of that level. Certain drugs like Carbamazepine and the act of lactation have been shown to cause low level Biotin deficiency, meaning that supplements will assist restore the body's balance. In fact, statistics suggest that Biotin deficiency is about 1 in 140,000 people. There is no robust evidence that taking Biotin supplements enhances hair or nail growth despite there being many supplements on the market. There is some evidence that taking high doses of Biotin can help with neurological illnesses (yet not the underlying mechanism) however this is not applicable to hair loss recovery. It is concluded that the supplement is not required with current scientific knowledge.

It is generally not disputed in the human biology fraternity (pathophysiology) that Vitamin B7 is an essential element needed by the body for its proper function including working against oxidation effects (see fact sheet on antioxidants) however there is little need for a supplement if a healthy balance diet is maintained.

Essential source The National Library of Medicine report February 2023 on Biotin deficiency.







We are adding Ginseng

HUSSSH is adding Panax Red Ginseng to the ingredients of their Hair Therapy Shampoo. Why?

One of the key reasons that our competitors suggest the use of Finasteride tablets is that its chemical makeup leads to restricting or blocking the male body from converting testosterone into DHT (dihydrotestosterone). DHT is considered to be one of the leading contributors to male pattern baldness. By stopping the cause hair recovery is expected. Cease the tablets and hair loss comes back.

Studies have shown that ginsenosides such as that found in Panax Red Ginseng has been shown to inhibit the enzyme 5-alpha reductase which is responsible for converting testosterone into dihydrotestosterone. In fact, ginsenosides have been shown to enhance sex drive rather than decrease it with the Finasteride chemicals, through stopping the testosterone from being converted to DHT. No wonder that some HUSSSH competitors are suggesting their customers take Viagra (Sildenafil) to counter the effect of Finasteride.





Antioxidants scavenge free radicals from the body cells and prevent or reduce the damage caused by oxidation. What does this definition mean to you and me.

Antioxidants can can prevent or slow the damage caused by free radicals. These are unstable molecules that the body produces as a reaction to environmental and other pressures. Free radicals or the oxidation process can increase the risk of inflammation along with many and various health issues. Antioxidants are sometimes called "free-radical scavengers".



The US Library of Medicine published a paper in 2010 PMC 3249911 in which it describes the stresses we place upon our bodies; they called this oxidative stress which can lead to a whole host of diseases and conditions.

The study further explains that the oxidative stress in effect attacks the body's natural operating functions which in turn leave us more vulnerable to illness and diseases. Oxidation impacts the fundamental systems in the body by wreaking havoc breaking down the proteins and fats that we need to live. The paper goes on to explain how certain natural substances in effect eat the bad substances and help bring back balance in the body. These good substances they call free radical scavengers or in technical terms antioxidants as they reverse the effects of oxidative stresses and thus reduce our risk of diseases.

One key issue of the oxidative side effect is hair loss, where the roots and hair follicles die off by being starved of essential nutrients. The eating or using of natural antioxidants can work towards the reversal of hair loss by re-establishing the pathways for nutrients. Removing excess stress from our lives and eating food rich in antioxidants will act in a positive way too. We are what we eat and the environment in which we live

Medical News Today article date 8th Nov 2023 is one published place to find further information on the key role of antioxidants. www.medicalnewstoday.com/articles/301506

ANTIOXIDAN

Argania spinosa kernel oil – Argan Oil

In addition to page 3 of this technical pack and also page 9 key ingredients reference is made to a publication that discusses the benefits of Argan Oil. The National Library of Medicine in the US published an important paper in 2010 under reference PMC 3819075. Effects of Tocotrienol Supplementation on Hair Growth in Human Volunteers.

Tocotrienols belong to the vitamin E family and are known as powerful antioxidants. Argan oil is known to be high in Tocotrienol. The study PMC 3819075 was to study the effect of Tocotrienols on hair loss. In the study both male and female volunteers in the 18-60 age range were enrolled. They had varying levels of hair loss, from different places on the scalp and with no visible evidence of new hair growth in the bald areas. The volunteers had systemic illnesses, high blood pressure, thyroid, chemotherapy or any scalp conditions. A control group were also enrolled as the base line. The study duration was 8 months.

The outcome showed that between 40% and 50% more hair growth in the bald areas compared to the baseline placebo group. This supports the understanding that natural Tocotrienol (vitamin E) support hair growth.

A further 21 other references are cited in this paper.



A 2015 study published via PubMed (ref 25842469) shows evidence that rosemary oil is effective in the treatment of androgenetic alopecia (AGA) in a blind randomised comparative trail against Minoxidil 2%. The study involved 50 people for each study plus a baseline. The report summary is shown below. What is significant is the effectiveness of both after three months is the same, no meaningful difference and at the 6 month point both showed significant hair growth. 2% Minoxidil is the strength suggested a safe for women. For men 5% is suggested. Note that Minoxidil is applied by spray to the scalp (topical application)

Rosmarinus officinalis L. is a medicinal plant with diverse activities including enhancement microcapillary perfusion. The present study aimed to investigate the clinical efficacy of rosemary oil in the treatment of androgenetic alopecia (AGA) and compare its effects with minoxidil 2%. Patients with AGA were randomly assigned to rosemary oil (n = 50) or minoxidil 2% (n = 50) for a period of 6 months. After a baseline visit, patients returned to the clinic for efficacy and safety evaluations every 3 months. A standardized professional microphotographic assessment of each volunteer was taken at the initial interview and after 3 and 6 months of the trial. No significant change was observed in the mean hair count at the 3-month endpoint, neither in the rosemary nor in the minoxidil group (P > .05). In contrast, both groups experienced a significant increase in hair count at the 6-month endpoint compared with the baseline and 3-month endpoint (P < .05). No significant difference was found between the study groups regarding hair count either at month 3 or month 6 (P < .05). The frequencies of dry hair, greasy hair, and dandruff were not found to be significantly different from baseline at either month 3 or month 6 trial in the groups (P > .05). The findings of the present trial provided evidence with respect to the efficacy of rosemary oil in the treatment of AGA.

A 2020 study published in Scientific African and with 34 references supporting their work showed that Rosemany oil and Cedar oil have similar treatment results as 2% Minoxidil.

The publication by Medical News Today (link below) explains more about the use of Rosemary Oil. This article was clinically reviewed in 2023.

Rosemary oil and hair growth: Research, effectiveness, and tips (medicalnewstoday.com)

These reports and other references are available on request.



Minoxidil Pharmaceutical Drug 2% and 5%

Fact Sheet

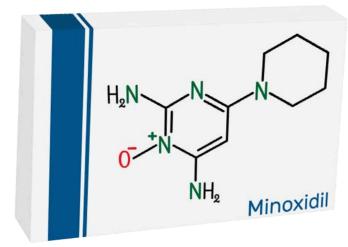
Minoxidil either under the brand name of Regaine or the generic versions is a low strength treatment for hair loss and in tablet form for the treatment of high blood pressure (hypertension) and acts as a vasodilator. It is a pharmaceutical product with approvals across the world for these treatment types. It does not require a prescription it is available via retail channels and online. It is a chemical substance. Taken by tablet for blood pressure and topically in a spray for hair loss. For hair loss 2% solution for women and 5% for men.

Being a chemical substance Minoxidil has several unwanted side effects. These side effects affect people in different ways, many may never be experienced, people may never experience any side effects, but the risks are there and especially so if other licensed or unlicensed pharmaceuticals are being taken at the same time. The published side effects include temporary hair loss, scalp irritation, change in hair texture, nausea, vomiting, weight gain, faster heartbeat, chest pain, shortness of breath, skin rashes, burning of the scalp, hair root inflammation. In some people the medication fails to work. The recommended dose is one ml of solution or a cap full if foam only to the affected area, twice a day on a dry scalp. For the spray this equates to about 10 sprays twice a day. This is the maximum dose. Continuous use after 16 weeks is not recommended by Regaine, the brand leader.

It is thought that the Minoxidil mode of action stimulates blood flow. So, this would include blood feed around the hair roots, getting more nutrients into the hair follicles; but there seems to be no evidence to support this. The indications for the tablets of Minoxidil has the clinical effect of lowering blood pressure by relaxing the arteries, this could influence those feeding the scalp.

The risk management plan used to manage public health for pharmaceuticals states Cutaneous application of Minoxidil has an anti-alopecic effect. Literature references highlight that minoxidil stimulates the growth of keratinocytes in vitro and in vivo together with hair growth in some patients with androgenic alopecia. The appearance of this phenomenon occurs after use of this medicine for a minimum period of 4 months, and varies according to each patient, although its mechanism of action remains unclear (having a parent company in pharmaceuticals enables HUSSSH to access this data)

The report goes on to say that Important risks of Minoxidil are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Minoxidil. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine) Under the current patient safety regulations the long-term effects have to be considered and the patient information updated, however until the regulatory authorities start to enforce this regulation the long-term risks will remain unknown.



Minoxidil Pharmaceutical Drug 2% and 5%

Fact Sheet

Minoxidil is an effective treatment for hair loss, based on the evidence of male users evident in the public domain. How it works is so far speculation and yet to be scientifically proven. The risk of side effects over time is missing as the data has not been generated.

The Minoxidil packaging is an aerosol so extra care is needed as its flammable, HUSSSH Hair Therapy Shampoo is in an unpressurized PET bottle.

Original article: https://www.mayoclinic.org/drugs-supplements/minoxidil-topical-route/side-effects/DRG-20068750

Each pharmaceutical must submit an environmental risk assessment before a licence is approved. However, the obligation to update is not clearly regulated. These reports cover the risks to the environment of the chemical components in the product. Seen below is the chemical structure of Minoxidil.

Products must be tested in accordance with Article 8 (3) of directive 2001/83/EC (as amended), an evaluation of the potential environmental risks posed by the medicinal product has been performed in accordance with the current CHMP guidance (EMEA/CHMP/SWP/4447/00 corr. 2, 2006). This assessment has to do with the chemical getting into the water systems, for example, having been washed away in the shower and entering the grey waste treatment systems.

There is a detailed scientific methodology to assess if the risk is or is not acceptable. CHMP guidance (EMEA/CHMP/SWP/4447/00 corr. 2, 2006) covers this matter.

The outcome is to show that a product is an acceptable risk or not. Acceptable meaning that the levels in the water (one aspect of the study) are so low as to not be considered a threat to the environment. Minoxidil does pose a threat, but the concentrations are so low as to not be considered worthy of any further follow up. The HUSSSH Hair Therapy Shampoo contains no chemical active ingredients, the oils and extracts are from nature.

To read the two risk assessment reports and the patient information leaflets a password link can be provided to our data room.

IDENTITY OF THE ACTIVE SUBSTANCE

Minoxidil

Chemical Abstracts Service (CAS) Registry Number: 38304-91-5 IUPAC name: 6-piperidin-1-ylpyrimidine-2,4-diamine 3-oxide

Molecular formula: C9-H15-N5-O Molecular weight: 209.2515 g/mol



There is only one treatment that has been clinically proven and approved by the regulatory authorities to block the effects of DHT, and that is the prescription drug finasteride. It is noted that this drug was developed to treat male prostate cancer and it was noticed with a lower dose (1 mg) that it was effective as a hair loss treatment. Such hair loss is called Alopecia. This is a prescription only medication requiring a GP consultation. The drug is not provided under the NHS scheme, so a private prescription is needed.

It is noted here that Finasteride cannot be taken by females. It has the effect of making them barren.

Finasteride is a prescription only medicine. It cannot be bought online or anywhere that would sell paracetamol. It is not available for free on the NHS for the treatment of hair loss. A doctor must issue a prescription having first seen you like they would for any other medical condition. There are now many on-line doctors that are writing prescriptions after a completed questionnaire and video consultation. These doctors are also writing prescriptions not only for Finasteride but also for combination pharmaceuticals which are not approved by the pharmaceutical regulator but can be compounded by a pharmacy. These are called unlicensed medications. Such products have no safety or side effect data sets and the pharmacist that makes up the products or sources them in, is taking the responsibility that they work for the patient. It is against the pharmaceutical guidelines of the MHRA (Medical and Healthcare Regulatory Agency, part of the Department of Health) to advertise prescription medications as well as unapproved mixture combinations of approved individual drug products – this is called Distance Selling.

The clinical evidence shows that Finasteride is effective in combatting the effects of DHT upon the hair follicles. In this sense, it is a DHT blocker, however it is not referred to by this name in the medical community. As a treatment for male pattern baldness, finasteride is sold in the form of tablets. One tablet must be taken every single day for as long as you wish to combat hair loss. Finasteride cannot provide a permanent cure for hair loss, so if you stop taking it, your hair loss will resume. Any new hair that has grown will fall out after you have stopped taking finasteride.

The clinical studies show that Finasteride starts to work quickly in the body. It gets to work reducing DHT levels straight away. But unfortunately, you won't notice improvements in hair loss immediately. It can take three or four months, even a year in some people, before an effect can start to be seen - a reduction in hair loss and any hair regrowth. Meaning taking one 1 mg tablet daily. The loss of hair in mean is thought to be caused by a combination of genetic factors and a particular hormone, DHT (dihydrotestosterone). DHT causes a decrease in the growth phase and thinning of the hair. This leads to male pattern hair loss. Finasteride acts to counter the DHT and help to resume the hair growth cycle.

FINASTERIDE

Finasteride Use and Side Effects

Fact Sheet

What is not made clear are the side effects when using Finasteride for prolonged periods. The patient information leaflet (see below) shows these side effects. Rash, reduced sex drive, low mood, tenderness around the nibbles and erectile disfunction problems. In fact, the MHRA have issued a formal warning associated with long term use of Finasteride. See below. As if to counter the erectile disfunction side effect on-line sellers such as Hims, Numan and others recommend to use of Viagra (Sildenafil in the generic form) to counter the problem. The worry here is the compounding side effects of using this drug. The drug works by increasing the flow of blood to the penis to create an erection. In doing this blood pressure is raised and in effect counters the side effects of Finasteride. The long-term effects of the regular use of both products together are unknown, at least there is not enough published data to be sure. To suggest that sildenafil only needs to work for a short period of time is not scientifically sensible to say. This said if Finasteride as the effect in some to cause erectile disfunction and Sildenafil operates to counteract, what are the two chemicals doing to your body.

For further information on the side effects the patient information leaflet has that is inside every pack of Finasteride 1 mg tablets is attached to this technical pack. Also attached is alert publication issued by the MHRA in April 2024 highlighting two important side effects, depression and erectile disfunction. Having a parent company that is in the pharma sector helps us have access to regulatory information.

There may be a wealth of evidence showing that finasteride is an effective treatment for male pattern baldness even showing that in 90% of the men stopped losing hair after taking finasteride. This makes it the most effective treatment for blocking DHT and treating male pattern baldness. Yet, if the person doesn't fancy the side effects that come with long term use, then when the stop taking the medication hair loss will resume. Whilst using the HUSSSH shampoo every day, or whenever you take a shower holds the hair loss at bay with no know side effects when used as suggested. And HUSSSH has case studies and photographic evidence proving their Hair Therapy Shampoo is effective at stemming hair loss in both male and female.

There are many companies that are promoting the use of liquid Finasteride in combination with Melatonin as well as Minoxidil for both male and female hair loss applications. This includes marketing and then selling online, importing combinations not licensed in the UK, preparing combinations in UK facilities. Even respected clinics are promoting the products. Such products do not come with the safety and protection that a MHRA licensed medicine Such products do not come with the safety and protection that a MHRA licensed medicine

There seems to be total lack of any supportive data with regards to mixtures, so the risk of use lies with the patient, the healthcare practitioner and the pharmacist who provides the product. With regards to the latter there are very clear guidelines issued by GPhC (General Pharmaceutical Council) for preparation of unlicensed medicines. The Royal Pharmaceutical Society has also issued a guidance document. In relation to the importing and supplying of products unlicensed in the UK the MHRA has also issued regulations. Should you wish to view these a link can be provided to our data room.

The MHRA is the Department of Health body – Medicines and Healthcare Products Regulatory Agency. They are the body that assesses and issues licenses for pharmaceutical products.

MHRA Safety Review of Finasteride Public, Assessment Report (Finasteride 5 mg and 1 mg) April 2024.



FINASTERIDE

Finasteride, 5 mg formulation sometimes called Proscar, is used to manage benign (noncancerous) prostatic hyperplasia (BPH). Finasteride, 1 mg formulation, sometimes called Propecia, is used to treat male pattern hair loss (MPHL). It belongs to a group of medicines called 5-alpha reductase inhibitors which block the conversion of testosterone to the androgen dihydrotestosterone (DHT) leading to a significant reduction in scalp and serum DHT. DHT is a hormone involved in the growth and repair of the prostate as well as the production of body hair. Finasteride is taken orally, with or without food as a film-coated tablet. It is available by prescription only and is not recommended for use in women or children. It is usually taken for a long time and if it is stopped, enlarged prostate symptoms or hair loss will usually come back. Finasteride 1 mg (Propecia) was first approved for use in MPHL in 1999 and finasteride 5 mg (Proscar) was first approved in 1992.

The pattern for treatment of male pattern hair loss is by entering a consultation with an online GP before the product can be prescribed. In section 4.3 of the MHRA assessment report it states

4.3 Online prescribing of finasteride

The online prescribing of finasteride may be viewed as convenient for patients however, it does raise the issue of patients obtaining finasteride by a route which does not easily allow them to be monitored for psychiatric side effects, as outlined in the product information. The MHRA has therefore engaged with other organisations such as the General Pharmaceutical Council (GPhC), General Medical Council (GMC), online pharmacies and the Care Quality Commission (CQC) to raise awareness of some of the issues highlighted with the online prescribing of finasteride. We also engaged with Digital Clinical Excellence (DiCE) which aims to provide a collective clinical voice for digital healthcare providers. They have recently created 'Best Practice Guidelines for online pharmacies when prescribing finasteride (Best Practice Guidelines digitalclinicalecellence.com)"

"Everyone has the right to safe, high-quality care – no matter how they access it. It's encouraging to see providers working together to learn from each other's expertise and experience to drive better care for people who use services." So says Tim Ballard, CQC's National Professional Advisor – PMS and Integrated Care who welcomed the new DiCE Best Practice Guidelines launched on 1st May 2024." They go on to say The timing is significant as the <u>April 2024 MHRA report</u> suggests many online pharmacies are unregulated, illegal or fraudulent. The guidelines aim to reduce unwarranted variation, help mitigate adverse effects of treatment and distinguish properly licensed and regulated services from those unqualified and potentially dangerous online sources." Best Practice Guidelines (digitalclinicalexcellence.com)

On 1st May the Chemist and Druggist which is the magazine and sourcing portal for all pharmacies ran with the headline "many on-line pharmacies unregulated, illegal of fraudulent (in relation to the MHRA report)

Finasteride

Shampoo

Hair Therapy Shampoo Reconstruction and Thickening.

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