



Secundum Artem

Current & Practical Compounding
Information for the Pharmacist.

COMPOUNDING FOR SCALP DISORDERS

GOALS AND OBJECTIVES

Goal: To provide information on the physiology and disorders of the scalp and some sample drugs and dosage forms used in their treatment.

Objectives: After reading and studying the article, the reader will be able to:

1. Discuss the physiology of the scalp and the function of the sebum, sweat glands and pores.
2. List at least five disorders of the scalp, their causes and differential diagnosis.
3. Describe different treatment approaches used in scalp disorders.
4. Evaluate various formulations used in the treatment of seborrheic dermatitis, dandruff, psoriasis, hair loss, lice and ringworm.

INTRODUCTION

Scalp disorders may be painful, annoying and unsightly. With an emphasis today in part of our society on appearance, many scalp disorders cause undue stress and embarrassment. Some scalp problems can be easily treated but many of them require treatment for many months or even years. Compounding pharmacists can significantly contribute to successful therapy by compounding for scalp disorders.

ANATOMY AND PHYSIOLOGY

The scalp consists of many parts and produces several substances. It includes the skin, sweat glands, sebaceous glands, hair shafts, hair, etc. When these are not functioning properly and in harmony with one another, various scalp disorders can occur.

Scalp: The scalp is the portion of the body consisting of skin and subcutaneous tissue normally containing hair that covers the neuro-cranium. It is especially rich in blood vessels; therefore, profuse bleeding may occur with scalp injuries. The functions of the scalp (skin) include protection and excretion. It secretes metabolic waste materials and toxins to remove them from the body; sweat to cool the body; and sebum to protect the skin itself.

Skin: Each layer of the skin (epidermis, dermis, subcutaneous) has a specific function. Included in the skin are the sebaceous glands that produce sebum and secrete it through the sebaceous ducts into hair follicles where it migrates to the surface of the skin. This flow of sebum removes dead skin cells that flake off from inside the hair follicle. Sebum consists of fatty acids and other substances and protects the skin by reducing the evaporation of water from the skin and blocks the penetration of excess water into the skin. This sebum is one of two constituents making up the lipid film present on the skin surface; the other being the lipids of the epidermal cells.

Pores: Pores in the skin are for the hair follicles. The pore size is related to sebaceous gland size; pores enlarge to accommodate a greater oil flow. Oftentimes acne clears up when the pores enlarge so that sebum is no longer impeded from moving through the pore.

Sweat Glands: Sweat glands consist of a single tube, the lower portion being coiled into a ball and the upper part, the duct, opens onto the surface of the skin. There are two types of sweat glands, the eccrine and the apocrine. The eccrine sweat glands, distributed all over the body, primarily regulate body temperature and eliminate toxic substances and

waste products; the perspiration is clear and consists of traces of salt, carbohydrates, protein and oil. The sweat they produce is primarily odorless. The apocrine sweat glands are primarily in the underarm area, around the nipples and in the genital area. They are stimulated by the same hormones that stimulate hair growth in the underarms and genital area. The fluid they secrete is milky and rich in organic material that is subject to bacterial decay, causing body odor. The hair entraps both sweat and bacteria.

Sebum: When the sebum gets stuck in the pores, whiteheads, blackheads, papules, pimples and cysts can ultimately occur. It is a result of the sebum getting delayed in its travels and clumping with dead skin cells, being acted upon by bacteria and ultimately blocking the opening to the skin surface. If pressure builds up, pustules and cysts result.

Hair: Hair grows on the scalp and each hair filament originates in a deep hair follicle, which penetrates into the dermis. At the base of the follicle is the papilla which is the center of hair growth that contains the capillaries and nerves that supply the hair. As new cells are formed and push previous cells upward, they gradually die and harden into a hair shaft, consisting of two layers; the cuticle and cortex. The outer layer, the cuticle, consists of flat, colorless overlapping cells. The cortex contains pigment and a tough protein called keratin, forming the bulk of the hair shaft. Coarse hair, as on the scalp, contains an additional inner core called the medulla. The hair is lubricated by sebaceous glands that are located in the hair follicle. Generally, human scalp hairs are shed every two to four years; body hairs are shed more frequently.

Hair growth: Hair growth is cyclical, consisting of three phases. The growing phase is the "Anagen" phase; about 90% of scalp hairs are in the anagen phase at any point in time. On a daily basis, about 50 to 100 scalp follicles go into the resting phase, or the "Catagen" phase, which involves 1% of the hairs daily. The shedding phase is the "Telogen" phase and approximately 10-20% of scalp hairs may be in the telogen phase at any point in time, completing the cycle.

SCALP DISORDERS AND THEIR TREATMENT

Seborrheic Dermatitis and Dandruff

Description: Seborrheic dermatitis is an acute or chronic papulosquamous dermatitis presenting with dry scales and underlying erythema; in some cases, pruritus is present. Dandruff occurs when there is mild scaling without any erythema; it can happen if the scalp is oily or dry. It may be the result of several factors, including hormonal imbalance, impaired metabolic nutrition, diet, tension, increased bacteria and fungi activity, biochemical changes in the scalp, topical medications and cosmetics. Seborrheic dermatitis occurs when there is general erythema without tight, thick, silvery scales. Psoriasis is evidenced by the presence of well-demarcated red plaques. The scaling of the scalp resulting from tinea capitis may appear to be dandruff or seborrheic dermatitis but alopecia is usually present in tinea capitis.

Treatment: Routine treatment for seborrhea of the scalp involves a shampoo that may contain tar, zinc pyrithione or selenium, used daily if appropriate. A ketoconazole 1% or 2%

shampoo can be used twice weekly. Solutions or lotions of topical corticosteroids can be used twice daily, if needed.

Psoriasis

Description: Psoriasis is an inflammatory skin disease that may be based upon a genetic predisposition. When the skin is injured or irritated, it tends to induce lesions of psoriasis at the site. There are several variants of psoriasis, with the most common being the plaque type. Psoriasis presents as silvery scales on bright red, well-demarcated plaques that may be accompanied by itching.

Treatment: The selected treatment of psoriasis in the scalp may be based on its extent and severity. Therapy can be initiated using a high or highest-potency corticosteroid preparation. Other measures include tar preparations, such as coal tar solution (LCD); also used are anthralin, calcipotriene and tazarotene. For the scalp, treatment can be initiated with a tar shampoo used daily. For thick scales, a 6% salicylic acid gel, phenol:mineral oil:glycerin mixture or fluocinolone acetonide 0.01% in oil under a shower cap at night followed by shampoo in the morning. Starting with low and increasing to higher potency, corticosteroids such as triamcinolone, fluocinolone, betamethasone dipropionate, fluocinonide, amcinonide, or clobetasol in solution form can be used twice daily.

Hair Loss

Description: Pattern, or androgenetic baldness, is the most common form of alopecia. It is of genetic predetermination with the earliest changes occurring on the front sides of the scalp and at the crown of the skull. The extent of hair loss is variable and unpredictable but may be experienced by approximately 80% of all men.

Treatment: A 5% solution of minoxidil alone or in combination with other active agents can be used in both male and female patients, generally twice daily. Those that respond are usually less than five years into their hair loss.

Description: Alopecia areata is believed to be the result of an immunologic process. There are typically patches that are smooth, without scarring. Tiny hairs, generally 2-3 mm in length, may be seen. At the edges of active lesions, small telogen or resting hairs can be easily removed. In some cases, all the scalp hair may eventually be involved. Alopecia areata is a self-limiting disease where there may be complete re-growth of hair in about 80% of cases. In some cases, mild alopecia areata is resistant to therapy.

Treatment: Severe forms may be treated by systemic corticosteroids; however, recurrences generally occur when therapy is discontinued. Corticosteroids can also be administered intralesionally; for example triamcinolone acetonide 2.5 to 10 mg/mL can be injected in aliquots of 0.1 mL every 1 to 2 cm in the involved areas. The total dose should not exceed 30 mg per month for adults. Another treatment includes daily use of anthralin 0.5% ointment.

Other therapeutic approaches involve the use of topical diphenylcyclopropanone and squaric acid dibutyl ester. These agents serve to sensitize the skin; this is followed by

application of progressively weaker concentrations designed to produce a slight dermatitis. This results in hair re-growth in 3 to 6 months in some patients.

Description: Drug-induced alopecia may result from thallium, excessive vitamin A, retinoids, antimetabolic agents, anticoagulants, antithyroid drugs, oral contraceptives, trimethadione, allopurinol, propranolol, indomethacin, amphetamines, salicylates, gentamicin and levodopa. Drug-induced alopecia is very disconcerting to the patient but it is reversible when the causative agent is discontinued.

Treatment: No real treatment is indicated here other than discontinuation of the causative agent.

Lice

Description: *Pediculus humanus var capitis* (the head louse: approximately 3-4 mm long) is the causative agent for pediculosis of the skin of the scalp. It is presented as pruritus with excoriation and the presence of nits on hair shafts; they are easiest to see above the ears and at the nape of the neck. Head lice can be spread by individuals sharing hats or combs and it is epidemic among children of all socioeconomic classes, especially in elementary schools. Adults in close contact with children may also get the infestation. It is important to distinguish pediculosis from seborrheic dermatitis prior to treatment.

Treatment: Options for treating head lice include ivermectin 0.8% lotion, malathion 0.5% or 1% lotion, permethrin 1% cream rinse and pyrethrins 0.17% to 0.33%. The ivermectin lotion is left on for up to 8 to 12 hours prior to rinsing off. The malathion is applied to the scalp and left on for up to 12 hours. The permethrin cream rinse is left on from 30 minutes to 8 hours prior to rinsing off and repeated in one week. Generally, after application of these preparations, it is important to meticulously remove the nits with a fine-tooth comb.

Ringworm

Description: Ringworm presents as a ring-shaped lesion with an advancing scaly border and central cleared area or as scaly patches with a distinct border on the skin or scalp. The affected areas may also itch. Generally there has been recent exposure to an infected cat; *Trichophyton rubrum* is the most common causative agent.

Treatment: Many of the topical antifungal agents can be used, including miconazole, clotrimazole, ketoconazole, econazole, sulconazole, oxiconazole, ciclopirox, butenafine and terbinafine. Topical dosage forms commonly used include creams, solutions and gels. If the product is exposed to wet environs, an ointment may be appropriate. Treatment should be continued up to two weeks after symptoms have resolved.

FORMULATIONS FOR TREATING SCALP DISORDERS

General Applications for Pruritus of the Scalp

RX HYDROCORTISONE 1% ANTIPRURITIC SCALP LOTION

Hydrocortisone	1 g
Menthol	250 mg
Polysorbate 80	0.25 mL
Ethanol 95%	25 mL
Propylene glycol	25 mL
Purified water	qs 100 mL

Mix the hydrocortisone and menthol with the polysorbate 80. Add the propylene glycol and ethanol and mix well. Add sufficient purified water to volume and mix well. Package and label.

Formulations for Seborrheic Dermatitis and Dandruff

RX SELENIUM SULFIDE 1% SHAMPOO

Selenium Sulfide	1 g
Propylene glycol	5 mL
Shampoo vehicle (Commercial)	qs 100 mL

Levigate the selenium sulfide with the propylene glycol. Add the shampoo vehicle to volume and mix well. Package and label.

RX ZINC PYRITHIONE 1% SHAMPOO

Zinc pyrithione	1 g (equivalent)
Propylene glycol	10 mL
Shampoo vehicle (Commercial)	qs 100 mL

Levigate the zinc pyrithione with the propylene glycol. Add the shampoo vehicle to volume and mix well. Package and label.

RX TRIAMCINOLONE 0.1% SCALP LOTION

Triamcinolone	100 mg
Propylene glycol	25 mL
Ethanol 95%	25 mL
Purified water	qs 100 mL

Mix the triamcinolone with the propylene glycol and ethanol. Add sufficient purified water to volume and mix well. Package and label.

RX ANTI-SEBORRHEA CLEAR LOTION

Progesterone	500 mg
Ethanol 95%	10 mL
Ethoxy diglycol	50 mL
Methylparaben	50 mg
Propylparaben	20 mg
Propylene glycol	1 mL
Purified water	qs 100 mL

Dissolve the progesterone in the ethanol. Add the ethoxy diglycol. Dissolve the methylparaben and propylparaben in the propylene glycol and add to the progesterone solution. Add sufficient purified water to volume and mix well. Package and label.

RX SULFUR SHAMPOO

Sulfur	1 g
Magnesium aluminum silicate	1 g
Ammonium lauryl sulfate	40 g
Lauramide DEA	4.5 g
Sodium chloride	200 mg
Methylparaben	50 mg
Propylparaben	20 mg
Purified water	qs 100 mL

Slowly add the magnesium aluminum silicate to about 50 mL of purified water while agitating and mix until smooth and uniform. Add the colloidal sulfur, ammonium lauryl sulfate, lauramide DEA, sodium chloride, methylparaben and propylparaben and mix well. Add sufficient purified water to volume and mix well. Package and label.

RX PHENOL, GLYCERIN AND MINERAL OIL SHAKE LOTION

Phenol	1 g
Glycerin	10 mL
Purified water	20 mL
Methylparaben	50 mg
Propylparaben	20 mg
Mineral Oil, Light	qs 100 mL

Dissolve the phenol, methylparaben and propylparaben in the glycerin. Add the purified water and mix well. Add the mineral oil and agitate. This is not an emulsion but is an immiscible shake-type lotion.

Formulations for Psoriasis**RX COAL TAR SHAMPOO**

Coal tar solution	2.8 g
Polysorbate 80	5 mL
Shampoo vehicle	qs 100 mL

Mix the coal tar solution with the polysorbate 80. Incorporate the shampoo vehicle and mix well. Package and label.

RX COAL TAR AND SALICYLIC ACID SCALP LOTION

Coal tar solution	10 mL
Salicylic acid	6 g
Polysorbate 80	1 mL
Ethanol 95%	20 mL
Propylene glycol	qs 100 mL

Mix the polysorbate 80 with the coal tar solution. Mix the salicylic acid with the alcohol and about 60 mL of the propylene glycol. Add the coal tar solution mixture slowly with mixing to the propylene glycol mixture. Add sufficient propylene glycol to volume and mix well. Package and label.

RX ANTHRALIN 1% AND COAL TAR 1% OINTMENT

Anthralin	1 g
Coal tar	1 g
Polysorbate 80	2 g
Aquabase	qs 100 g

Mix the coal tar with the polysorbate 80 and incorporate the anthralin. Incorporate into the Aquabase and mix until uniform. Package and label.

RX AFRICAN SCALP LOTION

Anthralin	250 mg
Salicylic acid	2.5 g
Coal tar solution	50 mL
Peanut oil	qs 100 mL

Dissolve the anthralin and salicylic acid in the coal tar solution. Add sufficient peanut oil to volume and mix well. Package and label.

RX ANTHRALIN 1% MEDICATION STICK

Anthralin	200 mg
Polyethylene glycol 3350	6.5 g
Polyethylene glycol 300	15 mL

Melt the polyethylene glycols together to a temperature about 55° C. Incorporate the anthralin and mix well. Pour into medication stick molds and allow to cool. Package and label.

RX CALCIPOTRIENE 0.003% LOTION

Calcipotriene 0.005% Cream	60 g
Propylene glycol	qs 100 mL

Mix the commercial calcipotriene 0.005% cream with sufficient propylene glycol to make 100 mL. Package and label.

RX FLUOCINOLONE ACETONIDE 0.01% IN OIL

Fluocinolone acetonide	10 mg
Vegetable oil	qs 100 mL

Incorporate the fluocinolone acetonide into a vegetable oil, such as sesame oil, almond oil, etc. and mix well. Package and label.

Formulations for Hair Loss**RX MINOXIDIL 5% AND RETINOIC ACID 0.01% SCALP LOTION**

Minoxidil	5 g
Retinoic acid	10 mg
Propylene glycol	20 mL
Ethanol 95%	qs 100 mL

Mix the minoxidil and retinoic acid with the propylene glycol. Add sufficient ethanol to volume and mix well. Package and label.

RX MINOXIDIL 2% AND FINASTERIDE 0.1% SCALP LOTION

Minoxidil	2 g
Finasteride	100 mg
Propylene glycol	20 mL
Ethanol 95%	qs 100 mL

Pulverize the required number of finasteride tablets and mix with about 75 mL of ethanol in a covered container and let set for a couple of hours. Filter through a paper filter to remove the excipients. Add the minoxidil and propylene glycol to the filtrate and mix well. Add sufficient ethanol to volume and mix well. Package and label.

RX SPIRONOLACTONE SCALP LOTION

Spirolactone	1 g
Methylcellulose	0.25%
Ethanol 95%	40 mL
Propylene glycol	20 mL
Purified water	qs 100 mL

Mix the spironolactone and methylcellulose with the propylene glycol. Add the ethanol and mix well. Add sufficient purified water to volume and mix well. Package and label.

RX IVERMECTIN 1% LOTION

Ivermectin	1 g
Propylene glycol	15 mL
Dermabase	30 g
Purified water	qs 100 mL

Mix the ivermectin with the propylene glycol to form a smooth paste. Incorporate the Dermabase and mix well. Slowly, add sufficient purified water to volume and mix well. Package and label.

Formulations for Ringworm

RX DIPHENYLCYCLOPROPENONE 0.1% TO 2.0% SOLUTIONS

Diphenylcyclopropenone	100 mg to 2 g
Acetone	qs 100 mL

Dissolve the diphenylcyclopropenone in sufficient acetone to volume. Package and label. Caution: Diphenylcyclopropenone is a strong sensitizing agent. Exercise care when preparing these solutions; wear appropriate masks, garb and gloves.

RX CLOTRIMAZOLE 1% SCALP LOTION

Clotrimazole	1 g
Propylene glycol	50 mL
Polyethylene glycol 300	qs 100 mL

Dissolve the clotrimazole in the propylene glycol and sufficient polyethylene glycol 300 to volume and mix well. Package and label.

RX SQUARIC ACID DIBUTYL ESTER 0.1% TO 1% SOLUTIONS

Squaric acid dibutyl ester	100 mg to 1 g
Acetone or Ethanol 95%	qs 100 mL

Dissolve the squaric acid dibutyl ester in sufficient acetone OR ethanol to volume. Package and label.

RX MICONAZOLE 1% AND TOLNAFTATE 1% SCALP LOTION

Miconazole	1 g
Tolnaftate	1 g
Propylene glycol	50 mL
Polyethylene glycol 300	qs 100 mL

Dissolve the miconazole and tolinaftate in the propylene glycol and sufficient polyethylene glycol 300 to volume and mix well. Package and label.

Formulations for Lice Infestation

RX MALATHION 0.5% TOPICAL LOTION

Malathion	500 mg
Isopropyl alcohol 70%	70 mL
Lavender oil	30 drops
Bay oil	3 drops
Ethanol 95%	qs 100 mL

Note: Compound this preparation in a well-ventilated area or use an exhaust hood since malathion fumes can be irritating to the mucous membranes of the nasal passages. Also, wear disposable gloves to prevent retaining the odor on the hands.

Disperse the malathion in the isopropyl alcohol. Add the fragrances and mix well. Add sufficient alcohol 95% to volume and mix well. Package and label.

RX KETOCONAZOLE 2% SOLUTION

Ketoconazole	2 g
Polyethylene glycol 300	80 mL
Propylene glycol	20 mL

Dissolve the ketoconazole in the polyethylene glycol 300 and propylene glycol and mix well. Package and label.

RX IVERMECTIN 1% CREME RINSE

Ivermectin	1 g
Polyethylene glycol 300	17 mL
Crema Rinse (Commercial)	qs 100 mL

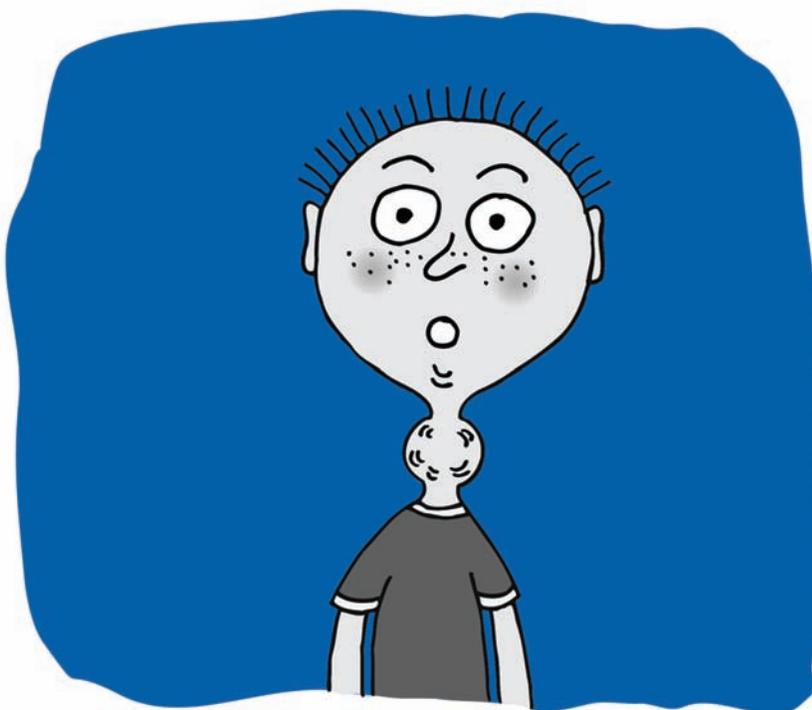
Mix the ivermectin with the polyethylene glycol 300 to form a smooth paste. Incorporate the crema rinse and mix well. It may be necessary to work the product in a mortar with a pestle to ensure uniform and small particle size of the ivermectin. Package and label.

**Extemporaneous
Formulations and Stability
Studies Available For:**

**Acetazolamide
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Bethanechol
Captopril
Chloroquine Phosphate
Cisapride
Clonazepam
Diltiazem HCl
Dipyridamole
Enalapril Maleate
Flecainide Acetate
Flucytosine
Hydralazine HCl
Ketoconazole
Labetalol
Metolazone
Metoprolol Tartrate
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