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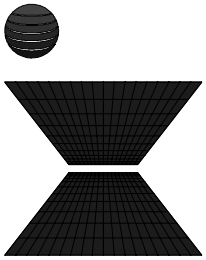
February 2001 "Pharmacy Perspectives: Fungal Infections" 707-000-01-002-H01



THIS MONTH—
"Pharmacy Perspective: Fungal Infections"

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In this lesson, we take a look at antifungal agents. Our goal is to concentrate on treatment of cutaneous infections. This lesson provides 1.25 hours of credit (0.125 CEUs), and is intended for pharmacists in all practice settings.

The program ID # for this lesson is 707-000-01-002-H01.
Pharmacists completing this lesson by February 29, 2004 may receive full credit.
(February 28, 2003 for California.)

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

Upcoming topics for continuous participants: Weight Management; Common Diagnostic Procedures; Drug-Food Interactions; Men's Health Issues; Dosing for Pediatric Patients; Menopause; Review of Alternative Therapies; Antifungal Agents; Cancer Chemotherapy.

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The objectives of this lesson are such that upon completion the participant will be able to:

1. Identify the various parts of the skin.
2. Discuss the characteristics of fungi.
3. Describe the etiology, symptoms and signs of common cutaneous fungal infections.
4. Explain the mechanism of action of antifungal agents.
5. List the most common adverse effects of antifungal agents.

INTRODUCTION

Fungal infections are common occurrences and can be divided into two major categories: 1) superficial, or cutaneous; and 2) deep or systemic. In this lesson we will concentrate primarily on the cutaneous variety.

Fungi are responsible for many cutaneous infections. In fact, certain individuals are affected episodically or at all times by one or more of these (i.e., nail infections and athlete's foot). To help assess the therapy of superficial fungal infections, it is essential to review the anatomy of the skin.

THE SKIN

The skin is a protective organ that covers the body and protects the underlying tissue from injuries, dehydration and invasion by pathogens. The skin may be divided into three major layers: epidermis, dermis and subcutaneous tissue.

Epidermis: The epidermis is the outermost layer of the skin, and contains no blood vessels. It receives its nutrition by diffusion from the underlying layers. The epidermis consists of several parts, the outermost of which is the stratum corneum, a layer that consists of dead, dry, keratinized cells that are constantly being replaced by new cells pushing up from the stratum germinativum. The stratum germinativum is the deepest layer of the epidermis. As the newly formed cells leave the stratum germinativum and move toward the surface, nourishment becomes inadequate, resulting in death of the cells and their conversion to keratin. Shedding of keratin from the skin is a normal physiologic process. The stratum germinativum consists of cylindrical cells that continually undergo division and supply newly formed cells that move upward toward the stratum corneum.

Dermis: The dermis is a continuation of the epidermis and contains numerous blood vessels, lymphatics, nerves, hair follicles, sweat and sebaceous glands.

Subcutaneous tissue: The subcutaneous tissue consists of elastic and fatty tissue and acts as a cushion and heat insulator.

CHARACTERISTICS OF FUNGI

Of the thousands of fungi, only 50 species are potentially infectious to humans, 25 of which cause cutaneous infections. Fungi are parasitic or saprophytic microorganisms that are incapable of synthesizing their food, and consequently they parasitize living tissue or saprophytize plants or animal remains. Fungi invade only dead tissue such as keratin, hair and nails. However, they are able to invade tissue of persons suffering from debilitating systemic diseases such as diabetes, lymphoma, and rheumatoid arthritis, and individuals whose immune systems have been compromised following the intake of corticosteroids, immunosuppressive agents, and antimetabolites. When the keratin of the skin becomes infected with fungi, the metabolites of these organisms as well as the proteolytic enzymes such as keratinase produced by the fungi diffuse into the living tissue under the keratin. Sensitivity to metabolites develops and the skin becomes inflamed, itchy and covered with tiny blisters. Progression of the infection causes the lesion to enlarge and become radially shaped with a scaly center and slightly raised inflamed periphery. Cutaneous fungal infections are known as "ringworm" due to the radial shape of the lesions.

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SUPERFICIAL FUNGAL INFECTIONS

There are three kinds of fungal microbes that can cause cutaneous infections in humans. They are: 1) **Trichophyton**, which usually infects the skin, hair and nails; 2) **Epidermophyton**, which affects the skin, nails, but not hair; and, 3) **Microsporum**, which involves the hair and skin, but rarely the nails.

1. Tinea pedis (Athlete's Foot or ringworm of the foot): Athlete's foot is the most common cutaneous fungal infection. It affects over one quarter of the population of the USA every year. It is estimated that 70% of the general population will be infected at least once in their lifetime. In warm regions of the world, fungal infection accounts for about 25% of all dermatological diseases.

Athlete's foot is caused mainly by *Trichophyton mentagraphytes, Trichophyton rubrum*, and occasionally by *Epidermophyton floccosum*. Typically, the infection begins in the toe web and then spreads to the sole or instep of the foot. The surface of the infected area is usually white, and macerated with scaly periphery. Severe cases may be accompanied by fissures and blisters. The infection triggers itching and provokes scratching, which may contribute to breaking the skin and providing the proper environment for the development of pyogenic secondary bacterial infection. The presence of secondary bacterial infection results in the formation of vesicopustules filled with cloudy liquid or yellow pus, and the affected area may become odoriferous. *Trichophyton rubrum* causes chronic athlete's foot, which is characterized by mild inflammation, scaly toe web, and thick soles. These microorganisms may resist treatment by becoming dormant for a relatively long time, but recur when environmental factors are favorable. Incidence of athlete's foot is higher in summer and in warm, humid climates. It is transmitted either directly by human contact or indirectly by exposure to contaminated objects. Walking barefooted on infected, moist floors such as swimming pools and locker rooms, and household objects such as floor mats, may result in spread of the infection.

Athlete's foot can be treated by both prophylactic and active methods. Prophylactic treatment includes avoidance of walking barefooted in public places and drying the feet, in particular the interdigital spaces after bathing or swimming. To reduce perspiration, dusting the feet especially between the toes with antiseptic or absorbing powder is recommended. Active treatment involves the use of topical preparations that include antifungal agents. In chronic persistent cases systemic antifungals may be helpful.

2. **Tinea Cruris** (Ringworm of the groin, or jock itch): Tinea cruris is an acute, subacute, or chronic fungal infection that affects the groin, perineum and perianal area of both males and females. The microorganisms responsible for this are *E. floccosum*, although the infection may be acquired from athlete's foot caused by *T. rubrum* and *T. mentagrophyte*. The infection manifests itself as a single or multiple erythematous, well-marginated patch(es) with slightly scaling surfaces. The patches become circular in appearance with a finely vesicular border, causing moderate to intense itching. Tinea cruris is usually predisposed by excessive perspiration, inadequate personal hygiene, maceration and friction. Application of topical antifungals as well as prophylactic treatment are effective.

3. **Tinea Corporis** (Ringworm of the body): Tinea corporis may be caused by several species of *Microsporum* and *Trichophyton*. It affects the non-hairy parts of the body. The lesions appear as single or multiple, scaly, circular and erythematous patches. The infection causes mild to moderate pruritus. Treatment can be achieved by using topical preparations containing antifungal agents.

4. **Pityriasis Tinea Versicolor**: This condition occurs as a result of infection due to *Malessezia furfur*. It primarily affects young adults and involves the smooth skin, especially that of the face, chest, trunk, shoulders and upper part of the back. The lesions appear as fawn yellow to brown in color, with irregular shapes. They become more noticeable in summer following exposure to the sun. The lesions, which do not get as tan as the surrounding skin, become more prominent. Tinea versicolor is asymptomatic, but may cause mild itching. Infected individuals usually seek treatment because of cosmetic concerns. This infection responds to topical anti-

fungal preparations.

5. **Tinea Unguium** (Ringworm of the nails or onychomycosis): Ringworm of the nails is caused by *T. mentagrophyte*, *T. rubrum* and *E. floccosum*. If left untreated, the infection tends to become chronic and more difficult to treat. It is characterized by paronychial inflammation, discoloration and distortion of the nail(s) involved. The nail becomes thick, lusterless, friable, grooved and the tip may separate from the nail bed. The infection, which is usually encountered more in the toenail than fingernail, may serve as a source of spreading to other parts of the body. Tinea unguium is resistant to topical antifungals, but may respond to systemic treatment.

6. **Vulvovaginal Candidias**: Vulvovaginal candidiasis is an infection of the vulva as well as the vaginal mucosa. It is more common during the childbearing years. This fungal infection is caused primarily by *Candida albicans*. It is characterized by intense itching, irritation, and an odorless white discharge. Factors such as pregnancy, prolonged intake of antibiotics or immunosuppressive agents, the use of estrogen-containing oral contraceptives and the presence of diabetes mellitus predispose *Candida albicans*.

ANTIFUNGAL AGENTS

A variety of agents are used in treating fungal infections, most of which are used topically. However, some of these drugs may be used systemically. A large number of topical antifungals are intended for self-treatment. If the patient follows instructions on the label, these OTC medications have been shown to be safe and effective.

1. **Clotrimazole** is an imidazole derivative azole antifungal that acts against various fungi including yeast, and dermatophytes. Its antifungal activity is due to its ability to alter cell membrane permeability by binding to phospholipids of the cell membrane of the microorganism, causing loss of potassium and other cellular constituents. A small amount of the drug is absorbed following topical intravaginal application. Clotrimazole may be used orally in the form of lozenges that are allowed to dissolve in the mouth for 15 to 30 minutes. Lozenges may be effective in treating oropharyngeal candidiasis or in the prevention of the disease in persons with HIV or who are using immunosuppressive therapy such as the intake of corticosteroids, antineoplastic drugs, or radiation in the treatment of cancer or following renal transplantation. The lozenges are not recommended for treating systemic fungal infections. Topical preparations of clotrimazole such as lotions, creams, or solutions are used in treating Tinea pedis, Tinea cruris, Tinea corporis, and Pityriasis Tinea versicolor. In complicated cases of Tinea pedis, Tinea unguium, and, in particular, in patients who failed to respond to treatment or have frequent relapse following topical therapy alone, systemic antifungals may be indicated with or without topical agents. Clotrimazole is also used intravaginally in vaginal tablets or cream forms for vulvovaginal candidiasis. It is recommended that vaginal tablets be inserted in appropriate single doses or in lesser doses for up to seven days. Both topical and oral therapies have resulted in 80 - 90% cure rates. The use of two, 100 mg vaginal tablets daily of clotrimazole for three days, or one 100 mg vaginal tablet daily for seven days have shown to be effective in treating vulvovaginal candidiasis. The cure rate is reduced during pregnancy. The use of clotrimazole cream for 7 - 14 days is effective. The use of single dose therapy of a 500 mg vaginal tablet with lactic acid is as effective as other therapies. Topical preparations that are available in 1% cream, 1% lotion and 1% solution, should be rubbed on the cleansed affected area and surrounding skin twice daily. In treating vulvovaginal candidiasis, two vaginal tablets containing 100 mg of the drug each, should be inserted intravaginally at bedtime for three consecutive days, or one vaginal tablet inserted at bedtime for seven consecutive days. The three-day regimen is not recommended during pregnancy. A 500 mg vaginal tablet may be used in uncomplicated vulvovaginal candidiasis.

Clotrimazole has no serious adverse reactions when used topically or intravaginally. Occasionally mild burning, erythema, pruritus, and/or irritation of the skin or the vagina have been reported. Other complaints following the use of vaginal tablets include vulval irritation, lower abdominal cramps, and bloating. Contact dermatitis has occurred following topical application of clotrimazole and other imidazole-derivative azole antifungals. Cross-sensitization is possible among these antifungals. Clotrimazole use should be discontinued if sensitivity to

the drug is confirmed. The use of lozenges may result in abnormal liver function tests as well as nausea, vomiting and pruritus. It should be remembered that, if no improvement occurs within two weeks for Tinea cruris or four weeks for Tinea pedis or Tinea corporis, the use of topical treatment should be discontinued and medical advice should be sought. Likewise, if improvement does not occur in 3 days for vulvovaginal candidiasis or if the condition persists for seven days following the use of vaginal tablets or clotrimazole cream, discontinuation of treatment is recommended. Clotrimazole lozenges that each contain 10 mg of the drug should be allowed to dissolve in the mouth for a period of 15 to 30 minutes.

2. **Econazole** is a fungistatic agent, but in high concentration may exert fungicidal activity. It acts by increasing permeability of the fungal cell membrane and blocking C-14 demethylation of sterols, thereby interfering with the synthesis of ergosterol. The nitrate salt of econazole is used in topical preparations. Dermal penetration of the drug is minimal. Econazole nitrate, which is available in 1% cream, lotion, or solution, is effective against dermatophyte and candidiasis. Pityriasis Tinea versicolor has responded positively to treatment with topical preparations of econazole.

The main adverse reactions to topical preparations of econazole include burning and stinging sensations, itching and erythema, but rarely contact dermatitis. These side effects appear to be transient and usually occur three to four days following therapy. For treating Tinea pedis, Tinea cruris, Tinea corporis, or Tinea versicolor, the topical preparation should be applied and rubbed into the affected area and the immediate surrounding skin once daily; whereas, in treating cutaneous candidiasis, the procedure should be duplicated twice daily. Tinea pedis may be treated for one month, while other infections should be treated for two weeks. If improvement does not occur, treatment should be reevaluated.

3. **Ketoconazole** possesses similar activity and mechanism of action to other imidazole-derivative azole antifungals. It is available in 2% cream and shampoo. It may be used orally to treat both superficial and deep fungal infections. It is well absorbed from the GI tract, and is distributed widely in the body following oral administration. Optimal absorption occurs when the drug is taken on an empty stomach. Metabolism of ketoconazole takes place in the liver. The metabolized drug is excreted in the bile and feces. Ketoconazole should not be given concurrently with drugs, such as cimetidine, ranitidine, famotidine and antacids, that reduce the acidity of the gastric juice. An increase in the pH of the GI fluid results in a decrease in absorption rate of the antifungal drug.

Nausea, vomiting, dizziness, abdominal pain, headache and insomnia have been reported following oral use. Hepatotoxicity, may be experienced, but it is reversible following discontinuation. Care should be exercised when ketoconazole is administered concurrently with other medications that may cause hepatotoxicity . A daily dose in the range of 200 to 400 mg orally for one week to 12 months, depending on the fungi involved and the infection site, is recommended.

4. **Miconazole:** This imidazole derivative is used topically in the form of 2% aerosol, aerosol powder, cream, vaginal cream, as well as vaginal suppositories, each containing 100 or 200 mg of the drug for treating cutaneous infection. Miconazole nitrate is effective against Tinea pedis, Tinea cruris, and Tinea corporis caused by various fungi, as well as cutaneous candidiasis and Pityriasis Tinea versicolor. The drug has been administered intravenously to treat fungal meningitis.

Adverse effects of topical and intravaginal use include burning, stinging, headache, hives, and pelvic cramps. Discontinuation of the use of these preparations is warranted if irritation and hypersensitivity emerge.

5. **Fluconazole:** is a broad spectrum bistriazole derivative that is related to the imidazole derivative azole antifungal agents. Its mechanism of action is similar to those of the imidazole derivatives. Fluconazole and other triazoles have affinity for fungal P-450 enzymes and are more specific in their inhibition than the imidazoles. Fluconazole is effective against many *Candida*, *Cryptococcus neoformans*, *Histoplasma capsulatum* and *Blasto-*

myces dermatitidis.

Fluconazole may be administered orally or intravenously. The drug is well absorbed from the GI tract. In healthy fasting adults, oral bioavailability may reach 90%, and peak plasma concentration is attained within one to two hours following oral administration. It has been reported that oral bioavailability of the drug did not change when given to HIV patients and that food did not interfere with its GI absorption. Fluconazole is eliminated from the body through the kidneys, and a small amount is excreted in the feces. The drug is widely distributed in body fluids and tissues after both oral and intravenous administration. Only 11-12% is bound to plasma protein. This is low compared to other systemic antifungals.

This drug is used in treating systemic candidal infections, as well as blastomycosis, coccidioidomycosis, and histoplasmosis. It is also used for antifungal prophylaxis against the aforementioned microorganism in patients with HIV infection, or in individuals who are immunocompromised. Prior to initiation of therapy, identification of the causative microorganism should be achieved. The drug is considered safe. About 5 to 7% of patients receiving fluconazole have experienced transient elevation of liver enzymes. Rare serious hepatotoxicity has been reported. About 2% of patients reported dizziness, and approximately 1% developed nausea, vomiting, abdominal pain, diarrhea, skin rash and headache. Most of these reactions occur more commonly in patients infected with HIV.

The concurrent administration of fluconazole and warfarin may increase prothrombin time. Monitoring prothrombin time in such cases is recommended. Likewise, levels of phenytoin and cyclosporin may increase by the presence of fluconazole. Glyburide and glipizide metabolism may decrease resulting in hypoglycemia. Usual adult oral dose is similar to the intravenous dose because fluconazole is well absorbed from the GI tract. Dosages depend on response of the patient, as well as the disease to be treated. Initial oral or IV doses of 200 mg followed by 100 mg daily for two or three weeks or longer is common. However, a dosage of up to 400 mg daily may be used. For the treatment of vulvovaginal candidiasis, a single dose of 150 mg is given once a month, or a single dose of 100 mg is given once a week, for up to six months.

6. **Itraconazole**: This triazole antifungal agent, and its principle metabolite hydroxyitraconazole, possesses a broad spectrum of activity against yeast, dermatophytes and other fungi that cause deep fungal infections. Likewise, it is used in the prophylaxis of fungal infections that may be encountered in patients with HIV. Itraconazole is used for onychomycosis of the toenails and onychomycosis of the fingernails caused by dermatophytes. The drug is available in capsule form, each containing 100 mg; solution form in a concentration of 10 mg/ml; and in solution of 10 mg/ml for intravenous injection. The initial dosage of orally administered itraconazole is 200 mg three times daily for three to four days and then 200 - 400 mg daily. It has been suggested that the therapy should be continued for at least three months. The recommended oral dose for treating onychomycosis is 200 mg once daily for 12 consecutive weeks. Another regimen involves the administration of itraconazole capsules in a dosage of 400 mg, once daily for one week each month, for three months. Involvement of the fingernails may require the administration of 200 mg of the drug twice daily during the initial week. This regimen should be repeated during the fifth week. Adverse reactions of itraconazole include nausea, vomiting, skin rash, headache, dizziness, hypertension, hepatic function abnormalities and hypokalemia.

7. **Terbinafine Hydrochloride** is an allylamine antifungal agent that acts by interfering with sterol biosynthesis by inhibiting the enzyme squalene monooxygenase. Depending upon its concentration, the drug can act as fungicidal or fungistatic. It is assumed that terbinafine acts as a fungicidal against the dermatophytes *Trichophyton*, *Epidermophyton*, and *Microsporum*. However, it may act as a fungicidal or fungistatic against yeast. It is also effective against fungi that cause systemic fungal infections. Terbinafine is used orally in treating onychomycosis. Treatment is usually effective, but prolonged, and it may require several months to cure the infection. The drug is distributed well in the stratum corneum, sebum, hair, and various parts of the nail. The ability of terbinafine

to reach high concentration in these parts of the skin is due to its highly lipophilic and keratophilic properties. The drug is capable of persisting in these tissues for weeks or months after cessation of treatment. The dose used in treating onychomycosis of the fingernail is 250 mg daily for a six-week course; and for toenail involvement the dose is 250 mg daily for up to 12 weeks. Due to potential for hepatotoxicity, liver function tests should be conducted in patients receiving terbinafine for more than six weeks. Unfavorable liver function tests should warrant discontinuation of therapy.

8. **Undecylenic Acid and its Salts** such as calcium undecylenate and zinc undecylenate are used topically in the treatment of Tinea pedis, Tinea cruris, and Tinea corporis. It is not effective in treating onychomycosis (tinea unguinum). It is available in concentrations of 10 - 25%. Zinc undecylenate is frequently used in combination with undecylenic acid because it enhances the fungistatic activity of the acid, and the zinc ion provides astringent activity to the product. The combination is most effective in acid pH, and is usually applied as an ointment, diluted solution, dusting powder, or powder aerosol. The diluted solution may cause a stinging sensation, especially to broken skin because of the presence of isopropyl alcohol. Other dosage forms are nonirritating and rarely cause sensitivity reactions. Dusting powder has the advantage of containing talc. This acts as an absorbent for moisture and wetness. These preparations should be applied twice daily after the affected area is cleansed and dried. Improvement should occur within two to four weeks. If infection persists, treatment should be reevaluated.

CONCLUSION

Fungi are formed in practically all environments. A limited number cause systemic and cutaneous diseases. Cutaneous fungal infections are common occurrences and may affect most individuals at least once in a lifetime. These conditions are treatable with topical and/or systemic antifungal preparations. Positive results may be achieved following self-treatment with OTC medications. It should be kept in mind that when using these drugs, patients should follow the instructions as well as the warnings and precautions stated on the label.

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	Poor			Average			Excellent
1. Relevance of topic to practice.	1	2	3	4	5	6	7
2. Author's ability to communicate.	1	2	3	4	5	6	7
3. Author's knowledge of topic.	1	2	3	4	5	6	7
4. Appropriateness of topic.	1	2	3	4	5	6	7

5. Do you have any further comments about this lesson? _____

_____

Please Select the Most Correct Answer

1. The epidermis:
   A. Contains sebaceous glands
   B. Has a vast network of nerves
   C. Is covered by keratin
   D. Is composed of only one layer
2. Fungi:
   A. Invade dead tissue as keratin
   B. Only cause cutaneous infections
   C. Are capable of synthesizing food
   D. Are always infectious to humans
3. Athlete's foot is also known as:
   A. Tinea unguinum
   B. Pityriasis tinea versicolor
   C. Tinea cruris
   D. Tinea pedis
4. Tinea cruris:
   A. Appears as a single or multiple erythematous patch having a circular appearance with finely vesicular borders
   B. Is transmitted only via sexual contact
   C. Does not cause itching
   D. Occurs only in males
5. Fluconazole is used:
   A. To boost patient's immune system against bacterial and fungal infections
   B. As a single oral dose of 50 mg once every six months for treating vulvovaginal candidiasis
   C. Primarily as a bacteriostatic agent
   D. In the active and prophylactic treatment of systemic candidiasis
6. The mechanism of action of clotrimazole is thought to be:
   A. Blocking protein synthesis
   B. Its ability to alter permeability of the cell membrane of fungi
   C. Increasing pH of the skin
   D. Blocks synthesis of para benzoic acid
7. Which of these is a side effect of systemically administered ketoconazole?
   A. Bronchial spasm
   B. Immunosuppression
   C. A reversible hepatotoxicity
   D. Hypotension
8. Tinea unguinum:
   A. Is characterized by severe itching
   B. Is resistant to topical treatment, but responds better to a systemic one
   C. Is another term for jock itch
   D. Always occurs as an acute inflammation
9. Onychomycosis is best treated by:
   A. Topical use of undecylenic acid
   B. Oral use of itraconazole
   C. Topical use of clomitrazole
   D. Topical application of econazole
10. The ability of oral terbinafine to reach high concentrations in stratum corneum, hair, and sebum is due to:
    A. Lipophilic and keratophilic properties
    B. Adequate blood supplies in the area
    C. Its neutral pH
    D. Its keratolytic property

Contributing Author
Farid Sadik, PhD, Dean
Univ.of South Carolina
College of Pharmacy
Columbia, SC

Executive Editor
William J. Feinberg,
BS Pharm, MBA

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