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Review Article

Econazole: Advances in Pharmacology, Formulation Strategies, And Clinical Applications

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Abstract

Fungal infections remain a major global health concern, affecting millions of individuals annually, particularly in tropical and subtropical regions. Superficial mycoses such as dermatophytosis and candidiasis represent a significant burden in developing countries, including India. Among topical antifungal agents, Econazole nitrate has been extensively utilised due to its broad-spectrum antifungal activity, favourable safety profile, and additional antibacterial properties. This review comprehensively discusses the chemistry, pharmacology, mechanism of action, pharmacokinetics, and spectrum of activity of econazole. Furthermore, conventional and advanced formulation approaches—including vesicular systems, nanotechnology-based carriers, and gel-based platforms—are critically analysed. Clinical applications, comparative efficacy, safety considerations, and future research perspectives are also explored. The review highlights the need for innovative drug delivery systems strategies to enhance therapeutic performance and patient compliance.

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1. INTRODUCTION

Worldwide, fungal diseases account for many cases of sickness and deaths from diseases, including but not limited to: HIV/AIDS, cancer, organ transplants, patients taking immunosuppressive and/or high-dose steroid therapy, and using other medications to suppress or destroy their ability to fight infection.[1] Fungal infections in people can be classified into three broad categories: superficial, subcutaneous and systemic.[2] Fungal infections that are classified as superficial occur far more commonly worldwide than either subcutaneous or systemic. It is estimated to be affecting approximately 20% to 25% of the total world population, and the incidence continues to increase.[3] The outermost layers of mucous membranes, hair, nails and skin can be affected by dermatophyte infection, which is often caused by dermatophyte fungi. The taxonomy of the dermatophyte fungi responsible for these infections is unique to geography, so certain species, such as Microsporum canis, Epidermophyton floccosum, T. mentagrophytes var. interdigitale, and Trichophyton rubrum, occur worldwide, while T. rubrum is the most common (dermatophytes) in developed countries and causes more tinea unguium, tinea cruris, tinea corporis, and tinea pedis than any other dermatophyte.[4] With a few exceptions, the tropics and subtropics are where subcutaneous mycoses are most common. These infections are mostly limited to the dermis and subcutaneous tissue, although they can also spread deeper, to the bone, and to the epidermis. Typically, external environmental sources like plants or soil are used to implant organisms. Because of this access point, these diseases are also referred to as the mycoses of implantation. Systemic fungal infections may affect multiple organs and are often initiated in the lungs (aspergillosis and some other mould infections due to inhalation) or from the host's own microbiome (candidemia from infectious lines or drainage from the stomach/intestine). The organisms that cause systemic fungal infections are classified into two groups: those that are opportunistic (e.g., Aspergillus or Candida species) and those that are truly pathogenic (i.e., dimorphic; capable of invading and growing in the normal host's tissues without any identifiable predisposition) infected by one of these two organisms") by the two-in-one infection.[5]

Topical antifungal agents

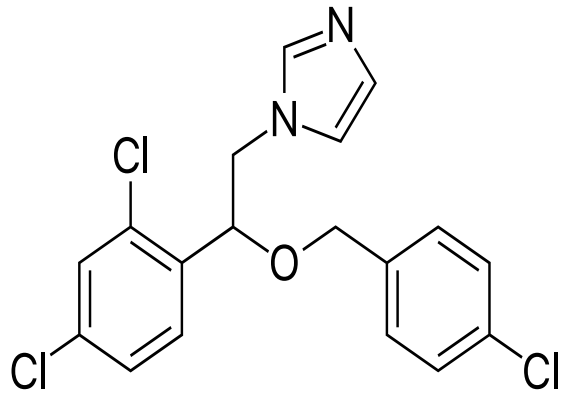
Fungal skin infections are treated with topical antifungals, such as creams, gels and lotions. The major classes of topical antifungal treatments are polyenes, azoles, and the allylamines/benzylamines. Topical antifungal therapies require that a patient self-administer treatment. Patients are likely to comply with this type of treatment since there are no significant systemic side effects, and the effectiveness of the treatment for the treatment of localised fungal infections is high. Systemic treatment over a long period of time may have the potential to cause a patient to encounter drug-drug interactions as well as cause other unwanted systemic side effects; therefore, systemic treatment is especially significant in this case. It is imperative for any topical antifungal product to have specific characteristics in order to be used as a topical treatment for fungal infections of the skin; the most important characteristic is lipophilicity. When the topical medication is applied to the skin, a depot of the medication is formed within the lipidic stratum corneum, and the medication is then slowly released into the dermis and epidermis. [6,7]

Econazole

Econazole, an antifungal imidazole derivative, was created by Janssen Pharmaceutica in 1969 and is used topically to treat dermatophytosis, superficial mycoses like tinea versicolor, and cutaneous candidiasis. Its structure is the same as that of miconazole, but it lacks one chlorine atom on one benzene ring.[8]

Numerous open studies have demonstrated the efficacy of econazole as a treatment for superficial mycoses. Several comparative studies have been conducted between econazole and clotrimazole and some of the more recent azole derivatives since econazole, one of the first antifungal azole derivatives identified, has been utilised in clinical settings for more than ten years. In clinical trials of vaginal candidiasis and several dermatophytic infections, it was shown to be on par with or better than clotrimazole.[9]

Chemistry and Physicochemical Properties

Structure	
IUPAC Name	1-{2-[(4-chlorophenyl) methoxy]-2-(2,4-dichlorophenyl) ethyl}-1H-imidazole.
Molecular Formula	$C_{18}H_{15}Cl_3N_2O$

Molecular Weight	381.7 g/mol
BCS Class	Class II
Half life	4 hours
Log P	5.5
Solubility	very slightly soluble in water, Soluble in methanol, sparingly soluble in chloroform, slightly soluble in ethanol.

Mechanism of action

14-α demethylase is cytochrome P-450 and an enzyme used to convert lanosterol to ergosterol; econazole interacts as it inhibits the synthesis of ergosterol (an important component of the cell membrane), leading to increased permeability of the cells and causing leakage of the contents.[10]

Pharmacokinetics[11]

Absorption

The only human pharmacokinetic research with topical application that has been published. After occlusive (1 patient) or nonocclusive (3 patients) application for 0.5 to 18 hours in 4 patients with dermatoses, approximately 90% of an applied dose (70 to 100 mg) of 1% econazole cream remained on the skin surface; occlusion only marginally increased the overall extent of skin penetration. Two patients received occlusive and non-occlusive applications for 90 and 30 minutes, respectively. In the central part of the dermis, econazole was present at a concentration of roughly 1 g/ml of tissue. considerably greater quantities in the horny layer (over 1000 μg/ml) and the epidermis (between 10 and 100 μg/ml). In one patient, 0.61% of the administered dose of econazole was eliminated in the urine after occlusive application of 70 to 100 mg of 1% radiolabelled cream for 16 hours. everything within 30.5 hours of the application date.

Distribution

Following IV administration to monkeys, econazole was rapidly distributed to body tissues, with only 3.4% of the administered radioactivity remaining in the plasma 1 hour after injection.

Metabolism

Following oral or intravenous administration to monkeys, econazole appears to undergo complex metabolic changes before excretion. More than 20 urinary metabolites have been separated, suggesting that biotransformation in the monkey includes oxidation of the imidazole ring, degradation of the oxidised imidazole ring, deamination and O-dealkylation. The antifungal activity of these metabolites has not been studied.

Excretion

Following a radiolabelled intravenous injection, the monkey's excretion happened somewhat slowly. The elimination half-lives of the two phases were 8.4 and 81 hours, respectively, and the plasma radioactivity was removed in a biexponential fashion. 39% of the radioactivity was eliminated in the urine and 45% in the faeces six days after the injection. 29% and 55% of radioactivity were found in the urine and faeces, respectively, six days after oral dosing.

Toxicity and safety concerns

Acute Toxicity

For 50% of the animals examined, the lethal single oral dose of econazole (LD50) was greater than 160 mg/kg in dogs, 463 to 520 mg/kg in mice, 668 to 920 mg/kg in rats, and 252 to 272 mg/kg in guinea pigs.[12] Larger dosages caused vomiting and/or diarrhoea but no other toxicity symptoms in dogs (200–2000 mg/kg in gelatine capsules and 800–1000 mg/kg in enteric coated capsules) and monkeys (300–2000 mg/kg).

Subacute Toxicity

A daily oral dose of 150 mg/kg caused vomiting and diarrhoea in dogs and monkeys, which resulted in several fatalities. as well as signs of liver damage that were absent at lower dosages (25 or 50 mg/kg). Rabbits receiving daily intravenous administration of 10 to 40 mg/kg for three weeks showed no clearly treatment-related effects; however, monkeys receiving 10 to 30 mg/kg daily for one month experienced intravascular sclerosis and significant soft tissue irritation close to the injection site with both the active drug and its vehicle alone. and CNS activation linked to dosage (ataxia, tremors, seizures), several of these animals at the higher doses experienced persistent diarrhoea, and an autopsy revealed some degenerative liver abnormalities.

Chronic Toxicity

Oral econazole was administered to rats at dosages of 5, 20, and 80 mg/kg per day and to dogs at doses of 2.5, 10, and 40 mg/kg per day during a 6-month-long-term trial. Six days a week.12 All of the rats that received the medication survived, except one that developed an abscess beneath the brain. Serum creatinine levels were slightly elevated in males that received doses of 20 and 80 mg/kg/day, and the livers of four animals that received doses of 80 mg/kg/day showed frequently-scattered vacuolar hepatocytes, although this was also observed in some controls. At a dose of 40 mg/kg/day, there were reversible histological findings in the liver that were not obviously dose related, as well as a decreased body weight in one female, low serum values of total protein, albumin, and cholesterol, and high values of alkaline phosphatase. All dogs survived the test.

Effect on Fertility

In a study of 320 male and female rats, 40 to 160mg/kg/day of oral econazole did not affect male or female fertility as compared with a control group.[12]

Effects on the Foetus

From days 6 through 15 to 18 of pregnancy, neither the fetuses of rats receiving 40 to 160 mg/kg/day nor the fetuses of rabbits getting 40 to 80 mg/kg/day showed any dysmorphogenic effects. However, when using Econazole, food consumption and weight growth decreased. A Review female, which led to a dose-related rise in the proportion of stillborn babies, a lower survival rate (12.5% at 160 mg/kg compared to 85.8% in controls), and weight gain in the progeny.[12] In a therapeutic trial

for vaginal candidosis, 99 newborns whose mothers received a daily 150 mg econazole vaginal suppository for one or two treatment sessions lasting three days each during pregnancy did not have any abnormalities (stage of pregnancy at time of treatment not stated).[13]

Local Toxicity

Econazole was roughly a tenth as active as neomycin in the toluidine blue-heparin dye "kick-off test," which measures allergenic activity; however, in the rat mast cell degranulation test, a "lower" concentration of econazole (0.9 mg/ml) did not cause degranulation, but "higher" concentrations (9 and 18 mg/ml) caused mast cell disruption.[14]

Conventional Formulations:

The econazole is available in several conventional dosage forms:

Topical Cream (1%): The most popular and well-established formulation is this one. To maintain stability and spreadability, it usually comprises econazole nitrate 1% in a water-miscible base with a variety of excipients like mineral oil, pegoxol 7 stearate, and preservatives like benzoic acid. It has been sold under brand names such as Ecoza and Spectazole (since discontinued) in the US.

Topical Foam (1%): Specifically designed to treat interdigital tinea pedis, a more contemporary version is sold under the brand name Ecoza foam. The application and penetration of the foam vehicle in the web gaps between the toes may be advantageous.

Topical Gels: Gelling agents such as Carbopol® 940 have been effectively used in studies to create econazole nitrate gels. Compared to conventional creams or ointments, these formulations have been demonstrated to be clear, homogenous, and appropriate for topical application. They may also offer the benefit of quicker drug release.

Vaginal preparations: These antifungal medications are primarily used to treat vulvovaginal candidiasis (vaginal thrush), a common fungal infection.

Novel Drug Delivery Approaches

Novel technologies in pharmaceutical formulation have played a major role in developing advanced drug delivery systems. Advanced drug delivery systems have been associated with improved efficacy, increased patient compliance, improved pharmacokinetics, and enhanced ability to target treatment areas compared to traditional systems. While they tend to be more expensive than traditional drug delivery systems, they offer tremendous promise as viable alternatives to delivering medications safely and effectively.[15]

Liposomes

Liposomes have been one of the primary known formulations for developing drug delivery technologies due to their established capability to encapsulate drug molecules and enable safe, efficient delivery of drugs. Liposomes performance concerning drug delivery is defined by the liposome's capability to control drug release and target specific cells or tissue(s). They also provide a barrier in the form of protection between the removal/destruction of the drug and thus extend the therapeutic action of the drug.[16,17] The way lipids are chosen has an effect on how drugs are loaded into liposomes. Appropriate phospholipids, along with the correct cholesterol and lipids, must be selected for bilayer formation to be able to withstand high concentrations of drug treatment in liposomes. The reason why phospholipids form a bilayer with stability is due to the amphipathic character of the phospholipid molecule. The two most natural phospholipids used to manufacture liposomes (PC and PE) are able to produce stable bilayers because they can be found in high quantities in both plant and animal sources (egg yolk and soya bean). Along with phospholipids, there are other substances used to produce liposomes and provide additional stability to liposomes, such as cholesterol, glycols (propylene glycol and polyethene glycol) and polymers (chitosan).[18,19]

Niosomes

Niosomes were developed as a new means of drug delivery. They are defined as vesicles that are made of bilayers of a nonionic surfactant and have been used for several years as such.[20] Niosomes can be made by mixing cholesterol and a single alkyl chain nonionic surfactant and then hydrating the resulting mixture with water. An example of this is the preparation of an economic niosome using varying ratios of cholesterol/span 80, which was accomplished using the thin-film hydration method.[21] The drug entrapment efficiency of niosomes is greater than that of liposomes. In addition, unlike niosomes, liposomes need to be stored and handled under a specific set of conditions and are relatively costly as compared to niosomes.[22]

Solid lipid nanoparticles

Solid lipid nanoparticles (SLN) are being considered as a new delivery system for topical cosmetic and pharmaceutical applications. SLNs can prevent chemical breakdown of sensitive compounds, provide controlled release of active ingredients, keep sunscreen ingredients on the skin for extended periods of time, and direct distribution by drug payloads into the upper layers of the skin of the user's body. Recently, SLNs and NLC as nanoparticle delivery systems have been studied as particulate delivery systems for different types of imidazole-type antifungal agents. The high lipophilicity of these drugs makes them good candidates for SLN encapsulation.[23,24,25,26,27,28]

Microemulsion

Microemulsion is an optically isotropic, thermodynamically stable solution made up of a single liquid phase containing small spherical liquid droplets ranging in size from approximately 10nm to 100nm (this size range may vary slightly depending on the authors).[29] Multiple pieces of literature have shown that microemulsions are good candidates for both dermal and transdermal delivery of many different types of drugs. In particular, microemulsions are classified as a promising means of delivering medication to the skin due to

their ability to improve the amount of drug absorbed and/or retained in the skin.[30] The solubility of drugs is increased when using a microemulsion product because of the possibility of including a relatively large percentage of lipophilic/hydrophilic phases into the microemulsion products that would help enhance partitioning from the vehicle to skin for a particular drug via the vehicle, since only the portion of a drug in solution form within the vehicle can penetrate through the skin. Thus, increased permeation of drugs through the skin and retention of drugs in the skin occur because of the action of microemulsions, which allow their components to interact with the stratum corneum's lipid layers.[31.32]

Nano emulsion

Nano-emulsions are clear, isotropic heterogeneous solutions of two immiscible oil and water phases that contain fine particulates in the form of a dispersed phase of nanodroplets containing drug substances, placed into liquid at a ratio of approximately 95% liquid to 5% dispersed. The stability of the nano-emulsion is maintained by an interfacial layer of surfactant and co-surfactants.[33] Compared to traditional emulsions, nano medications offer more stability, greater surface area, and faster absorption into your body's cells after being ingested, which helps to increase their solubility in water and therefore their potential for bioavailability (the rate at which an active ingredient is made available in the bloodstream).[34]

Polymeric micelles

Polymeric micelles are a type of micelle made from block copolymers. Block copolymers contain both hydrophilic and hydrophobic monomers, and the polymeric micelles form through self-assembly at a specific concentration and temperature. Polymeric micelles are commonly used for drug delivery as they possess many desirable characteristics, including: biocompatibility; nanoscale (or small); core-shell structure; morphology; formation of micelles; high stability; and low toxicity.[35] When the critical micelle concentration of amphiphilic block copolymers is exceeded, they can form nanoscopic (10–100 nm) structures known as micelles with a core-shell structure. As a result, an amphiphilic block copolymer's hydrophobic regions create a hydrophobic core (the reservoir for encapsulated drug) and the hydrophilic regions provide a steric barrier to micelle aggregation, leading to increased solubility of the micelles in aqueous environments.[36,37,38]

Clinical Efficacy

Animal studies have demonstrated that econazole has activity against experimental cutaneous candidiasis and dermatophytosis in guinea pigs39, vaginal candidiasis in the rat39, and selected ocular infections caused by fungi in the rabbit40. Econazole was generally more potent than the reference drug tolnaftate against the dermatophytes examined; the MIC for total inhibition of the Microsporum species ranged from 0.1 to 1.0 µg/mL, while the MIC for total inhibition of the Trichophyton species was between 0.01 and 1.0 µg/mL.[11]

Comparison with other antifungal agents

The data showed that both econazole and miconazole had good antifungal activity against C. albicans, with miconazole exhibiting the most activity. Whereas all other antifungal drugs tested were equally effective against non-C. albicans species (i.e., C. tropicalis and C. parapsilosis), miconazole and itraconazole were significantly more effective than both econazole and fluconazole. When analysing the antifungal activity of all four agents against C. tropicalis and C. parapsilosis, the results suggest that itraconazole has the greatest antifungal effect, with only econazole or miconazole being statistically different from itraconazole for these species. The MIC range for econazole, itraconazole, miconazole, and fluconazole is reported as 0.016 to 16, 0.032 to 16, 0.016 to 16 and 0.25 to 64 µg/mL, respectively. [41]

Marketed Products

Name	Dosage	Strength	Route	Labellar
Spectazole	Cream	10mg/1g	Topical	Physicians' Total Care, Inc.
Econazole nitrate topical foam, 1%	Aerosol/foam	10mg/1g	Topical	Xiromed, LLC
Ecoza	Aerosol/foam	10mg/1g	Topical	Glenmark Therapeutics Inc., USA
Econasil	Kit	10mg/1g	Topical	Puretek Corporation
Ecostatin Vaginal Ovule 150mg	Suppository	150mg	Vaginal	Bristol Myers Squibb

CONCLUSION

Econazole nitrate is a well-established and therapeutically effective imidazole antifungal drug for the treatment of superficial fungal infections, particularly dermatophytosis and candidiasis, which continue to be a major global health concern. Its method of action, which involves inhibiting ergosterol manufacture, results in significant antifungal activity as well as extra antibacterial effects. Despite their demonstrated efficacy and favourable safety profile, traditional topical formulations such as creams and lotions have limitations such as inadequate skin penetration, limited retention, and low bioavailability.

The development of sophisticated formulation techniques, including liposomes, niosomes, solid lipid nanoparticles, microemulsions, nanoemulsions, and polymeric micelles, has improved significantly in order to overcome these obstacles. By increasing solubility, skin penetration, controlled drug release, and drug retention at the target site, these innovative drug delivery methods improve therapeutic outcomes. Among these, systems based on nanocarriers show great promise for improving patient compliance, lowering dose frequency, and overcoming drug resistance.

In conclusion, a viable strategy for enhancing topical antifungal therapy is the combination of cutting-edge pharmaceutical technologies with well-known antifungal medications like econazole. To optimise therapeutic advantages and broaden clinical applications, future research should concentrate on large-scale clinical validation, the creation of cost-effective formulations, and the investigation of targeted delivery systems.

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