SỬ DỤNG THUỐC KHÁNG NẤM HỆ THỐNG TRÊN MỘT SỐ ĐỐI TƯỢNG ĐẶC BIỆT

Ths.BS. Hoàng Trung Hiếu

– Khoa Lâm sàng 2

Mở đầu

- Nhiễm nấm da là một tình trạng thường gặp trên LS.
- Sử dụng việc kháng nấm hệ thống trong nhiều trường hợp đặc biệt còn gặp nhiều khó khăn

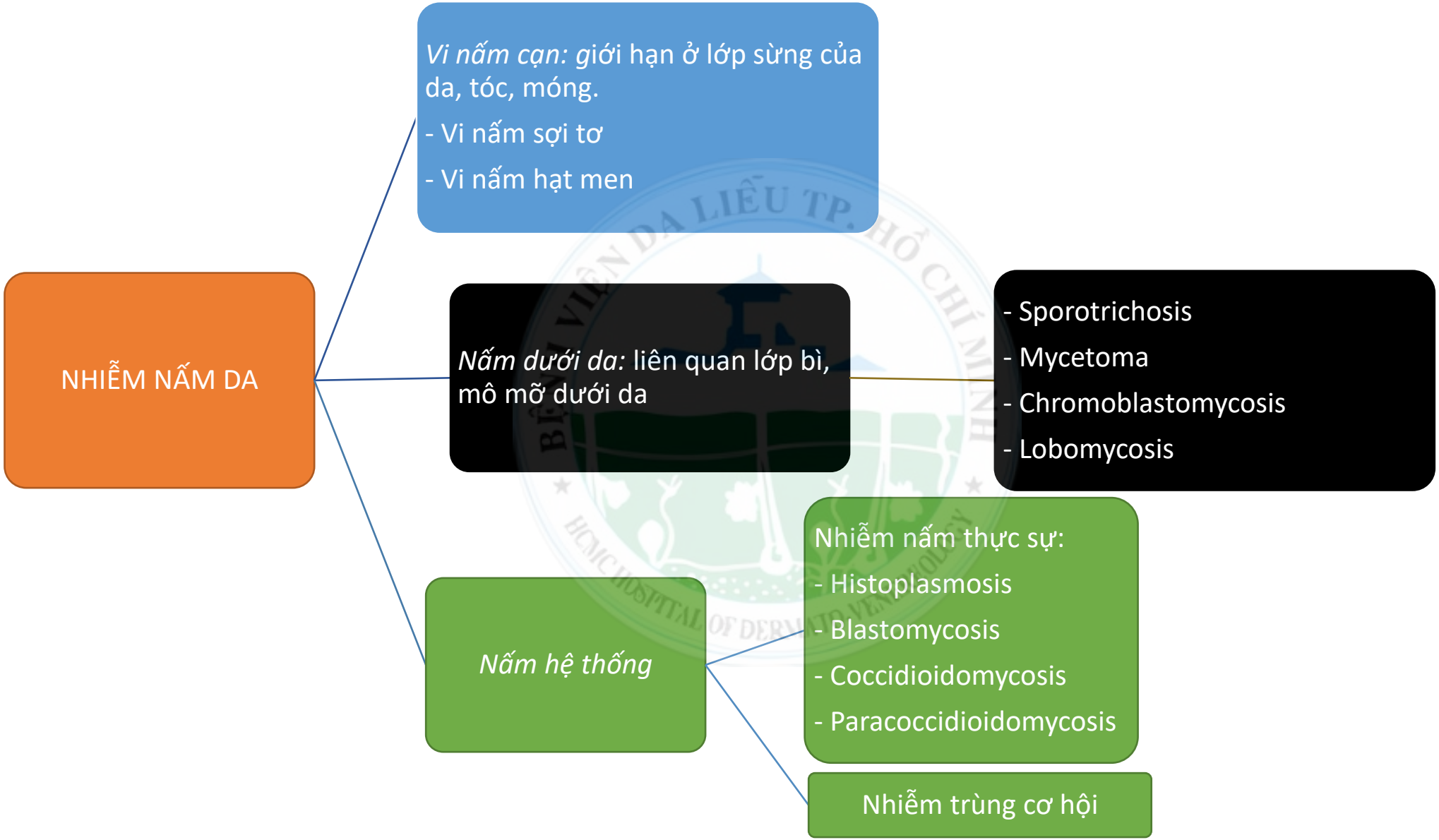
NỘI DUNG

1. Tổng quan nấm da
2. Thuốc kháng nấm
3. Một số lưu ý trên các đối tượng đặc biệt

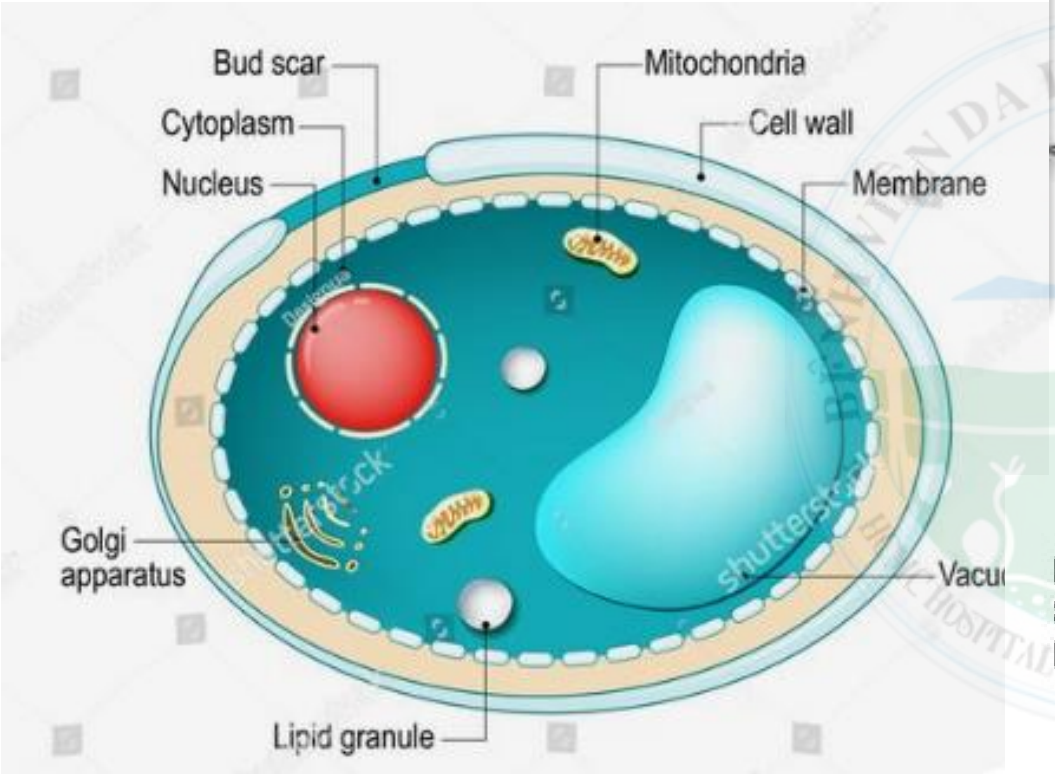
1. Tổng quan nhiễm nấm da

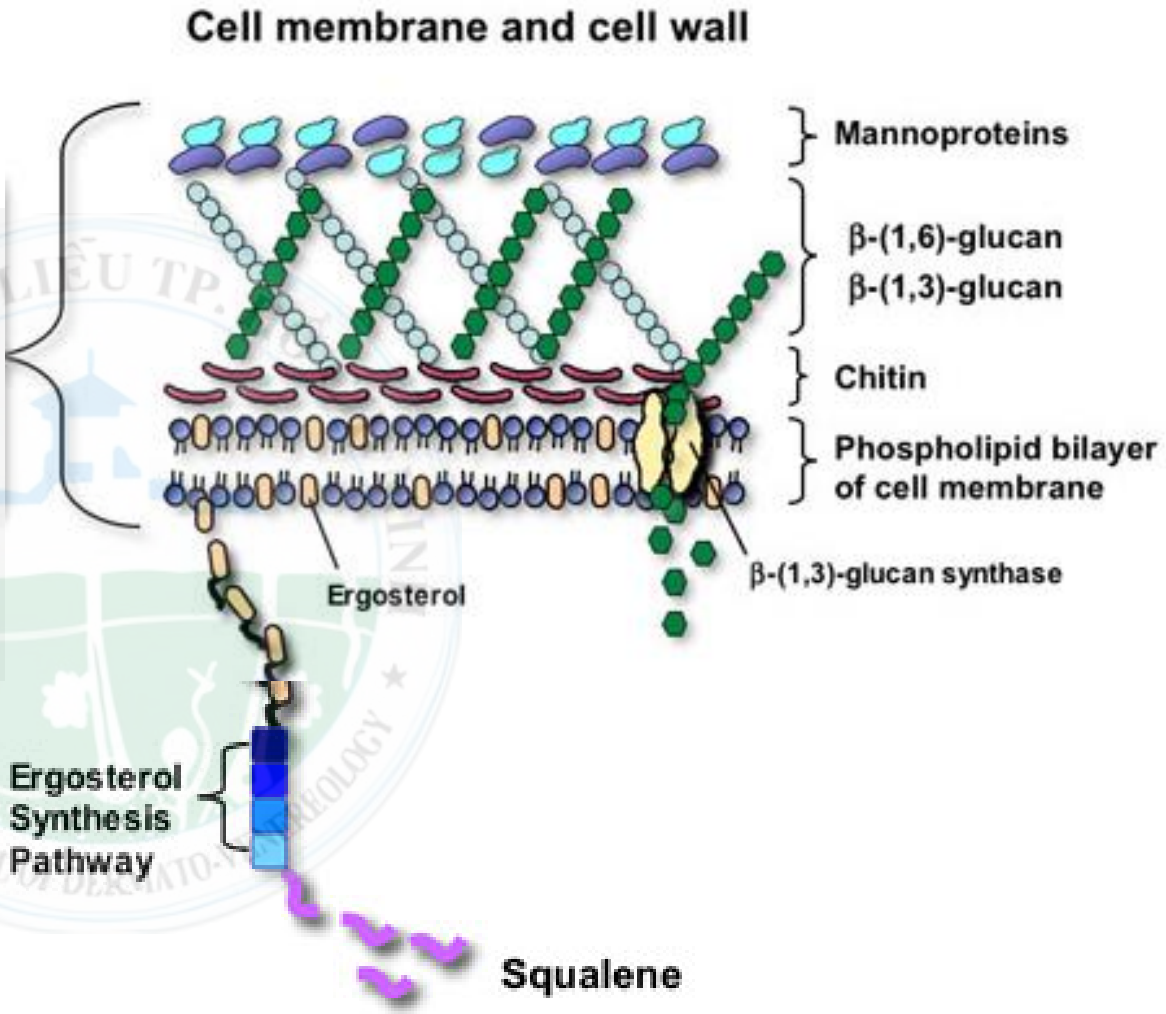
ORGANIZATION OF CUTANEOUS MYCOSES	
Superficial	Involve stratum corneum, hair, or nails
Subcutaneous	Involve dermis or subcutaneous tissue Often due to implantation
Systemic ("deep")	Involve dermis or subcutaneous tissue
"True" pathogens	Skin involvement usually reflects hematogenous spread or extension from underlying structures
Opportunistic	Primary or secondary skin lesions in immunocompromised hosts

Bolognia_4th_edition, "Antimicrobial drugs", Ch127, pp.2229-2239



Fitzpatrick's Dermatology 9th edition, "Antifungals", chapter 188, pp.3436-3449

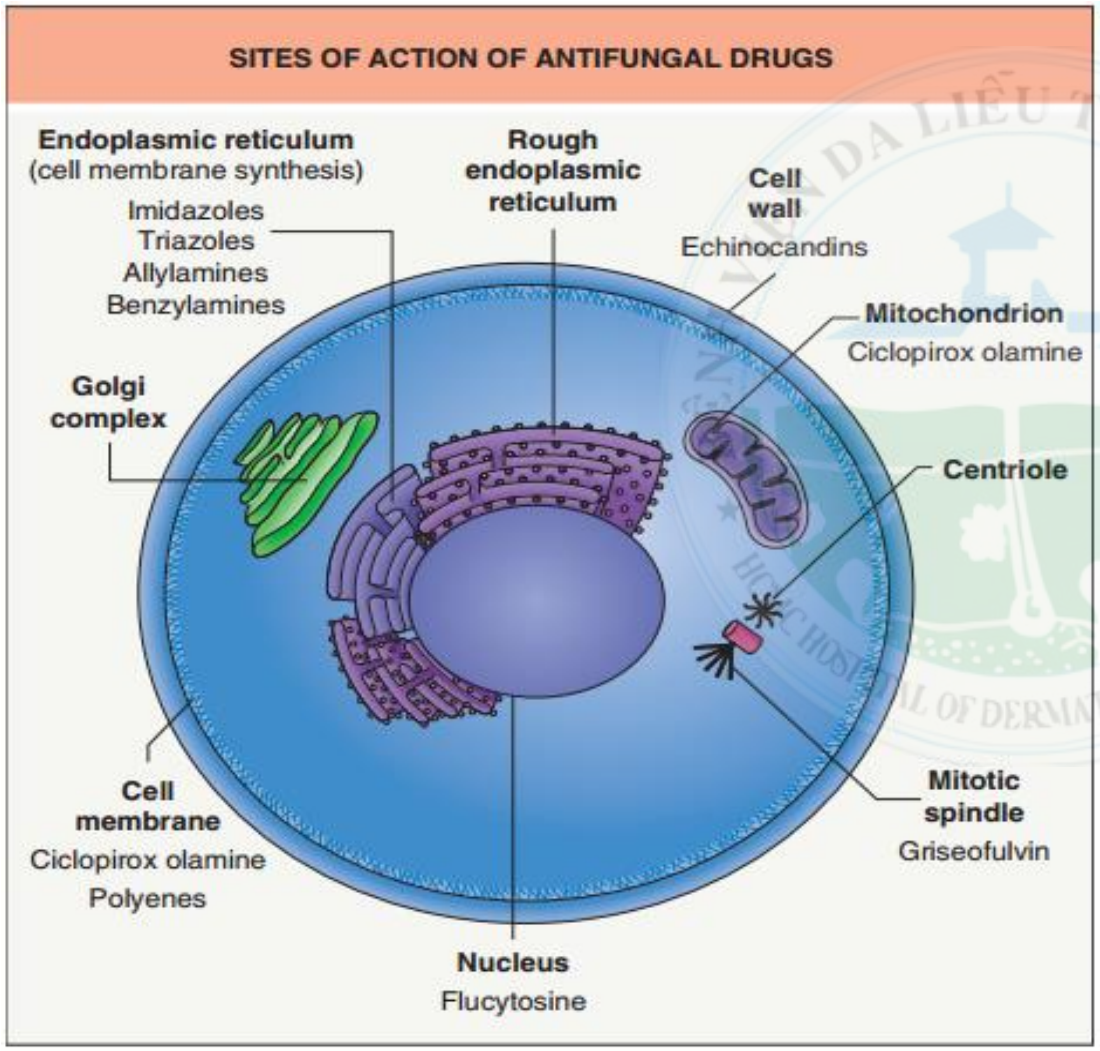




https://id.pinterest.com/pin/613685886707168720/

https://drfungus.org/knowledge-base/antifungal-pharmacology/

2. Thuốc kháng nấm



- 4 đích tác động chính là:
- Màng tế bào
- Thành tế bào
- Tổng hợp DNA/RNA
- Cơ chế khác: vi ống, ti thể,…

Bolognia_4th_edition, “Antimicrobial drugs”, Ch127, pp.2229-2239

Màng tb

- Polyenes
- Azoles
- Allylamine, benzylamine

Thành tb

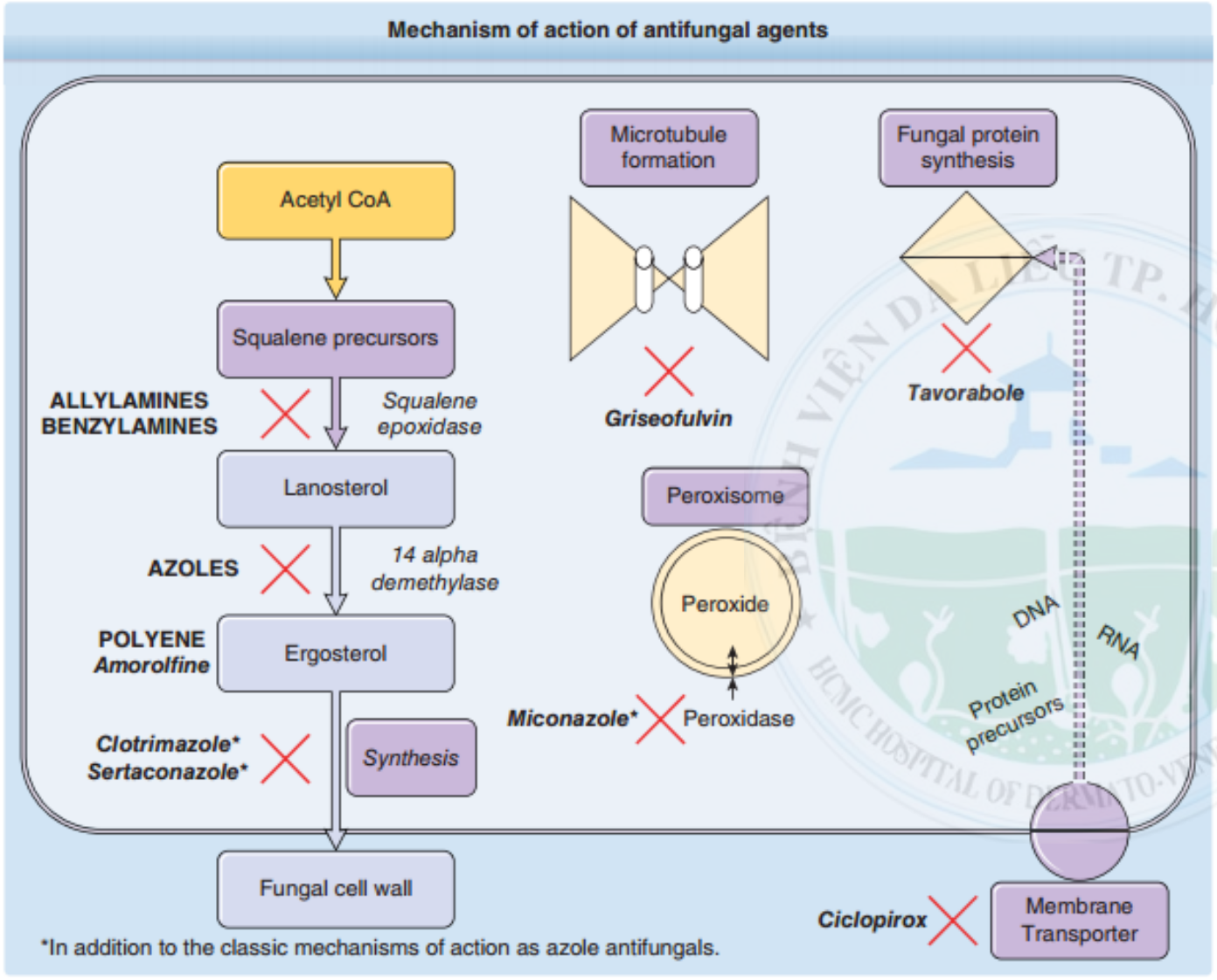
- Ức chế tổng hợp Glucan:
  echinocandins

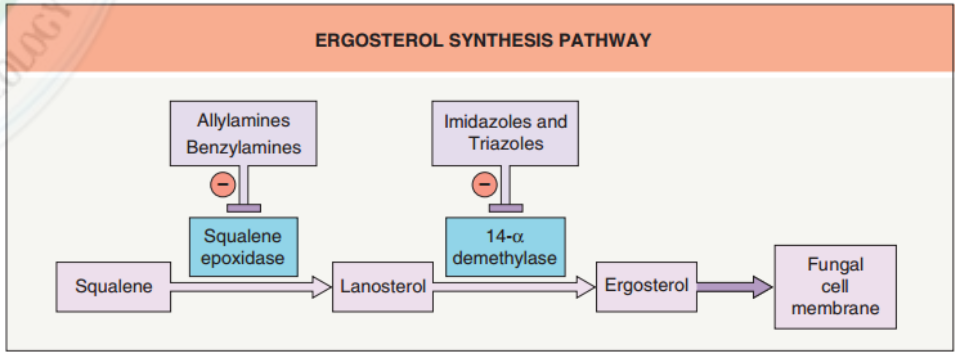
Tổng hợp DNA/RNA

- Flucytosine

Cơ chế khác

- Thoi phân bào: Griseofulvin
- Selenium sulfide
- Ciclopirox olamine

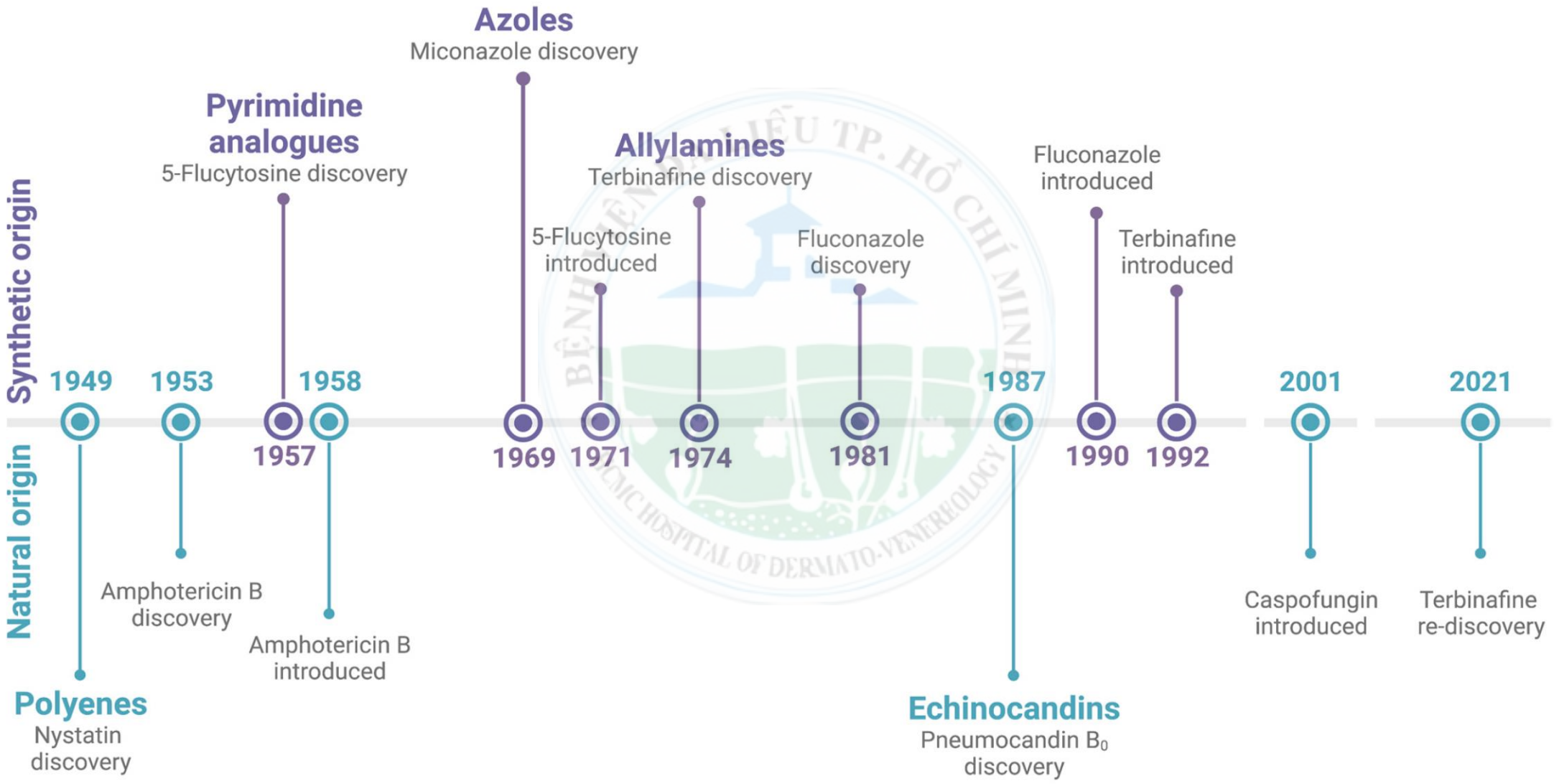




Fitzpatrick's Dermatology 9th edition, "Antifungals", chapter 188, pp.3436-3449

Bolognia_4th_edition, "Antimicrobial drugs", Ch127, pp.2229-2239

Lịch sử ra đời



Chỉ định của các thuốc kháng nấm thường dùng

TABLE 42.2 In Vitro and in Vivo Activity of Common Antifungal Agents

Class	Drug Name	Mechanism of Action	Organisms Treated
Polyene antibiotics	Nystatin	Binds to cell membrane sterols causing cell leakage and permeability changes	Yeast (*Candida*)
Azoles	Miconazole Clotrimazole Ketoconazole Econazole Oxiconazole Sulconazole	Inhibits ergosterol synthesis blocking 14α-demethylation of lanosterol	Dermatophytes, *Malassezia furfur*, *Candida*
Azoles (subset)	Luliconazole Efinaconazole	Same as azoles above	Dermatophytes, *Candida*[a]
Allylamines	Naftifine Terbinafine	Inhibits ergosterol synthesis by blocking action of squalene epoxidase	Dermatophytes (both drugs) *Candida*[b] (only terbinafine)
Benzylamines	Butenafine	Same as allylamines above	Dermatophytes, *Candida*[b]
Oxaborole	Tavaborole	Inhibits protein synthesis by binding to leucyl-tRNA synthetase	Dermatophytes, *Candida*

[a]Activity against *Candida* species is relatively weak compared with the other azole antifungal agents.
[b]Activity against *Candida* species is relatively weak compared with the azole antifungal agents.

Dermatophytes

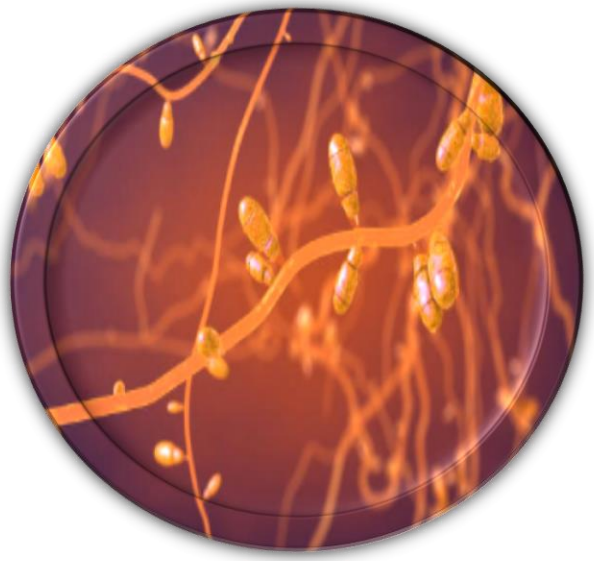


TABLE 42.3 Minimum Inhibitory Concentrations of Antifungal Agents Activity Against Dermatophytes (Mean mg/mL)

Fungus (# of strains)	Terbinafine	Naftifine	Ketoconazole
Trichophyton species (13)	<0.06	0.07	0.21
Microsporum species (6)	<0.06	0.07	0.35
Epidermophyton flocossum (5)	<0.06	<0.06	0.11

Lower minimum inhibitory concentrations indicate stronger inhibition of dermatophytes by allylamines/benzylamines relative to the azole agents.
Data from Shadomy S, Espinel-Ingroff A, Gebhart RJ. In-vitro studies with SF 86-327, a new orally active allylamine derivative. *Sabouraudia*. 1985;23(2):125–132.

TABLE 42.4 Minimum Inhibitory Concentrations of Antifungal Agents Activity Against Dermatophytes (Mean mg/mL)

Fungus (# of strains)	Butenafine	Naftifine	Clotrimazole	Efinaconazole (# strains)
Trichophyton rubrum (41)	0.007	0.031	0.267	0.003 (130)
Trichophyton mentagrophytes (22)	0.012	0.035	0.266	0.005 (129)
Microsporum canis (14)	0.024	0.100	0.266	0.18 (2)

Lower mean inhibitory concentrations indicate stronger inhibition of dermatophytes by allylamines/benzylamines relative to the azole agents.
Data from Maeda T, Takase M, Ishibashi A, et al. Synthesis and antifungal activity of butenafine hydrochloride (KP-363), a new benzylamine antifungal agent. *Yakugaku Zasshi*. 1991;111:126–137.

Q42.5 We can summarize the in vitro antidermatophyte potency as follows:[90,98,106,112,113,118,119,155,156]

butenafine > terbinafine > ciclopirox = naftifine > azoles.

Candidas

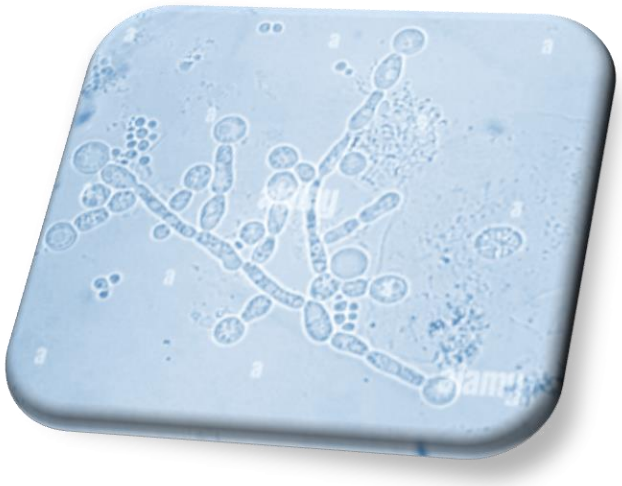


TABLE 42.5 Minimum Inhibitory Concentrations of Antifungal Agents Activity Against *Candida Albicans* (Mean mg/mL)

Study (# of strains)	Butenafine	Terbinafine	Naftifine	Ketoconazole	Clotrimazole
Maeda et al.[118] (57)	3–100	–	3–100	–	0.64
Shadomy et al.[113] (10)	–	128	128	0.51	–
Georgopapadakou and Bertasso[163] (1)	–	8	64	16	–

Lower mean inhibitory concentrations indicate stronger inhibition of *Candida* by azole agents relative to the allylamines/benzylamines.

ciclopirox = azoles > butenafine > naftifine > terbinafine .

Các đối tượng đặc biệt

1. BN Suy gan

2. Trẻ em

3. PNCT

	Terbinafine	Itraconazole	Fluconazole	Griseofulvin
Structure	Allylamine	Triazole	Triazole	Spiro-benzo[*b*]furan
Formulations	Tablet, oral granules	Capsule, oral suspension, IV, tablet	Tablet, oral suspension, IV	Tablet, oral suspension
Peak levels post-dosing	2 hours	3–5 hours	1–2 hours	2-6 hours
Half-life	36 hours (27–30 hours—granules)	21 h (37–40 hours—solution)	30 hours	9-21 hours
Percentage bio-availability	40%[a]—Tablets 36%–64%—Granules	55%	>90%	25-70%
Impact of food	Tablets not affected by food; granules to be sprinkled on food	Capsules: highest levels: full meal or fasted with cola beverage Suspension: take without food	Not affected by food intake	Absorption is significantly enhanced by administration with or after a fatty meal
Protein-binding	>99%	99.8%	11%–12%[b]	84%
Metabolism	Significant first-pass hepatic metabolism; CYP2C9, 1A2, 3A4, 2C8, 2C19 major isozymes; no active metabolites	Extensive metabolism in liver by CYP3A4; active metabolite: hydroxyl-itraconazole	Little first-pass hepatic metabolism, much of dose is excreted as unchanged parent drug	Hepatic, major metabolites are 6-demethyl-griseofulvin and its glucuronide conjugate
Excretion	Renal 70%; clearance decreased 50% in renal impairment or hepatic cirrhosis	Renal 40% inactive metabolites; fecal 3%–18% parent drug	Renal 80% as parent drug, 11% metabolites; 2% feces	Renal 50%, 1% excreted unchanged in urine; 36% in feces

Comprehensive Dermatologic Drug Therapy 4th

Systematic Review of Antifungal-Induced Acute Liver Failure

Eyad Gadour [1] , Ahmed Kotb [2]

1. Gastroenterology and Hepatology, University Hospitals of Morecambe Bay National Health Service (NHS) Foundation Trust, Lancaster, GBR 2. Hepatobiliary Surgery, Glan Clwyd Hospital, Wales, GBR

Gadour E, Kotb A (October 21, 2021) Systematic Review of Antifungal-Induced Acute Liver Failure. Cureus 13(10): e18940. DOI 10.7759/cureus.18940

Study ID/Year	Study design	Country	Sample size(n)	Exposure	Outcome
Rodrıguez et al., 1999 [32]	Cohort study	UK	69,830	Oral antifungals with a background rate of 0.6 per100 000 person-month	Ketoconazole and itraconazole were the two oral antifungals associated with a marked increase of clinical acute liver injury.
Perveze et al., 2006 [33]	Case study	US	1	Oral terbinafine for three months	terbinafine-induced severe liver a case of terbinafine-induced severe liver failure
Paredes et al., 2007 [34]	Case study	US	1	Oral terbinafine for twelve weeks	aspartate aminotransferase (1282 IU/L), alanine aminotransferase (1044 IU/L), and bilirubin (5.9 mg/dL); platelet level decreased to 77 × 103/mm3
Kao et al., 2013 [35]	Cohort study	Taiwan	90,847	Ketoconazole, 12 fluconazole, eight griseofulvin, three itraconazole and two terbinafine	The incidence rates (IR) of DILI per 10k persons 31.6, 4.9, 4.3, 3.6 and 1.6 for fluconazole, ketoconazole, griseofulvin, itraconazole and terbinafine, respectively.
Chan et al., 2014 [36]	Case study	Malaysia	1	34-year-old with elevated liver enzymes due to fluconazole (IV) 200 mg stat followed by IV 100 mg daily.	ALT and total bilirubin level further rose to 2394 U/L and 94 µmol/L on day 6
Gayam et al., 2018 [37]	Case study	US	1	IV fluconazole 200 mg daily	On day 3 AST of 25kIU/L, an ALT of 6.5k IU/L, a GGT of 210 IU/L, alkaline phosphatase of 130 IU/L, a total bilirubin 2.3 mg/ dL, and a direct bilirubin 0.4 mg/ dL

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Abstract

Antifungals are effective antimicrobial agents broadly used in medical practice. Severe acute liver failure from oral or IV administration of antifungals is a rare but long-standing clinical challenge. We aimed to approximate the risk of clinical acute liver injury among users of oral antifungals in the general population. This review was completed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Six articles were included, comprising case reports and cohort studies, after eliminating duplicate publications. No randomized control studies were found. In all studies, the duration of antifungal use was associated with significantly increased liver enzyme levels.

Although it is not very common for patients on antifungals to develop acute liver failure, the prognosis is often good with swift discontinuation of the drug and proper treatment. Liver function evaluation before treatment and periodic monitoring every three to six weeks after commencement of treatment is suggested.

Gadour E, Kotb A (October 21, 2021) Systematic Review of Antifungal-Induced Acute Liver Failure. Cureus 13(10): e18940. DOI 10.7759/cureus.18940

Journal of *Fungi*

MDPI

Review

Pre-Existing Liver Disease and Toxicity of Antifungals

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Abstract: Pre-existing liver disease in patients with invasive fungal infections further complicates their management. Altered pharmacokinetics and tolerance issues of antifungal drugs are important concerns. Adjustment of the dosage of antifungal agents in these cases can be challenging given that current evidence to guide decision-making is limited. This review aims to evaluate the existing evidence related to antifungal treatment in patients with pre-existing liver disease. This article also provides suggestions for dosage adjustment in patients with varying degrees of hepatic impairment, after accounting for established pharmacokinetic and pharmacodynamic relationships with regard to antifungal dru

Table 1. Clinical chemistry criteria for DILI.

Anyone of the Following *:
ALT elevation $\geq 5 \times$ ULN ¶
ALP elevation $\geq 2 \times$ ULN ¶, especially with accompanying elevations in concentrations of 5′-NT or GGT
ALT elevation $\geq 3 \times$ ULN ¶ and simultaneous TB elevation $\geq 2 \times$ ULN ¶

DILI: drug-induced liver injury; ALT: alanine transaminase; ULN: upper limit of normal; AST: aspartate transaminase; ALP: alkaline phosphatase; 5′-NT: 5′-nucleotidase; GGT: γ-glutamyl transpeptidase; TB: total bilirubin. * After other causes have been ruled-out [15]. ¶ In cases of pre-existing abnormal biochemistry before the administration of the implicated drug, ULN is replaced by the mean baseline values obtained prior to drug exposure [15].

Table 2. Antifungal agent dosage adjustment for patients with hepatic impairment.

Antifungal Agent	Severity of Hepatic Impairment by Child–Pugh Score		
	Score 5–6 (Class A)	**Score 7–9 (Class B)**	**Score 10–15 (Class C)**
AmB preparations	No recommendations available		
Flucytosine	No recommendations available, use with caution, TDM recommended Authors' comment: extra caution when combined with AmB preparations		
Fluconazole	No recommendations available, use with caution		
Itraconazole	No recommendations available, strongly discouraged unless benefit exceeds risk, use with caution and under close monitoring, TDM is recommended		
Voriconazole	50% reduction of maintenance dosage and TDM are recommended		No recommendations available, use only if benefit outweighs risk, close monitoring and TDM are recommended Authors' comment: reduction of maintenance dosage to about one-third may be considered
Posaconazole	No dosage adjustment is recommended, TDM when oral suspension is used Authors' comment: TDM may also be considered when tablet or intravenous drug formulation is used		
Isavuconazole	No dosage adjustment is recommended		No recommendations available, use only if benefit outweighs risk
Caspofungin	No dosage adjustment is recommended	Reduced maintenance dose from 50 mg to 35 mg daily Authors' comment: in critically ill patients, reduced dosage may lead to decreased drug exposure	No recommendations available

Các đối tượng đặc biệt

1. BN Suy gan

2. Trẻ em

3. PNCT

TRẺ EM

Table III. Guidelines for use of systemic antifungal agents in tinea capitis

Drugs	FDA indications	Ages approved	Dosing	Duration (wk)	Formulations
Fluconazole	Candidiasis, Candidemia	Approved for systemic candidiasis to preterm infants <29 wk	6-12 mg/kg/dose	3-8	Solution: 10 mg/mL; 40 mg/ Tablet: 50 mg, 100 mg, 150 200 mg
Itraconazole	Candidiasis, Cryptococcus, Histoplasmosis	IDSA recommends for children >5 y	5-10 mg/kg/d	2-6	Capsules: 100 mg; Solution: 10 mg/mL
Griseofulvin	Tinea, onychomycosis	>2 y	15-25 mg/kg/d (micro); 10-15 mg/kg/d (ultramicro)	6-12	Micro solution: 125 mg/5 ml Tablet: 500 mg; Ultramicro tablet: 125 mg, 250 mg
Terbinafine	Tinea, onychomycosis	>4 y	<25 kg: 125 mg daily; 25-35 kg: 187.5 mg daily; >35 kg: 250 mg daily	6	Tablet 250 mg; Granules 125 mg, 187.5 mg

FDA, Food and Drug Administration; *IDSA*, Infectious Disease Society of America.

- Hiện tại chưa có guideline cụ thể cho nhóm tuổi nhỏ 0-2 tuổi

http://dx.doi.org10.1016/j.jpeds.2016.12.042

Box 1: Oral antifungals with their FDA approval status
Griseofulvin - FDA labeled use ≥2 years (dosing <2 years recommendation not established)
Terbinafine - FDA labeled use ≥4 years
Fluconazole - approved for children ≥6 months for oropharyngeal candidiasis
Itraconazole - not licensed for use in children but recommended for use in pediatric onychomycosis by British Association of Dermatologists
FDA - Food and Drug Administration

- Griseofuvin: off-label an toàn từ 1 tháng tuổi (10 mg/kg/ngày).
- Terbinafin: dữ liệu an toàn cho trẻ từ 1 tuổi
- Itraconazole: chứng cứ an toàn cho trẻ từ 3 tuần tuổi.
- Fluconazole: chứng cứ an toàn cho trẻ từ 3 tuần tuổi

Use of Antifungals in Pediatric Superficial Dermatophytosis, DOI: 10.4103/ijpd.IJPD_33_20.
https://www.nhs.uk/medicines/terbinafine/who-can-and-cannot-take-or-use-terbinafine/

Tinea in Tots: Cases and Literature Review of Oral Antifungal Treatment of Tinea Capitis in Children under 2 Years of Age

Table II. Literature review

Authors	Year	Treatment	Pts	Age	Dermatophyte isolated	Treatment duration	Reported adverse effects	Reported recurrence	Country	Study type
Binder et al[10]	2009	Itraconazole 5 mg/kg/d	7	3-46 wk	*M canis*	3-6 wk	None	None	Austria	Prospective
Michaels et al[11]	2012	Griseofulvin 25 mg/kg/d + ciclopirox shampoo	1	32 wk	*T tonsurans*	8 wk	None	None	USA	Case report
Atanasovski et al[9]	2011	Griseofulvin 20 mg/kg/d + ketoconazole shampoo	1	3 wk	*M canis*	3 wk	None	None	USA	Case report
Gilaberte et al[1]	2004	Griseofulvin microsize 15 mg/kg/d	6	3-52 wk	*M canis* (2), *M audouinii** (2), *T verrucosum* (1), *T tonsurans* (1)	6-12 wk	None	Initial failed treated w/fluconazole subsequently achieved cure w/griseofulvin*	Spain	Retrospective
Gilaberte et al[12]	2003	Griseofulvin 15 mg/kg/d + ketoconazole shampoo	1	4 mo	*M audouinii*	8 wk	None	None	Spain	Case report
Chang et al[13]	2002	Itraconazole 25 mg/2.5 mL/d as 3 1-wk pulses w/2-3 w breaks	1	4 wk	*T rubrum*	2 mo	None	None	Korea	Case report
Aste et al[14]	2004	Terbinafine 62.5 mg	1	6 wk	*M canis*	4 wk	None	None	Italy	Case report
Larralde et al[15]	2010	Griseofulvin 20 mg/kg/d, Fluconazole 5 mg/kg/d	2	4-6 wk	*T mentagrophytes*	4-9 wk	None	None	Argentina	Case report
Romano et al[16]	2001	Griseofulvin 10-15 mg/kg/d ultra/micro (13) Terbinafine 52.5 mg/d (2)	15	4-52 wk	*M canis* (9), *T. violaceum* (1), *T tonsurans* (1), *T mentagrophytes* (3), *T erinacei* (1)	2.5-8 wk	None	None	Italy	Case report
Weston et al[17]	1998	Griseofulvin 20 mg/kg/d	1	5 wk	*T tonsurans*	4 wk	None	None	USA	Case report
Ambooken et al[18]	2013	Griseofulvin 10 mg/kg/d ultramicrosize	1	4 wk	*M gypseum*	6 wk	None	None	India	Case report
Zaraa et al[19]	2013	Griseofulvin 15 mg/kg/d	4	6-48 wk	*M canis, T violaceum, T mentagrophytes, T verrucosum*	6-12 wk	None	None	Tunisia	Retrospective
Al-Fouzan et al[120]	1992	Griseofulvin (unknown dosage)	91	20 d-2 y (subgroup)	*M canis, T violaceum*	6-8 wk	None	None	Kuwait	Retrospective
Al-Fouzan et al[127]	1993	Griseofulvin 10 mg/kg/d + topical therapy	30	<2 y	*M canis, T violacium, M audouinii*	4-10 wk	None	None	Kuwait	Prospective
Gondim-Goncalves et al[21]	1992	Griseofulvin 125 mg/d	1	90 d	*M canis*	6 wk	None	None	Brazil	Case report
Koumantaki et al[22]	2001	Itraconazole 50 mg/d for two 1-wk pulses	1	8 mo	*M canis*	6 wk	None	None	Greece	Case report
Koumantaki et al[23]	2001	Terbinafine 125 mg/d 4 wk, then doubled for 4 wk	1	1 year	*M canis*	8 wk	None	None	Greece	Prospective
Ungar et al[24]	1997	Griseofulvin 15 mg/kg/d	1	19 d	*T rubrum* and *T mentagrophytes*	4 wk	None	None	USA	Case report
Valari et al[25]	2006	Fluconazole 6 mg/kg/d	1	3 mo	*T rubrum*	3 wk	None	None	Greece	Case report
Wilmer and Wollina[26]	1998	Griseofulvin 10 mg/kg/d, Terbinafine 62.5 mg/d	1	10 mo	*T mentagrophytes*	4 wk Griseofulvin, Terbinafine 4 wk	None	Failed griseofulvin, cure post terbinafine	Germany	Case report

- Tổng 168 cases, trong đó 121 trẻ từ 0-12th.
- Sử dụng cả 4 loại kháng nấm uống.
- Tất cả trẻ đều đáp ứng tốt và không ghi nhận tác dụng phụ đáng kể

http://dx.doi.org10.1016/j.jpeds.2016.12.042

Các đối tượng đặc biệt

1. BN Suy gan

2. Trẻ em

3. PNCT

Table 1 US FDA categorization of common oral and topical antifungals

FDA categories	Oral agents	Topical agents
A Controlled studies of women failed to demonstrate a risk to the fetus in the first trimester, and the possibility of fetal harm appears remote		Nystatin
B Either animal studies do not indicate a risk to the fetus and there have been no controlled studies in pregnant women, or animal studies have indicated fetal risk but controlled studies of pregnant women failed to demonstrate a risk	Terbinafine	Clotrimazole Terbinafine Ciclopirox Naftifine Oxiconazole
C Either animal studies indicate a fetal risk and there have been no controlled studies of women, or there are no available reports of studies of women or animals	Ketoconazole Fluconazole low-dose regimen (150 mg/day) Itraconazole Griseofulvin	Econazole Miconazole Ketoconazole Selenium sulfide
D There is positive evidence of fetal risk, but there may be certain situations where the benefit may outweigh the risk (e.g., life-threatening or serious diseases for which other drugs are ineffective or carry a greater risk)	Fluconazole high-dose regimen (400–600 mg/day) Voriconazole	
X There is definite fetal risk, according to studies of animals or humans or on the basis of human experience, and the risk clearly outweighs any benefit in pregnant women	–	–

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Một vài lưu ý khác

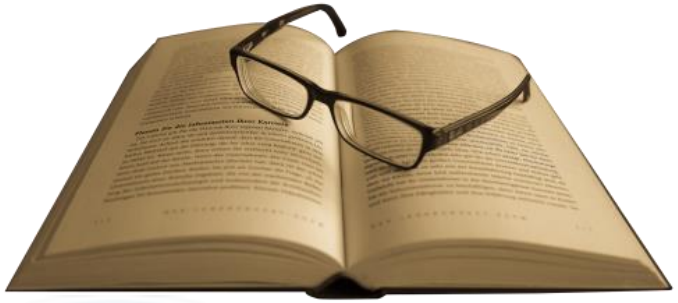
- Tính kháng viêm: 1 vài thuốc kháng nấm bôi được chứng minh có hiệu quả kháng viêm, có lợi trong nấm da do Dermatophyte, hay các bệnh da viêm khác: *Azoles, Allylamine/benzylamine, Ciclopirox olamine.* Trong nhóm azole có bifonazole và **Ketoconazole** có tính kháng viêm mạnh hơn cả (ngang bằng *Hydrocortisone 1%*), nên được dùng nhiều trong viêm da tiết bã.
- Tính kháng khuẩn: Azoles (Clotrimazole, econazole, miconazole, oxiconazole, sertaconazole), terbinafine có thể kháng 1 số vi khuẩn gram (+) và gram (-)

Propylene Glycol-Induced Irritancy

- Propylene glycol là 1 thành phần được dùng để tăng tính thấm của một số loại thuốc khi bôi trên da, và có thể như là *"con dao 2 lưỡi"* vì làm tăng nguy cơ kích ứng (và dị ứng) trong tỉ lệ nhỏ BN, đặc biệt khi bôi lên da đang viêm, nứt hay loét.

Generic Name	Trade Name	Cream Contains Propylene Glycol
Nystatin	Various	Yes
Amphotericin B	Various	Yes
Miconazole	Micatin, Monistat-Derm	No
Clotrimazole	Lotrimin, Mycelex	No
Ketoconazole	Nizoral	Yes
Oxiconazole	Oxistat	Yes
Econazole	Spectazole	No
Sulconazole	Exelderm	Yes
Sertaconazole	Ertaczo	No
Luliconazole	Luzu	Yes
Efinaconazole	Jublia	n/a
Naftifine	Naftin	No
Terbinafine	Lamisil	No
Butenafine	Mentax	Yes
Butenafine	Lotrimin Ultra-OTC	Yes
Ciclopirox	Loprox	No
Selenium sulfide	Selsun, Exsel	n/a
Tavaborole	Kerydin	n/a

Tài liệu tham khảo



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THANK
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