

黴特克舒 錠 250 公絲

Fungitech Tablets 250mg

成分：Each Tablet contains：

Terbinafine Hydrochloride.....250mg

賦形劑：

Silicon Dioxide Microns、Starch Potato、Lactose、Pyrrolidinone Polymer、Magnesium Stearate、Calcium Carboxymethyl Cellulose.

臨床藥理：

Terbinafine 是屬於 Allylamine 之衍生物，具廣效抗黴菌作用。對於皮黴菌(Dematophytes)，菌絲黴菌(Moulds)與某些同質二形性黴菌(Dimorphicfungi)，在低濃度即有殺黴菌作用(Fungicidal)。對酵母菌(Yeasts)的作用，則依不同的菌種而有殺黴菌或抑黴菌作用(Fungistatic)。

Terbinafine 可干擾黴菌麥角硬脂醇(Ergosterol)早期之生合成，導致麥角硬脂醇之不足及細胞內積聚很多的 Squalene，然後造成黴菌細胞的死亡。其作用機轉是 Terbinafine 抑制黴菌細胞膜上的 Squalene epoxidase，此酵素(Squalene epoxidase)的作用與細胞色素 P450 系統(Cytochrome P450 System)無關，且 Terbinafine 不會影響荷爾蒙或其他藥物代謝。口服此藥品，藥物會集中皮膚、頭髮與指甲上，可達到殺黴菌作用。

藥物動力學：

口服 250 公絲單一劑量，在 2 小時內可達 0.97 微克/公撮($\mu\text{g/ml}$)的最高血中濃度。其吸收半衰期為 0.8 小時，分佈半衰期為 4.6 小時。

Terbinafine 的生體可利用率不受食物影響。與高脂肪食物併用時，由於吸收比慢，並且有血中最高濃度及曲下面積之關係，其生體利用率可提高 40%，但其劑量不需調整，除非必要時。

Terbinafine 與血漿蛋白結合力很強，可達 99%。它能藉擴散作用穿透真皮層，而集中親脂性的角質層中。Terbinafine 也可分泌於皮脂中，因此在毛囊、頭髮與多皮脂皮膚中可達到相當高的濃度。在治療最初幾個星期後，Terbinafine 也可達到指甲內。生體轉化後的代謝物，不具有抗黴菌作用，它主要是由尿液中排出，其廓清半衰期為 17 小時。Terbinafine 在體內不會有累積作用，其藥物動力學也不受年齡影響。腎功能或肝功能障礙者的藥物廓清率可能降低，而使得血中 Terbinafine 濃度較高。(依 Antimicrob Agents Chemother 1995 Dec;39(12):2738-41. 與 Clin Exp Dermatol. 1989 Mar;14(2): 110-3.文獻刊載)

適應症：

甲癬(Onychomycosis)、髮癬(Tinea capitis)，嚴重且廣泛且經局部

治療無效的皮膚黴菌感染。

在試管內最小抑制濃度：

易感受的菌種	微克/毫升
深紅色髮癬菌	0.003-0.006
鬚瘡小芽胞癬菌	0.003-0.01
禿髮癬菌	0.003
疣髮癬菌	0.003
Schonleinii 氏髮癬菌	0.006

大小芽胞菌	0.006-0.01
花斑小芽胞菌	0.003
糠疹小芽胞菌	0.006
絮狀表皮癬菌	0.003-0.006
中度感受的菌種	
煙煙色麴菌	0.1-1.56
申克氏孢子絲菌	0.1-0.4
白色念珠菌	
酵母菌型	25.0-100
菌絲型	0.23-0.7
Parapsilosis 念珠菌	0.8-3.1
卵圓皮屑芽胞菌	0.2-0.8
環狀皮屑芽胞菌	0.8
從動物實驗中顯示，口服 Terbinafine 後，藥物集中在皮膚，頭髮及指甲上可達殺黴菌作用。	

用法用量：

成人：一天一次 250 毫克

兒童：小孩超過 3 歲以上

體重<20 公斤	62.5 毫克一天一次
體重 20~40 公斤	125 毫克一天一次
體重>40 公斤	250 毫克一天一次

在 3 歲以下的小孩，沒有足夠資料顯示可以使用。治療時間是依感染型態及嚴重度而定。

治療時間：

皮膚感染：

足癬(趾間性，厚皮性) 2~6 星期

體癬、股癬 2~4 星期

皮膚念珠菌感染 2~4 星期

頭皮、毛髮的感染：

髮癬：4 星期。髮癬主要發生於小孩身上。

灰指甲(甲癬)：大部份的病人須使用 6~12 星期的治療療程。

指甲甲癬：大部份需要 6 星期

腳指甲甲癬：大部份需要 12 星期

有些病人其指甲長得慢，則需更長的時間，最理想的臨床效果會在停藥後及細菌培養檢查為陰性後的幾個月才看到，這是與健康指甲生長的時間有關。

特別劑量資訊：

老年人：

沒有證據顯示老年人的劑量需不同於年輕病人的劑量，但老年人要服用 Terbinafine 時，必須考慮到原先已有腎或肝功能障礙的情況。

肝或腎功能障礙者：

穩定且慢性肝或腎功能異常的病人(肌胺酸酐廓清率小於 50 公撮/分鐘或血清肌胺酸酐大於 300 微莫耳/公升)，應使用建議劑量的一半。此類病人並應在用藥前後追蹤檢查其肝功能。

禁忌：對 Terbinafine 過敏者。

使用上之限制：

注意：

肝或腎功能障礙者，口服 Fungitech 須只使用在外用治療無法使用時，3 歲以下的小孩，不建議使用，並且也沒有經驗。

懷孕與授乳者：

胎兒毒性與受精率的動物實驗，顯示無此不良作用。懷孕者使用黴特克舒的經驗很少，建議懷孕婦女不要使用，除非使用黴特克舒可能的好處大於可能的危險性。Terbinafine 可出現在乳汁中，口服使用黴特克舒者不可授乳。

其他：

沒有特別的症狀，像一般不舒服，頭痛，偶而有報導過，有發現幾個病例是味覺喪失(發生率為 0.125%在臨床實驗中)，當停藥後，就恢復正常，也有幾個個案是肝炎及膽汁鬱滯性的肝功能異常。對已存在的慢性但穩定的肝功能異常者，如使用 Fungitech 時，有更進一步惡化或明顯障礙的症狀時，Fungitech 應該停止使用。對嗜中性白血球減少症也有少數個案。

藥物過量：

至今無藥物過量之病例報告，急性口服藥物過量的主要徵候是腸胃症狀，例如噁心或嘔吐，可以洗胃或解除症狀的支持性療法來治療。

注意事項：

Terbinafine 用於嚴重且廣泛並經局部外用治療無效的皮膚黴菌感染時，限由皮膚科專科醫師處方使用。

口服 Terbinafine 須只用在外用治療無法使用時。

當病人有懷疑因下列症狀如無理由的噁心、食慾缺乏、疲倦而肝功能異常時，則須做肝功能檢查。如果病人檢查出為肝功能不正常時或病人有明顯症候例如：黃疸、茶尿、大便顏色蒼白時，則立刻停止使用本藥品。患者服用藥物超過六週時，建議檢測肝功能檢查。

相互作用：

根據人體外與健康受試者實驗結果，Terbinafine 對經由細胞色素 P450 代謝的藥品(如 Cyclosporin，口服避孕與 Tolbutamide)，對其廓清率的影響微乎其微。Terbinafine 的血漿廓清率可被促進代謝之藥物(如 Rifampicin)提高，而抑制細胞色素 P450 藥物(如 Cimetidine)則可降低 Terbinafine 的廓清率。Terbinafine 與上述二類藥物併用時，應調整其劑量。

副作用：

頻率的估測：非常普通 $\geq 10\%$ ，普通 $\geq 1\%$ 到 $<10\%$ ，不常見 $\geq 0.1\%$ 到 $<1\%$ ，稀少 $\geq 0.01\%$ 到 $<0.1\%$ ，非常稀少 $\geq 0.001\%$ 到 $<0.01\%$ 。基本上 Terbinafine 的耐受性良好，副作用是輕度至中度的，且是暫時性的。

非常普通的副作用：胃腸方面，例如飽脹、噁心、消化不良、輕度腹痛、腹瀉、沒有胃口，及不是很嚴重的皮膚反應，例如：紅疹與蕁麻疹。肌肉與骨骼的反應(關節痛、肌痛)。

不常見的副作用：味覺障礙(含味覺喪失)，通常停止使用本藥品數星期後即可恢復。

稀少的副作用：曾有報告指出使用 Terbinafine，有肝膽障礙(本質上主為膽汁鬱滯)，包含非常稀少的肝臟衰竭個案。

非常稀少的副作用：嚴重的皮膚變化(例如：Stevens-Johnson 症候群，皮膚毒性壞死)及過敏反應等都曾報告過。如果皮膚反應有漸進式發展，則應該停止使用本藥品。血液方面障礙，例如嗜中性白血球減少症，顆粒性白血球缺乏症，血小板減少症。曾有掉頭髮的報告，但進一步的原因，還不明確。

儲存：25°C 以下避光、陰涼、乾燥及小孩接觸不到之處所貯存，

避免吸潮。

包裝：2~1000 錠鋁箔盒裝、塑膠瓶裝

衛署藥製字第 045950 號

G-8144 號



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Fungitech Tablets 250mg

Composition : Each Tablet contains :

Terbinafine Hydrochloride.....250mg

Other ingredients :

Silicon Dioxide Microns 、 Starch Potato 、 Lactose 、 Pyrrolidinone Polymer 、
Magnesium Stearate 、 Calcium Carboxymethyl Cellulose.

Clinical Pharmacology :

Terbinafine belongs to Allyamine derivatives, with extensive effects for antifungus. Terbinafine possesses fungicidal to Dermatophytes 、 Moulds and some other alike nature of Dimorphic fungus, even if low condensation. The fungicidal or fungistatic effects to yeasts are different from the fungus.

Terbinafine will interfere with the early phases compound of fungus Ergosterol, leads to insufficient of Ergosterol and builds up plenty of Squalene in cell, causes the death of fungus cell. The mechanism is Terbinafine restrains the Squalene epoxidase of fungus cell membrane, it is unconcerned with the effects of the enzyme(Squalene Epoxidase) and Cytochrome P450 System, Terbinafine also would not influence the metabolism of Hormone and other medicines. Take Fungitech Tablet orally, the medicine act is centralized on skin 、 hair and nail to reach the effect of Fungicidal.

Pharmaceutical dynamics :

Take 250mg simplex dosage orally, will reach 0.97 μ g/ml highest concentration in the blood within 2 hours. The assimilation half- life is 0.8 hour, the distribution half-life is 4.6 hours.

The bioavailability of Terbinafine is independent of food. Taking together with high fat food, the bioavailability can be increased 40%, owing to the absorbency is relative low, the highest concentration in the blood and curved superficial contents. But the dosage adjustment is not needed, unless it is necessary.

Terbinafine can be strongly integrated with plasma protein, to reach a figure of 99%. It can pass through inner skin cortex by diffusion effect, and centralize into greasephile cuticle. Terbinafine also excretes in sebum, therefore, it can reach a relatively high concentration in follicle 、 hair and multisebum derma. After few weeks of initial treatment stage, Terbinafine can also reach to nail.

The metabolite of bio-converting, does not possesses antifungal effects, it is mainly emitted from urine, its clean up half-life is 17 hours. Terbinafine does not have summation in the body. The pharmaceutical dynamics is not connected with age. The pharmaceutical clean up rate may be lower for the patient who has kidney or liver dysfunction, which causes the Terbinafine concentration in the blood is comparative high.

(Ref :

1.Antimicrob Agents Chemother. 1995 Dec;39(12):2738-41

2.Clin Exp Dermatol. 1989 Mar;14(2):110-3.)

Indications :

Onychomycosis 、Tinea capitis, derma fungal infection which is severe, extensive and partly treated in vain.

The lowest restrain concentration in the test tube:

Susceptible fungus	μg/ml
Garnet tinea capitis	0.003-0.006
Sycosis microsporum canis	0.003-0.01
Trichophyton tonsurans	0.003
Trichophyton wart	0.003
Schonleiniitinea tinea capitis	0.006

Macrospore and microsporum canis 0.006-0.01

Versicolor Pityriasis microsporum canis 0.003

Pityriasis microsporum canis 0.006

Flocculent epidermophyton 0.003-0.006

Medium susceptible fungus.

Smudgei asporgillus 0.1-1.56

Sporothrix Schenckii 0.1-0.4

Candida albicans

Yeasts 25.0-100

Hypha 0.23-0.7

Parapsilosis candida 0.8-3.1

Pityrosporum orbiculare 0.2-0.8

Pityrosporum annular 0.8

Animal experiments show the after taking Terbinafine oral tablet the medicine act is centralized on skin 、hair and nail to reach the effect of Fungicidal.

Dosage & administration :

Adult : 250mg once a day

children : above 3 years old

weight<20KG 62.5mg once a day

weight20~40KG 125mg once a day

weight>40KG 250mg once a day

No sufficient information shows Terbinafine can be used on the children under 3years old. The treatment duration depends on the infection mold and the serious condition.

Treatment duration :

Cutaneous infection :

Feet tinea(between the toes, pachyderm) 2~6weeks

Ringworm of the body 、tinea cruris 2~4weeks

Cutaneous candida infection 2~4weeks

Infections of scalp 、hair :

Tinea capitis : 4weeks.Tinea capitis occurs mostly on children.

Onychomycosis : most patients need a 6~12weeks period of treatment.

Fingernail onychomycosis : most patients need 6 weeks.

Toenail onychomycosis : most patients need 12 weeks.

For the patients whose nail growth rate is slow, a longer period may be needed.

Desirable clinical result will be seen several months after stopping medication and the germiculture test result is negative, this is related to the growth time for healthy nail.

Particular dosage information :

Elderly people :

There is no evidence demonstrates that the dosage for the elderly should be different from the young patients'. However, the elderly patients should consider the original condition of kidney or liver dysfunction before taking Terbinafine.

Patients with liver or kidney dysfunction :

Patients with stable and chronic liver or kidney dysfunction

(Creatinine clean up rate smaller than 50ml/min. or Serum Creatinine greater than 300μmol/l) may take the half dosage of the recommendation.

These patients should trace the liver function before and after taking the Terbeinafine.

Contraindiction : allergy toTerbinafine.

Restrictions while using this medicine :

Warnings :

For liver and kidney dysfunction patients, Fungitech oral tablets can only be used when external treatment is incapable. Children under 3 years old are not recommended, there is also no therapy experience for children under 3years old.

Pregnancy and breast-feeding :

Animal tests for fetus toxicity and fertility rate reveal that there are no harmful effects. Pregnant women are not recommended to use Fungitech Tablets for there are few therapy experiences for pregnant women, unless the possible advantages are greater than the possible danger. Terbinafine may appear in breast milk, patients should not take Fungitech while breast-feeding.

others :

No special symptom, but ordinary uncomfortable 、 headache

Cases have been announced occasionally. Several cases of losing the sense of taste are disclosed (in clinical experiments, the occurrence rate is 0.125%), after stopping the medication, return to normal, there are also several cases of liver dysfunction of hepatitis and cholestasis. For liver dysfunction patients who are being chronic but steady, while taking Fungitech, further worse or obvious obstacle conditions happen, should stop using Fungitech.

There are also few cases regarding neutropenia.

Overdose :

So far, there is no case report for overdose. The main symptom for acute oral overdose is gastrointestinal symptom, such as nausea or vomiting, it can be remedied by the way of gastric lavage or supportive therapy of relieving the condition.

Notes :

Using Terbinafine for partial external remedy in vain on severe and extensive dermatophytes infection, dermatologist prescription only. Oral Terbinafine should only use when external remedy is incapable. When patient occurs the following symptoms, ought to examine liver function. Such as unreasonable nausea 、 loss of appetite 、 unusual tiredness or weakness with liver malfunction. In case abnormal is found for the patient's liver function or obvious signs such as icterus 、 dark urine 、 pale stools, should stop use this medicine immediately. If patients take this medicine over six weeks, liver function examination is advised.

Interaction :

According to the experiments on external use and healthy testers reveal that Terbinafine has extremely trifling influence on those drugs clean up rate which the metabolism is via cytochrome P450 (such as Cyclosporin 、 oral contraceptive 、 and Tobutamide). Metabolism accelerator (such as Rifampicin) may raise the plasma clean up rate of Terbinafine, and the drugs with restraining cytochrome P450 (such as Cimetidine) may lower the clean up rate of Terbinafine. While take Terbinafine together with the above two medications, adjust the dosage is suggested.

Side effect :

Frequency evaluation : very common $\geq 10\%$, common $\geq 1\% \sim < 10\%$, less common $\geq 0.1\% \sim < 1\%$, rare $\geq 0.01\% \sim < 0.1\%$, extraordinary rare $0.001\% \sim < 0.01\%$. Basically, the duration of Terbinafine is fine. Side effect is minor to medium and temporality.

Very common : gastrointestinal pain, such as tympanites 、 nausea 、 indigestion 、 minor stomachache 、 diarrhea 、 loss of appetite, and not serious skin reaction, such as : red rash and hives; muscles and bones pain (aching joints and muscles)

Less common : changes in taste(including loss of taste), normally it can be recovered after stopping this medicine few weeks later.

Rare : there are reports indicates that liver and gall problems (virtually mainly in cholestasis) may occur after using Terbinafine, including extraordinary rare liver exhaustion case.

Extraordinary rare : cases regarding serious skin changes (such as : Stevens-Johnson symptoms, skin toxicity necrosis) and allergic reactions etc. have been reported. In case there is gradual progress developing on skin reaction, ought to stop using this medicine.

Blood obstacle, such as neutropenia 、 agranulocytosis 、 thrombocytopenia.

Depilation case has been reported, however, the further reason is undefined.

Storage :

Store this medication below 25°C , away from direct light 、 excess heat and moisture, and keep out of reach of children.

Supply : 2~1000 tablets, blisters 、 plastic bottled.