Fluconazole transdermal

Publication info: Adis R&D Insight . (Dec 2, 2015).
ProQuest document link

Full text: DRUG PROFILE - Fluconazole transdermal

Watson Pharmaceuticals (USA) was developing a patch to deliver fluconazole [*topical antifungal nail patch - Watson, fluconazole transdermal patch - Watson, onychomycosis patch - Watson*] directly to the infected nail bed, utilising its proprietary transdermal technology, for the treatment of onychomycosis. However, following a review of clinical data, Watson has decided to discontinue development of this product.

Fluconazole is a synthetic, triazole antifungal that is available as Diflucan ®by Pfizer as tablets, a powder for oral suspension, and as an injection for IV infusions. Although Diflucan ®was officially approved by the US FDA for the treatment of vaginal yeast infections in 1994, the FDA did not approve the use of fluconazole for onychomycosis.

In Watson Pharmaceuticals' 2002 Annual Report, the company reported that positive results were obtained in its phase II, proof-of-concept trial in 2001. After 3 months, 78% of patients using the onychomycosis patch reported an improvement in fungal infection, compared with only 40% of placebo recipients. The incidence of adverse effects was also reportedly low in the trial.

Two phase III trials of Watson Pharmaceuticals' fluconazole patch were underway in the US; enrolment in these two trials was completed in 2002. These 1-year treatment studies, with active and placebo groups, will include post-treatment follow-up evaluations for an additional 6 months. Preliminary results from these two trials indicated that although the product demonstrated a significant greater number of complete cures, compared with placebo, in one trial, a significant advantage over placebo was not seen in the second trial (Reference: 809029201). Following further analysis of these clinical results, Watson announced in February 2004 that it has discontinued development of this product (Reference: 809030970).

Adverse Event

In two multicentre, double-blind, phase III trials, a total of 670 patients with toenail onychomycosis were randomised to receive topical antifungal therapy (fluconazole), or placebo, applied daily for 12 months. Preliminary results demonstrated that fluconazole was well tolerated, with a low incidence of adverse effects (Reference: 809029201).

Therapeutic Trials

Mycoses

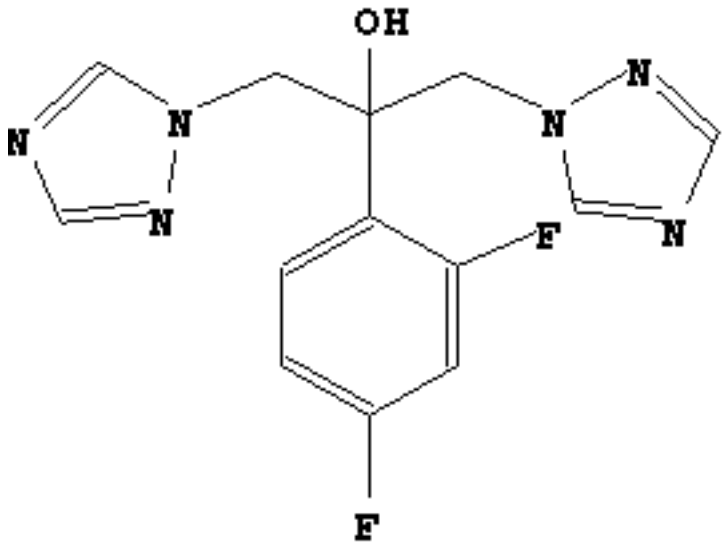
Preliminary results from two multicentre, double-blind, phase III trials in 670 patients with toenail onychomycosis showed that Watson's fluconazole transdermal patch may be beneficial in this population. Patients were randomised to receive topical antifungal therapy (fluconazole), or placebo, applied daily for 12 months. Patients were evaluated at 6, 12, 15 and 18 months. In one trial, antifungal therapy resulted in a significantly greater number of clinical cures, compared with placebo. Complete cure required success on three parameters: growth

of a completely clear nail, negative fungal culture, and a negative potassium hydroxide test. In the second trial, no significant difference in complete cure rates were seen between antifungal and placebo recipients (Reference: 809029201).

References

809029201. Watson Pharmaceuticals Announces Preliminary Results From Phase III Onychomycosis Trials. Watson Pharmaceuticals Inc. Media Release. : 10 Dec 2003. Available from: URL: http://www.watsonpharm.com. English. USA

809030970. Watson Pharmaceuticals Reports Earnings Per Share Of $0.48 for Fourth Quarter 2003. Watson Pharmaceuticals Inc. Media Release. : 5 Feb 2004. Available from: URL: http://www.watsonpharm.com. English. USA



History of Drug Development

Event date	Update date	Update type	Significant	Details
20031111	20031111	New Profile	true	New profile
20031111	20031111	Phase Change	true	Phase-III clinical trials in Onychomycosis in USA (Transdermal)
20031211	20031217	Scientific Update	true	Data from a media release have been added to the adverse events and Mycoses therapeutic trials sections (9029201)

20040205	20040212	Phase Change	true	Discontinued - Phase-III for Onychomycosis in USA (Transdermal)
20151201	20151202	Financial Update	true	Credit Suisse financial data update

Development Phases

Phase	Country	Indication	Route of Administration	Formulation	On Fast Track	Qualifiers and Comments
Discontinued(III)	USA	Onychomycosis	Transdermal	Patch	false	

Subject: Azoles;Small-molecules;Triazoles

Substance: Substance Substance: 1H-1,2,4-Triazole-1-ethanol, α-(2,4-difluoro-phenyl)-α-(1H-1,2,4-triazol-1-ylmethyl)-; CAS: 86386-73-4;

Drug synonym: Fluconazole transdermal patch - Watson Pharmaceuticals, Onychomycosis patch - Watson Pharmaceuticals

Molecular formula: C13H12F2N6O

Generic name: Fluconazole transdermal

Origin of substance: Fixed combination: No

Route of administration: Transdermal

Mechanism of action: 14-alpha-demethylase-inhibitors

Therapeutic class: D1: Antifungals, DermatologicalD01A-C: Imidazole and triazole derivativesD01A-C15: Fluconazole

Indication: Onychomycosis

Drug status: Inactive

Company information: Name: Watson Pharmaceuticals, Public, Is-Large-Pharma; Pharmaceutical; Role: Originator; Region: USA;

Highest phase: Discontinued(III)

Language: English

Document type: Report