

# Fixed Drug Eruption Against Rupatadine Fumarate

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**Abstract:** Second generation of antihistaminics have better therapeutic efficacy and more predictable pharmacological responses at lower doses than older compounds. However, new compounds have a reduced adverse reaction profile; clinicians can also encounter some unexpected adverse effects of these newer compounds. We report the first case of fixed drug eruption of rupatadine fumarate, which was confirmed by oral provocation test.

**Key Words:** Rupatadine fumarate, fixed drug eruption, oral provocation test

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After industrial development, allergic diseases (rhinitis, eczema, asthma, urticaria, etc) increased rapidly. For a main part of the population suffering from allergic symptoms of rhinitis, eczema, asthma, or urticaria, antihistaminic drugs form a mainstay of therapy. During the 1980s, investigation of new-generation antihistaminics was a major step toward higher specificity and a better safety profile in antihistaminics. Second-generation antihistaminics have better therapeutic efficacy, better safety profiles, and more predictable pharmacological responses at lower doses. Rupatadine is a second-generation antihistamine with increased affinity to histamine receptor H1; it is also a potent platelet-activating factor antagonist.

However, new compounds have a reduced adverse reaction profile; clinicians can also encounter some unexpected adverse effects of these newer compounds. Here is a case of fixed drug eruption (FDE) following ingestion of rupatadine. The allergy was confirmed by oral provocation test. In the literature, this is the first report of an adverse effect of this new antihistaminic drug, which was confirmed by oral provocation test.

## CLINICAL REPORT

A 16-year-old girl who has taken a depression medication (citalopram 5 mg/d) 6 months ago was prescribed rupatadine 10 mg/d for her allergic rhinitis and otopruritus. After taking the first dose at night, in the morning she felt a tingling and burning sensation over her body. Mild swelling, erythema, light brown pigmentation, and erosion and crusting on legs, arms, and chest followed over the next few hours. She has had breathing difficulty. Cutaneous examination revealed superficial, crusted lesions of FDE on the arms and legs. The lesions subsided with 1 mg/kg prednisolone intramuscularly administered in about hours.

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**FIGURE 1.** FDE lesion on the forearm due to rupatadine fumarate.

Two weeks later, oral provocation test was performed, and this test produced similar lesions of FDE after 5 minutes after the quarter-dose rupatadine intake (Figs. 1 and 2).

## DISCUSSION

Fixed drug eruption is one of the commonest types of adverse cutaneous drug reactions. Over 100 drugs are known to induce FDE.<sup>1</sup> It is most frequent with penicillins, tetracyclines, sulfonamides, sulfones, pyrazolones, barbiturates, and phenolphthalein. A number of first-generation antihistamine drugs such as cyclizine lactate, diphenhydramine hydrochloride, phenothiazines, dimenhydrinate, and hydroxyzine are known to cause FDE. Among the second-generation antihistaminics, only loratadine, levocetirizine, and cetirizine have been reported to cause FDE.<sup>2</sup>

At the recommended dose (10 mg/d), when compared with placebo, it does not produce any significant adverse effect whatsoever on the cognitive or psychomotor function of healthy volunteers. Similarly, the frequency of sedation with rupatadine was similar to that observed with placebo.<sup>3</sup> In the literature, second-generation antiallergic drugs such as cetirizine, which is a piperazine derivative, and levocetirizine, which is an active (R)-enantiomer of cetirizine, have significantly greater antiallergic effects; they have low incidence of adverse reactions and its convenient once-a-day-dosage schedule. Dryness of mouth, headache, gastrointestinal disturbances, dizziness, sedation and cardiovascular adverse effects, and maculopapular and urticarial eruptions due to cetirizine may occur occasionally in the patient.<sup>3,4</sup> To the best of our knowledge, FDE due to the second generation of antihistamines has been documented except in rupatadine.<sup>5</sup> We report this case to highlight a novel adverse effect of rupatadine fumarate.



**FIGURE 2.** FDE lesion on the leg due to rupatadine fumarate.

## CONCLUSIONS

Clinicians should be aware of this adverse effect, because with extensive use of these newer drugs, other similar cases may come to light in the future.

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