



**A CASE REPORT OF ORNIDAZOLE AND OFLOXACIN DRUG COMBINATION  
INDUCED GENERALISED BODY SWELLING AND ITCHING WITH FEVER**

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**ABSTRACT**

Ig E mediated hypersensitivity is a common manifestation. Common drugs involve are analgesics, antibiotics, Streptokinase and also radiocontrast media. The market in India is flooded with Fixed dose combinations (FDCs) and majority of them are irrational. Prescribing these irrational FDCs promote irrational prescription. Here we present a case of 28 year old male who had generalized body swelling, itching and fever after he took fixed dose combination of Ofloxacin and Ornidazole.

**KEYWORDS:** Ig E mediated hypersensitivity, Fixed dose combinations, Irrational prescription, Ofloxacin, Ornidazole.

**INTRODUCTION**

Fixed Dose combinations (FDCs) are defined as large number of pharmaceutical preparations containing two or more drugs in a fixed dose ratio. Advantages are convenience and over all better patient compliance, certain drug combinations are synergistic (levodopa + carbidopa), the therapeutic effect of two components being same may add up while the side effects being different may not (amlodipine + atenolol), the side effect of one component may be counteracted by the other (thiazide + a potassium sparing diuretic)<sup>[1]</sup> while disadvantages of these FDCs are the patient may not actually need all the drugs present in a combination: he is subjected to additional side effects and expense, the dose of these FDCs drugs cannot be adjusted and individualised. Adverse effect, when it occurs, cannot be easily ascribed to the particular drug causing it. Contraindication to one component (allergy, other conditions) contraindicates the whole product.<sup>[1]</sup> The time course of action of the components may be different, altered renal or hepatic function of the patient may differently affect the pharmacokinetics of the components. Unfortunately, only a handful of FDCs are rational and justified, while far too many are produced and vigorously promoted by the pharmaceutical industry are irrational.<sup>[1]</sup> The Essential Medicine list is prepared with due consideration to disease prevalence, efficacy, safety, and comparative cost-effectiveness of medicines. Out of the 414 medicines included in the 19<sup>th</sup> list of WHO List of Essential Medicines, 27 are FDCs. We included 24 FDCs out of 376 entities in the National List of Essential Medicines of India (NLEM) 2015.<sup>[2]</sup> This brings us to the discussion of rational use of medicines

and Bill of Rights. Right patient, Right drug, Right dose, Right frequency, Right duration and Right cost which can be afforded by the patient. Health care professionals along with pharmacists must know that they are the main tool to educate patients about advantages of rational use of medicine. Here we present a case of a 28 year old male who had swelling and itching of whole body along with fever due to FDCs of Ofloxacin(Quinolone) + Ornidazole (Nitroimidazole).

**CASE REPORT**

We are presenting a case of Ofloxacin + Ornidazole induced generalized body swelling with itching of whole body along with fever. However the patient did not have any rash. To start with the patient suffered from acute gastroenteritis for which he went to near by physician who prescribed him tablet Ofloxacin + Ornidazole FDCs(200/500) BD along with Oral rehydration solution. On first day after taking the tablet twice (morning and evening) he was fine. However on second day when he took morning dose of Ofloxacin + Ornidazole within 1 hour he started having swelling of lips which spread to whole face and later involve the whole body along with itching of whole body and fever. He immediately visited AIIMS Patna Dermatology Department. There was no other history of any vaccination or other drug intake. On examination his pulse was 78 beats /min BP was 132/84 mm of Hg. There was no icterus, pallor and lymphadenopathy. However there was generalized oedema. Lab investigation findings were as follows.(Hb- 13gm/dl, TLC- 8500/ cu mm, N- 73%, L=18%, M=3%,E=6%,B=0% ESR- 45mm, Random blood sugar 110mg/dl, Urea- 18mg/dl and Creatinine-

0.9mg/dl along with sodium – 140meq/l and potassium – 3.8meq/l, Liver function tests along with Lipid profile were in normal limits.) His ECG was absolutely normal. A provisional diagnosis of drug induced hypersensitivity was made. The combination of Ofloxacin + Ornidazole was immediately stopped and he was put on Levocetirizine 5mg tab OD, Dexamethasone 4mg IV BD, Pan 40 tab OD, Paracetamol 650 mg tab SOS for fever. The patient recovered fully in 3 days. When the patient was inquired about any significant past history he told that 3 months back he had very serious skin reaction from Ibuprofen (which was prescribed for ankle sprain) for which he was admitted in the hospital for 1 week which was later diagnosed as Steven Johnson Syndrome for which he was kept on IV fluids, antibiotics, corticosteroids and antihistaminics in local nearby hospital. The patient was also advised to go for Drug allergy test in order to fine out different drugs from which he is allergic to. However there was no other significant family history.

### DISCUSSION

The terms “drug allergy,” “drug hypersensitivity,” and “drug reaction” are often used interchangeably. Drug reactions encompass all adverse events related to drug administration, regardless of etiology. Drug hypersensitivity is defined as an immune-mediated response to a drug agent in a sensitized patient. Drug allergy is restricted specifically to a reaction mediated by IgE.<sup>[4]</sup>

Drug hypersensitivity results from interactions between a pharmacologic agent and the human immune system. These types of reactions constitute only a small subset of all adverse drug reactions. Allergic reactions to medications represent a specific class of drug hypersensitivity reactions mediated by IgE.<sup>[4]</sup> Here the patient if left untreated suddenly passes into anaphylactic shock.<sup>[5]</sup> Ornidazole and Ofloxacin FDCs induced skin reactions are not common however few case reports have been reported with the same class of drug combinations with Norfloxacin and Tnidazole.<sup>[6]</sup> Irrational FDCs of Quinolone and Nitoimidazole are continued to be prescribed in Git infections to cover up the diagnostic imprecision.<sup>[7]</sup> One important aspect in this case is that patient also has a significant history of Steven Johnson Syndrome which itself is life threatening manifestation. Here this patient needed a drug allergy test. Another important part of adverse drug reactions (ADRs) is causality assessment and ADR reporting to nearby peripheral ADR reporting centre. This case of ADR under WHO UMC SCALE<sup>[8]</sup> for causality assessment comes under probable category. As Dechallenge was positive means on stopping the suspected drug the ADRs subsided however Rechallenge was not attempted. From Dermatology Department at AIIMS Patna the case was reported to Pharmacology department AIIMS Patna and from here the details were uploaded on Vigiflow to be submitted to National Coordinating Centre Ghaziabad.

### CONCLUSION

Our case is due to an irrational FDCs and prescription. The health care professionals must be careful in prescribing FDCs as most of the FDCs in market are irrational which further leads to increase chance of ADR which directly puts burden on the pockets of the patients.

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