

Drug-Induced Cutaneous Adverse Reaction in a Patient with Osteoarthritis and Type 2 Diabetes Mellitus: A Case Report

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Abstract:

➤ Background:

Cutaneous adverse drug reactions (CADRs) are among the most frequently encountered medication-related complications in hospitalized patients, particularly those receiving polypharmacy regimens. Non-steroidal anti-inflammatory drugs (NSAIDs) are well-documented triggers of hypersensitivity-mediated dermatological reactions.

➤ Case Summary:

We report the case of a 35-year-old female patient with right knee osteoarthritis and a four-year history of Type 2 Diabetes Mellitus who developed diffuse erythematous skin lesions over the thighs and abdomen following initiation of Zerodol SP (Aceclofenac + Paracetamol + Serratiopeptidase) and Tenlin M Forte (Teneligliptin + Metformin). Clinical evaluation, causality assessment, and temporal correlation identified the NSAID combination as the probable causative agent.

➤ Outcome:

Prompt withdrawal of Zerodol SP, substitution with paracetamol monotherapy, and supportive care led to complete resolution of the cutaneous reaction. The patient was discharged in stable condition on Day 6.

➤ Conclusion:

This case underscores the importance of systematic ADR monitoring, early clinical pharmacist intervention, and individualized therapeutic decision-making in patients with comorbidities.

Keywords: Cutaneous Adverse Drug Reaction; NSAID Hypersensitivity; Aceclofenac; Erythema; Drug Safety; Pharmacovigilance; Osteoarthritis; Type 2 Diabetes Mellitus.

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I. INTRODUCTION

Adverse drug reactions (ADRs) account for a significant proportion of hospital admissions and inpatient complications worldwide. Among these, cutaneous adverse drug reactions (CADRs) are the most common manifestation, encompassing a clinical spectrum ranging from mild maculopapular exanthems to life-threatening conditions such

as Stevens-Johnson syndrome and toxic epidermal necrolysis [1]. Non-steroidal anti-inflammatory drugs (NSAIDs) constitute one of the most frequently implicated drug classes in drug-induced skin reactions, owing to their widespread use in managing musculoskeletal disorders and pain. The pathophysiological mechanisms underlying NSAID-induced cutaneous reactions include inhibition of cyclooxygenase (COX) enzymes, resulting in altered arachidonic acid

metabolism and subsequent overproduction of leukotrienes and prostaglandins, thereby triggering inflammatory and immunological skin responses [2]. Patients with comorbidities such as Type 2 Diabetes Mellitus are particularly vulnerable to ADRs due to altered immune responses, impaired skin barrier function, and concurrent polypharmacy. The role of clinical pharmacists in pharmacovigilance encompassing ADR detection, causality assessment, and therapeutic modification is integral to patient safety in such complex clinical scenarios [3]. Herein, we report a case of suspected NSAID-induced cutaneous adverse drug reaction in a hospitalized patient managed for right knee osteoarthritis with a background of Type 2 Diabetes Mellitus, highlighting the clinical presentation, assessment methodology, and successful management strategy.

II. CASE PRESENTATION

➤ Patient Demographics and History

A 35-year-old female patient (referred to as Patient S. for confidentiality) was admitted to the Orthopaedics Department on 12 October 2025 with a chief complaint of severe right knee pain, progressive swelling, joint stiffness, and restricted range of movement persisting over several weeks. Examination and clinical investigations led to a diagnosis of right knee osteoarthritis with active inflammation. Her past medical history was significant for Type 2 Diabetes Mellitus diagnosed four years prior, for which she had been receiving regular antidiabetic therapy. No known drug allergies were reported prior to the current admission. The patient was a non-smoker and did not consume alcohol.

Table 1 Patient Demographics and Clinical Profile

Parameter	Details
Age / Gender	35 years / Female
Height / Weight	160 cm / 62 kg
BMI	24.2 kg/m ²
Social History	Non-smoker, non-alcoholic
Known Allergies	None reported
Admission Date	12 October 2025
Discharge Date	17 October 2025

Table 1: Summary of patient demographics and clinical profile at admission.

➤ Medication History

Following admission, the patient was initiated on the following pharmacotherapy:

Table 2 Prescribed Medications During Hospitalization

S. No.	Drug (Brand Name)	Composition	Dosage & Frequency
1	Tenlin M Forte	Teneligliptin + Metformin 20/500 mg	Oral, once daily
2	Zerodol SP	Aceclofenac + Paracetamol + Serratiopeptidase	Oral, twice daily

Table 2: Medications prescribed during hospitalization with dosage details.

No pre-existing drug allergies or prior adverse reactions were documented in the patient's medical history.

III. CLINICAL FINDINGS

➤ Cutaneous Manifestations

Approximately 24–48 hours following initiation of pharmacotherapy, the patient developed the following cutaneous manifestations:

- Diffuse erythematous skin rashes distributed over the bilateral thighs and abdominal region
- Localized erythema with well-demarcated borders and mild warmth on palpation
- Mild pruritus and cutaneous irritation
- Absence of vesiculation, bullae, or mucosal involvement
- No angioedema, urticaria, or systemic anaphylactic features

The patient remained hemodynamically stable throughout the episode with no evidence of respiratory distress or cardiovascular compromise.

➤ Clinical Photographs

Clinical photographs documented with informed patient consent demonstrated the following:



Fig 1 Diffuse Erythema Over the Abdominal Region Observed Approximately 48 Hours Post-Initiation of NSAID Therapy. (Photographed with Informed Patient Consent.)



Fig 2 Bilateral Erythematous Lesions Over Right and Left Thighs.

- Note: The diffuse distribution without vesiculation or mucosal involvement. (Photographed with informed patient consent.)

➤ Investigations

The following investigations were performed to evaluate the extent of the reaction and exclude systemic involvement:

- Complete Blood Count (CBC): Within normal limits; no eosinophilia detected
- Renal Function Tests (RFT): Serum creatinine and blood urea nitrogen within reference range
- Random Blood Glucose Monitoring: Blood glucose levels adequately controlled
- Physical Dermatological Examination: Erythematous lesions confined to thighs and abdomen; no mucosal, conjunctival, or genital involvement

No evidence of systemic infection, haematological abnormality, or organ dysfunction was identified. Patch testing or formal allergy workup was not performed at this stage. The clinical picture was consistent with a drug-induced cutaneous hypersensitivity reaction.

➤ Causality Assessment

Causality assessment was performed using the Naranjo Adverse Drug Reaction Probability Scale [4].

The temporal association between initiation of Zerodol SP (Aceclofenac + Paracetamol + Serratiopeptidase) and onset of cutaneous manifestations, combined with improvement following drug withdrawal, yielded a Naranjo score consistent with a probable adverse drug reaction.

The WHO-UMC causality classification was additionally applied, categorising this reaction as Probable / Likely, based on the following criteria:

- Plausible temporal relationship between drug administration and onset of skin reaction

- Known pharmacological mechanism supporting NSAID-induced cutaneous hypersensitivity
 - Clinical improvement following withdrawal of the suspected causative agent
 - No alternative aetiology (e.g., infection, contact dermatitis, systemic disease) identified
- Severity was classified as moderate as per the Hartwig and Siegel scale, given that the reaction necessitated drug discontinuation and therapeutic modification, though it did not result in prolonged hospitalisation or organ damage.

➤ Therapeutic Intervention

Upon identification of the suspected cutaneous ADR, the following management steps were undertaken:

- Immediate discontinuation of Zerodol SP (Aceclofenac + Paracetamol + Serratiopeptidase)
- Initiation of Paracetamol monotherapy as an alternative analgesic for pain management in osteoarthritis
- Continuation of Tenlin M Forte (Teneligliptin + Metformin) for glycaemic control, as this was not implicated in the reaction
- Adequate oral hydration to support drug clearance and skin recovery
- Regular blood glucose monitoring to maintain glycaemic stability
- Renal function monitoring given concurrent NSAID exposure and antidiabetic therapy
- Observation and documentation of skin lesion progression

The clinical pharmacist documented the ADR in the patient's medication record and reported it through appropriate pharmacovigilance channels in accordance with institutional protocol.

➤ Outcome and Follow-Up

Following discontinuation of Zerodol SP and initiation of supportive measures, the patient demonstrated progressive clinical improvement. Erythema over the thighs and abdomen began to subside within 48–72 hours of drug withdrawal. No new cutaneous lesions developed, and the patient experienced significant reduction in pruritus and discomfort. The patient remained haemodynamically stable throughout the observation period. Blood glucose and renal function parameters remained within acceptable limits. She was discharged on 17 October 2025 (Day 6 of admission) in a stable clinical condition with instructions to avoid NSAIDs and related compounds in the future. At discharge, the patient was counselled regarding the suspected drug reaction, the importance of informing future healthcare providers of this ADR, and the need for follow-up review if symptoms recurred. A medication alert was documented in her discharge summary.

IV. DISCUSSION

This case illustrates a clinically significant drug-induced cutaneous adverse reaction in a patient receiving combination NSAID therapy for osteoarthritis in the context of concurrent antidiabetic treatment. The temporal onset of

erythematous lesions following initiation of Zerodol SP and their resolution upon withdrawal strongly implicates the NSAID-containing combination as the causative agent. Aceclofenac, a phenylacetic acid derivative and selective COX-2 inhibitor with partial COX-1 activity, has been associated with cutaneous hypersensitivity reactions including erythema, urticaria, and fixed drug eruptions [5]. The mechanism is thought to involve COX-1 inhibition, which diverts arachidonic acid towards the 5-lipoxygenase pathway, increasing leukotriene production and promoting mast cell degranulation and inflammatory cascades in the dermis [2]. The absence of mucosal involvement, bullae, or systemic compromise in the present case allowed exclusion of severe cutaneous reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis, which require urgent and escalated management.

The clinical pattern was most consistent with a maculopapular exanthem or drug-induced erythema, representing the commonest form of NSAID-related cutaneous ADR [6]. The role of the clinical pharmacist was pivotal in this case. Early recognition of the temporal association between drug initiation and symptom onset, systematic causality assessment, recommendation for drug withdrawal, and ADR reporting all contributed directly to a favourable patient outcome. This highlights the importance of integrating pharmacovigilance activities into routine clinical pharmacy practice. The patient's comorbid status (Type 2 Diabetes Mellitus) may have contributed to heightened susceptibility to cutaneous adverse reactions. Diabetic patients often exhibit subclinical immune dysregulation and impaired skin integrity, which may amplify the inflammatory response to drug-induced triggers [7]. This underscores the need for heightened vigilance when prescribing NSAIDs to patients with diabetes or other immunomodulatory conditions. Future management of pain in this patient should prioritise NSAID-free analgesic strategies, including paracetamol, topical analgesics, or physiotherapy, with NSAIDs strictly contraindicated given the documented adverse reaction. Patient education regarding avoidance and the importance of disclosing this ADR to future prescribers is paramount.

V. CONCLUSION

We present a case of probable NSAID-induced cutaneous adverse drug reaction manifesting as diffuse erythema in a patient with osteoarthritis and Type 2 Diabetes Mellitus. Prompt identification, causality assessment, and therapeutic modification by the clinical pharmacist resulted in complete resolution of the reaction and uneventful recovery. This case reinforces the essential role of clinical pharmacists in monitoring, detecting, and managing medication-related harms in complex, multimorbid patients, and highlights the need for careful drug selection and ongoing pharmacovigilance in clinical practice.

➤ Patient Consent Statement

Written informed consent was obtained from the patient for the use of clinical data, including photographs, for academic publication. The patient's identity has been

anonymised in accordance with ethical standards for case report publication.

➤ Conflicts of Interest

The authors declare no conflicts of interest.

➤ Funding

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