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Levosulpiride-induced extrapyramidal symptoms: A 15-case series from a tertiary care centre.

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Abstract

Background

Levosulpiride, a dopamine D2 receptor antagonist commonly used in India for gastrointestinal disorders, has been increasingly associated with extrapyramidal symptoms (EPS), especially with prolonged use and in fixed-dose combinations (FDCs) with proton pump inhibitors (PPIs). Despite its widespread use, awareness of its neurological adverse effects remains limited.

Objective

To present a case series highlighting the clinical profile, management, and outcomes of patients who developed extrapyramidal symptoms (EPS) following levosulpiride use, with an emphasis on the importance of early detection and rational prescribing practices.

Methods

A prospective observational case series was conducted at the ADR Monitoring Centre of Maharaja Krushna Chandra Gajapati Medical College and Hospital, Berhampur, Odisha. Fifteen patients presenting with neurological symptoms following levosulpiride administration were systematically evaluated. Detailed clinical histories, imaging, and laboratory investigations were performed to rule out alternative causes. Causality was assessed using the WHO-UMC scale, and all cases were reported to PvPI. Levosulpiride was withdrawn in all cases, and treatment was tailored to symptom type.

Results

Among 15 patients (8 females, 7 males; aged 18–66 years), drug-induced Parkinsonism was most common (10 cases), followed by acute dystonia (2), tardive dyskinesia (2), and akathisia (1). The onset ranged from 9 to 164 days post-levosulpiride initiation. Most patients improved post-withdrawal. Fixed-dose combinations were implicated in prolonged exposure.

Conclusion

Levosulpiride, even at therapeutic doses, can cause significant and sometimes persistent extrapyramidal symptoms. This case series underscores the importance of restricting its use to short durations, monitoring for neurological symptoms, and educating both prescribers and patients. Regulatory action against inappropriate FDCs and improved pharmacovigilance reporting are warranted to ensure safer therapeutic outcomes.

Recommendations

Use levosulpiride short-term with regular neurological checks. Educate patients and caregivers to recognize early symptoms. Avoid high-risk groups. Prefer safer alternatives. Stop immediately if EPS occurs. Report to pharmacovigilance. Avoid unnecessary fixed-dose combinations.

Keywords: Levosulpiride, Extrapyramidal Symptoms, Drug-induced Parkinsonism, Acute Dystonia, Tardive Dyskinesia, Akathisia, Pharmacovigilance, Adverse Drug Reaction, Fixed-Dose Combination.
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Introduction

Levosulpiride, a selective dopamine D2 receptor antagonist, is widely used in India for managing various gastrointestinal disorders, including functional dyspepsia, gastroesophageal reflux disease (GERD), and irritable bowel syndrome (IBS). [1] It is frequently prescribed in combination with Proton Pump Inhibitors (PPIs) in fixed-dose regimens, optimizing symptomatic relief through its prokinetic and antiemetic properties [2].

Typically, levosulpiride is recommended for short-term use (15–30 days); however, prolonged therapy has been associated with significant adverse effects. Notably, due to its action on dopamine D2 receptors in the nigrostriatal pathway, chronic use—even at therapeutic doses—can lead to extrapyramidal symptoms (EPS) such as parkinsonism, dystonia, akathisia, and tardive dyskinesia. These effects highlight a potential safety concern in the prolonged administration of levosulpiride, particularly in populations requiring extended treatment [3]

Despite its prevalent usage and efficacy, the long-term safety profile of levosulpiride, especially in fixed-dose combinations with PPIs, remains insufficiently characterized. There is a critical need for comprehensive studies evaluating the incidence and risk factors associated with EPS in patients undergoing extended treatment with levosulpiride. Addressing this gap could guide safer prescribing practices and inform clinicians about potential monitoring strategies to mitigate adverse outcomes.

Objectives

This case series aims to systematically report the adverse drug reactions (ADRs) associated with Levosulpiride, focusing on the clinical manifestations, management strategies, and outcomes of patients experiencing Levosulpiride-induced extrapyramidal symptoms (EPS). Emphasis is placed on the critical need for early detection and timely intervention to prevent serious complications. By highlighting the risks of Levosulpiride, especially when used as an over-the-counter medication, this series advocates for more cautious prescription practices.

Methodology

The systematic evaluation of patients presenting with neurological symptoms potentially related to Levosulpiride use was assessed at the Outpatient Department (OPD) of Maharaja Krushna Chandra Gajapati Medical College and Hospital, Berhampur, Odisha. Clinical history like medical history, family history, and past interventions were obtained from each patient, encompassing their medical background, comprehensive drug history, duration of Levosulpiride use, and the onset and progression of extrapyramidal symptoms (EPS). To ensure accurate diagnosis and exclude alternative causes of neurological symptoms, patients underwent diagnostic investigations, including imaging studies such as computed tomography (CT) and magnetic resonance imaging (MRI), as well as relevant laboratory tests like CBC, serum electrolyte, Random Blood Sugar, LFT, RFT, TSH. Each case was reported to the ADR Monitoring Centre and assessed using the WHO causality assessment tool. Levosulpiride was discontinued in all suspected cases, and alternative medications such as Levodopa-Carbidopa and Trihexyphenidyl were prescribed. Supportive care, including hydration, and physiotherapy was provided. Patients were followed up to assess the resolution of EPS symptoms. The data were then analyzed to assess the relationship between Levosulpiride use and the onset of EPS, guiding the clinical management of these cases.

Case presentation

Case 1

A 53-year-old male was prescribed 75 mg of levosulpiride for acute gastritis and took the medication for 46 days. After 30 days, he developed bradykinesia, gait disturbance, and dysarthria. These symptoms persisted for 30 days. He was treated with levodopa 50 mg TDS and trihexyphenidyl 2 mg OD, leading to a final diagnosis of drug-induced Parkinsonism. At the two-month follow-up, he was free of extrapyramidal symptoms (EPS).

Case 2

An 18-year-old male was given 75 mg of levosulpiride for GERD and used it for 14 days. Nine days after starting the medication, he experienced acute dystonia, tremors, and a decline in motor activity. These symptoms lasted for 40 days. He was treated with clonazepam 0.25 mg OD and diphenhydramine 25 mg IV BD. The final diagnosis was drug-induced acute dystonia, with minor EPS noted at the two-month follow-up.

Case 3

A 55-year-old male was on 75 mg of levosulpiride for chronic gastritis for 202 days. Symptoms of decreased speech, tremors, poor attention, decreased movements,

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and decreased memory and thinking appeared after 164 days and lasted for 60 days. He was treated with tofisopam 50 mg OD and memantine 5 mg OD. The final diagnosis was drug-induced Parkinsonism, with mild EPS observed at the two-month follow-up.

Case 4

A 65-year-old male took 75 mg of levosulpiride for GERD over 77 days. He developed a decline in motor activity, decreased verbalization, and tremors 22 days after starting the medication. These symptoms persisted for 50 days. Treatment included levodopa 50 mg TDS and trihexyphenidyl 2 mg OD. The final diagnosis was drug-induced Parkinsonism, and he was EPS-free at the two-month follow-up.

Case 5

A 45-year-old female was prescribed 75 mg of levosulpiride for acute gastritis and took it for 90 days. She experienced decreased daily activities, asymmetric bradykinesia, and marked hypophonia 30 days after starting the medication. These symptoms lasted for 50 days. She was treated with levodopa 50 mg TDS and trihexyphenidyl 2 mg OD. The final diagnosis was drug-induced Parkinsonism, with mild EPS at the two-month follow-up.

Case 6

A 38-year-old female took 75 mg of levosulpiride for acute gastritis for 20 days. She developed inner restlessness, tremors, and involuntary movements 15 days after starting the medication. These symptoms persisted for 40 days. She was treated with syndopa 125 mg TDS and propranolol 40 mg. The final diagnosis was tardive dyskinesia, with mild EPS at the two-month follow-up.

Case 7

A 57-year-old female was on 75 mg of levosulpiride for GERD for 60 days. She experienced hallucinations, head tremors, decreased motor activity, hypophonia, and altered sensorium 45 days after starting the medication. These symptoms lasted for 50 days. She was treated with syndopa 125 mg TDS and propranolol 40 mg. The final diagnosis was drug-induced Parkinsonism, with mild EPS at the two-month follow-up.

Case 8

A 60-year-old male was prescribed 75 mg of levosulpiride for chronic gastritis and took the medication for 40 days. Twenty days after initiation, he developed rigidity, tremor, and decreased arm swing. These symptoms lasted for 45 days. He was treated with levodopa 50 mg TDS and trihexyphenidyl 2 mg OD. The final diagnosis was drug-induced Parkinsonism. At follow-up, he was free of extrapyramidal symptoms (EPS).

Case 9

A 41-year-old female was on 75 mg of levosulpiride for irritable bowel syndrome (IBS) and used it for 18 days. On the 10th day, she developed acute dystonic reactions characterized by tongue protrusion and upward gaze deviation. These symptoms lasted for 7 days. She was treated with promethazine 25 mg intramuscularly and clonazepam 0.5 mg orally. The final diagnosis was drug-induced acute dystonia, and the symptoms resolved completely.

Case 10

A 66-year-old male received 75 mg of levosulpiride for gastroesophageal reflux disease (GERD) and continued therapy for 85 days. On the 40th day, he developed hand tremors, mask-like facies, and slowness in daily activities. These symptoms persisted for 55 days. He was treated with syndopa 125 mg TDS. The final diagnosis was drug-induced Parkinsonism, with mild EPS noted at the two-month follow-up.

Case 11

A 29-year-old female took levosulpiride 75 mg for functional dyspepsia for 25 days. After 12 days of therapy, she developed akathisia and a sense of inner restlessness. These symptoms lasted for 20 days. She was treated with propranolol 40 mg and clonazepam 0.25 mg OD. The final diagnosis was drug-induced akathisia. Her EPS symptoms resolved by the two-month follow-up.

Case 12

A 58-year-old male was prescribed 75 mg of levosulpiride for GERD and took it for 32 days. On the 25th day of treatment, he developed generalized rigidity, decreased verbal output, and tremors. These symptoms persisted for 40 days. He was treated with syndopa 125 mg and trihexyphenidyl 2 mg OD. The final diagnosis

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was drug-induced Parkinsonism, with mild EPS symptoms persisting at follow-up.

Case 13

A 36-year-old female took levosulpiride 75 mg for GERD over 60 days. On the 30th day, she began to experience rest tremor, muscle stiffness, and psychomotor retardation. These symptoms lasted for 50 days. She was treated with levodopa 100 mg TDS. The final diagnosis was drug-induced Parkinsonism, with significant improvement in symptoms by the two-month follow-up.

Case 14

A 62-year-old male was prescribed 75 mg of levosulpiride for reflux esophagitis and took it for 70 days. After 50 days of therapy, he developed dysarthria, shuffling gait, and tremors. The symptoms persisted for 45 days. He was treated with levodopa 50 mg TDS and propranolol 40 mg. The final diagnosis was drug-induced Parkinsonism, with partial resolution of symptoms at the two-month follow-up.

Case 15

A 50-year-old female was on levosulpiride 75 mg for 45 days (indication not specified). On the 28th day of therapy, she developed facial grimacing, choreiform hand movements, and agitation. These symptoms lasted for 60 days. She was treated with tetrabenazine 25 mg OD along with supportive therapy. The final diagnosis was tardive dyskinesia, with moderate symptoms remaining at the time of follow-up.

Table No-1:-Demographic Details of Cases taking levosulpiride in FDC and develop EPS:

Case	Age	Sex	Race	Occupation	Location
1	53	Male	Indian	Farmer	Rural Ganjam
2	18	Male	Indian	Student	Urban Berhampur
3	55	Male	Indian	Retired	Rural Ganjam
4	65	Male	Indian	Retd. Railway Worker	Urban Berhampur
5	45	Female	Indian	Homemaker	Rural Aska
6	38	Female	Indian	Teacher	Urban Berhampur
7	57	Female	Indian	Homemaker	Rural Digapahandi
8	60	Male	Indian	Laborer	Rural Hinjilicut
9	41	Female	Indian	Housemaid	Urban Berhampur
10	66	Male	Indian	Pensioner	Rural Buguda
11	29	Female	Indian	Nurse	Urban Berhampur
12	58	Male	Indian	Shopkeeper	Rural Chikiti
13	36	Female	Indian	Teacher	Urban Berhampur
14	62	Male	Indian	Farmer	Rural Soroda
15	50	Female	Indian	Anganwadi Worker	Rural Ganjam

Table No-2 :- Patients History

Case	Medical History	Family History	Past Interventions
1	Nil significant	Nil	None
2	Nil significant	Nil	None
3	Type 2 DM (well-controlled)	Negative for movement disorders	Oral hypoglycemics
4	Hypertension	No neurological illness	Antihypertensives
5	Hypothyroidism	No family history	Levothyroxine
6	Nil	Nil	None
7	Nil	Nil	None
8	Tobacco user	No neuropsychiatric illness	None
9	Nil	Nil	None

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10	Diabetes, Hypertension	Nil	Oral medications
11	Nil	Nil	None
12	Alcoholic liver disease	Nil	Abstinence
13	Nil	Nil	None
14	Hypertension, Cataract	Nil	Cataract surgery
15	Nil	Nil	None

Table No-3 :- Diagnostic Test Results

Case	Imaging	Lab Tests & Findings	Interpretation
1	CT Brain – Normal	CBC, LFT, RBS – All normal	No neurological or metabolic abnormalities
2	CT Brain – Normal	CBC – Normal; Electrolytes – Normal	No hematologic or electrolyte imbalance
3	MRI – Age-related atrophy	RBS – 146 mg/dL, HbA1c – 6.8%; CBC – Normal	Controlled diabetes; age-related changes
4	CT Brain – Normal	BP 138/90; CBC, LFT – Normal	Mild hypertension; normal imaging and labs
5	CT Brain – Normal	TSH – 6.1 µIU/mL (mild ↑); CBC – Normal	Subclinical hypothyroidism; otherwise, normal
6	CT Brain – Normal	CBC – Normal; Thyroid panel – Normal	No systemic or neurologic abnormalities
7	MRI – Mild cerebral atrophy	CBC – Normal; RFT – Normal	Age-related brain changes; normal kidney function
8	CT Brain – Normal	CBC – Mild anemia (Hb: 10.9 g/dL)	Mild anemia; no neurologic abnormality
9	CT Brain – Normal	CBC, LFT – Normal	No systemic or neurological abnormalities
10	MRI – Ischemic changes	FBS – 158 mg/dL; LFT – Mild SGPT ↑	Mild cerebrovascular changes; mild metabolic abnormalities
11	MRI – Normal	CBC, TSH – Normal	No detectable abnormalities
12	CT – Normal	LFT – Raised bilirubin (2.1 mg/dL), SGOT ↑	Alcoholic liver dysfunction; normal brain imaging
13	MRI – Normal	CBC, Electrolytes – Normal	No abnormalities detected
14	CT Brain – Mild atrophy	CBC – Normal; BP 142/92	Mild age-related brain atrophy; borderline hypertension
15	MRI – Normal	CBC – Normal; LFT – Normal	No neurological abnormalities, systemic labs normal

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Table No-4 Drugs and ADR Profiles of Cases taking levosulpiride in FDC and develop EPS:

Case	Indication	Dose (mg)	Duration of Use (days)	Onset (days)	Symptoms	Duration of Symptoms (days)	Treatment	Diagnosis	2-Month Follow-up
1	Acute gastritis	75	46	30	Bradykinesia, gait disturbance, dysarthria	30	Levodopa 50 mg TDS, Trihexyphenidyl 2 mg OD	Drug-induced Parkinsonism	EPS free
2	GERD	75	14	9	Acute dystonia, tremors, reduced motor activity	40	Clonazepam 0.25 mg OD, Diphenhydramine 25 mg IV BD	Drug-induced acute dystonia	Minor EPS
3	Chronic gastritis	75	202	164	Decreased speech, tremor, poor attention, bradykinesia	60	Tofisopam 50 mg OD, Memantine 5 mg OD	Drug-induced Parkinsonism	Mild EPS
4	GERD	75	77	22	Motor decline, decreased verbalization, tremors	50	Levodopa 50 mg TDS, Trihexyphenidyl 2 mg OD	Drug-induced Parkinsonism	EPS free
5	Acute gastritis	75	90	30	Reduced daily activities, bradykinesia, hypophonia	50	Levodopa 50 mg TDS, Trihexyphenidyl 2 mg OD	Drug-induced Parkinsonism	Mild EPS
6	Acute gastritis	75	20	15	Inner restlessness, tremors, involuntary movements	40	Syndopa 125 mg TDS, Propranolol 40 mg	Tardive dyskinesia	Mild EPS
7	GERD	75	60	45	Hallucinations, head tremors, hypophonia, altered sensorium	50	Syndopa 125 mg TDS, Propranolol 40 mg	Drug-induced Parkinsonism	Mild EPS
8	Chronic gastritis	75	40	20	Rigidity, tremor, reduced arm swing	45	Levodopa 50 mg TDS, Trihexyphenidyl 2 mg OD	Drug-induced Parkinsonism	EPS free
9	IBS	75	18	10	Tongue	7	Promethazi	Drug-	Resolved

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					protrusion, upward gaze		ne 25 mg IM, Clonazepam 0.5 mg	induced acute dystonia	completely
10	GERD	75	85	40	Hand tremors, mask-like facies, slow activities	55	Syndopa 125 mg TDS	Drug-induced Parkinsonism	Mild EPS
11	Functional dyspepsia	75	25	12	Akathisia, inner restlessness	20	Propranolol 40 mg, Clonazepam 0.25 mg OD	Drug-induced akathisia	Resolved
12	GERD	75	32	25	Rigidity, hypophonia, tremors	40	Syndopa 125 mg, Trihexyphenidyl 2 mg OD	Drug-induced Parkinsonism	Mild EPS
13	GERD	75	60	30	Rest tremor, stiffness, psychomotor retardation	50	Levodopa 100 mg TDS	Drug-induced Parkinsonism	Improved
14	Reflux esophagitis	75	70	50	Dysarthria, shuffling gait, tremors	45	Levodopa 50 mg TDS, Propranolol 40 mg	Drug-induced Parkinsonism	Partial resolution
15	Not specified	75	45	28	Facial grimacing, choreiform hand movements, agitation	60	Tetrabenazine 25 mg OD	Tardive dyskinesia	Moderate symptoms

Discussion

The present case series highlights the spectrum of extrapyramidal symptoms (EPS) associated with levosulpiride (LSP) use, including drug-induced parkinsonism, acute dystonia, tardive dyskinesia, and akathisia. The onset of these symptoms varied from as early as 9 days to as late as 164 days after initiating LSP therapy, with symptom durations ranging from 7 to 60 days. Treatment strategies were tailored to the specific EPS manifestations, and while some patients achieved complete resolution, others experienced persistent mild to moderate symptoms at follow-up.

Comparatively, a study narrated ten cases of LSP-induced dyskinesia and one case of parkinsonism, with a median symptom start of 13 months [4]. Notably, none of their patients achieved complete symptom resolution, underscoring the potential for prolonged EPS even after LSP discontinuation. Likewise, a systematic review highlighted noteworthy risks of movement disorders, especially parkinsonism and tardive dyskinesia, related to LSP use [5].

In contrast to a study [6], the present case series observed earlier symptom onset, with some cases presenting within two weeks of LSP initiation. This discrepancy may be attributed to differences in patient demographics, LSP dosing, and concurrent medications.

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For instance, the use of fixed-dose combinations of LSP with proton pump inhibitors (PPIs) has been implicated in enhancing LSP's bioavailability, potentially increasing the risk of EPS.

Management of LSP-induced EPS remains challenging. While withdrawal of LSP is the primary intervention, adjunctive therapies such as anticholinergics, benzodiazepines, and dopaminergic agents are often employed based on symptomatology. However, as evidenced by our series and previous reports, symptom resolution is variable, and some patients may experience persistent deficits.

Given the potential for serious and sometimes irreversible EPS with LSP use, especially in the treatment of non-psychiatric conditions like gastrointestinal disorders, clinicians should exercise caution. Regular monitoring for early signs of EPS, patient education, and consideration of alternative therapies when appropriate are essential to mitigate risks.

Conclusion

This case series underscores the significant risk of extrapyramidal symptoms (EPS) associated with levosulpiride, even when used at standard therapeutic doses for gastrointestinal disorders. Drug-induced Parkinsonism was the most frequently observed adverse effect, followed by acute dystonia, tardive dyskinesia, and akathisia. The onset of symptoms varied widely, indicating the need for vigilant monitoring throughout therapy. While some patients recovered completely after drug withdrawal and symptomatic management, others experienced persistent or partially resolved EPS. Given these findings, levosulpiride should be prescribed with caution, especially for long durations, and patients should be regularly assessed for early neurological symptoms. Alternatives with safer neurological profiles should be considered where appropriate, and patient awareness about potential adverse effects must be improved to ensure timely reporting and intervention.

Generalizability and Limitations of the Study

This case series is limited by its small sample size and single-center design, which restrict generalizability. Being retrospective, it is prone to recall bias. The absence of a control group prevents comparison with patients who did not develop EPS. Follow-up was short, potentially missing long-term or delayed symptoms. Baseline neurological assessments were incomplete, making it difficult to rule out pre-existing conditions. Polypharmacy and comorbidities were not fully controlled, possibly confounding the findings. The use of levosulpiride in fixed-dose combinations complicates the attribution of effects. Causality assessment relied on semi-subjective WHO criteria without confirmatory tools like challenge–dechallenge–rechallenge. Lastly, no pharmacogenetic or serum drug level monitoring was performed, limiting insights into individual susceptibility.

Recommendations

Based on the findings of this case series, the following recommendations are proposed to minimize the risk of levosulpiride-induced extrapyramidal symptoms (EPS):

Restrict Long-Term Use: Levosulpiride should not be used for prolonged periods, particularly beyond 2–4 weeks, unless necessary. Periodic re-evaluation of the indication and risk-benefit balance is essential.

Monitor Neurological Status Regularly: All patients on levosulpiride should be monitored for early signs of EPS, such as tremors, bradykinesia, rigidity, restlessness, or abnormal movements. Baseline and periodic neurological assessments are advised, especially in elderly patients or those on other CNS-active medications.

Educate Patients and Caregivers: Patients should be informed about possible EPS and advised to report any new motor or behavioral symptoms immediately. Caregivers can play a key role in recognizing subtle behavioral or motor changes.

Avoid in High-Risk Populations: Levosulpiride should be used with extreme caution or avoided altogether in patients with a personal or family history of Parkinson's disease, previous EPS from other medications, or those concurrently taking other dopamine-blocking agents.

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Prefer Shorter Duration Alternatives: Consider alternative therapies with better neurological safety profiles (e.g., prokinetics with minimal dopamine antagonism) for gastrointestinal conditions where appropriate.

Stop the Drug at the First Sign of EPS: Immediate discontinuation of levosulpiride at the earliest sign of extrapyramidal involvement can improve outcomes and reduce the risk of persistent neurological deficits.

Report to Pharmacovigilance Authorities: All suspected cases of levosulpiride-induced EPS should be reported to national pharmacovigilance programs (e.g., PvPI in India) to enhance post-marketing safety surveillance.

Discourage Use in Fixed-Dose Combinations (FDCs): Regulatory authorities and prescribers should critically evaluate the necessity of levosulpiride-containing FDCs, as these may contribute to inadvertent prolonged use without clinical monitoring.

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1.Dr. Suvendu Kumar Panda: Conceptualization, data acquisition, manuscript drafting, and correspondence.
2.Dr. Snehasini Dash: Clinical evaluation, literature review, and data analysis.
3.Dr. Pratyush Mishra: Manuscript revision and editing.
4.Dr. Jasmine Mahanta: Clinical data collection and patient follow-up.
5.Dr. Mousumi Pradhan: Pharmacovigilance documentation and final proofreading.

Conflict of Interest

The authors declared no conflict of interest.

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List of Abbreviations

ADR: Adverse Drug Reaction
AKT: Akathisia (clinically recognized as a symptom, not always abbreviated)
BD: Bis in Die (Twice Daily)
CT: Computed Tomography
EPS: Extrapyramidal Symptoms
FDC: Fixed-Dose Combination
GERD: Gastroesophageal Reflux Disease
IBS: Irritable Bowel Syndrome
IM: Intramuscular
IV: Intravenous
LSP: Levosulpiride
MRI: Magnetic Resonance Imaging
OD: Once Daily
OPD: Outpatient Department
PPI: Proton Pump Inhibitor
PvPI: Pharmacovigilance Programme of India
QD: Quaque Die (Once a day – sometimes used interchangeably with OD)
TDS: Ter Die Sumendum (Three Times a Day)
WHO-UMC: World Health Organization - Uppsala Monitoring Centre

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