

**Pacific Pharmaceuticals Ltd.**

Lahore, Pakistan

**Levopraid ® 50**

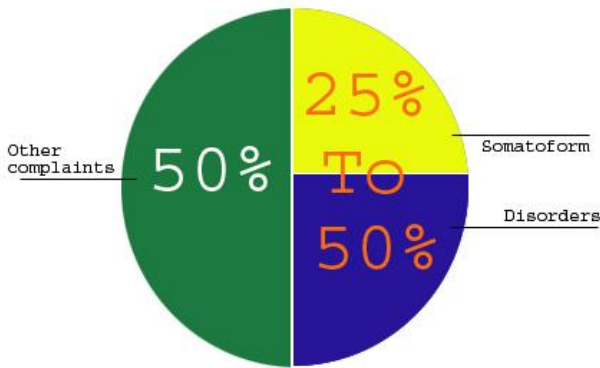


**It's all in the HEAD But BODY bears the BURNDEN**

**Somatoform Disorders:**

When symptoms suggest a physical disorder, which is actually not present & present & the patient does not get better despite the doctor's best symptomatic treatment.

**Significantly higher incidence:**



**Complications:**

Unnecessary & repetitive investigations & surgery Drug Dependence. High cost of unnecessary treatment. Continuous change of doctors

Studies have shown that from a quarter to one half of the patients attending general practitioners actually suffering from Somatoform Disorders.  
Ref: Court C. Report urges better psychological care. BMJ 1995;310:1027.

**The DSM IV describes 5 subtypes of Somatoform disorders**

- 1**Body Dysmorphic disorders | **2**Pain disorders | **3**Hypochondriasis | **4**Conversion disorders

**And the most common  
5 SOMATIZATIONS DISORDERS  
with following symptoms**

**GIT Symptoms:**

- ❖ Nausea, vomiting
- ❖ Abdominal Pain
- ❖ Heart Burns
- ❖ Gas, Flatulence
- ❖ Diarrhoea

**Sexual Symptoms:**

- ❖ Burning sensations in sexual organs
- ❖ Pain during intercourse
- ❖ Impotency

**Genitourinary Symptoms:**

- ❖ Urinary retention or difficulty in urinating.
- ❖ Increased frequency of urinations.

**Pseudoneurological Symptoms:**

- ❖ Amnesia
- ❖ Blurred Vision
- ❖ Difficulty in swallowing
- ❖ Muscle weakness or fatigue

**Cardiopulmonary Symptoms:**

- ❖ Shortness of breath
- ❖ Palpitation
- ❖ Chest Pain

**Pain Symptoms:**

- ❖ Pain of extremities
- ❖ Back Pain
- ❖ Joint Pain
- ❖ Other Pains

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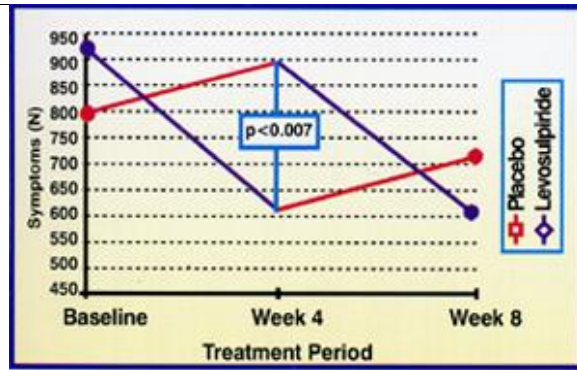
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Levopraid® 50

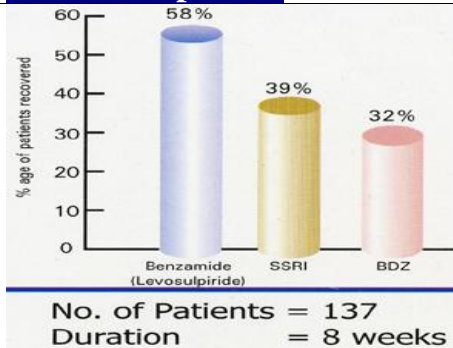


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**The only psychotropic drug indicated to the treatment of somatoform disorders<sup>2</sup>**



**More effective than SSRIs and Benzodiazepines.<sup>1</sup>**



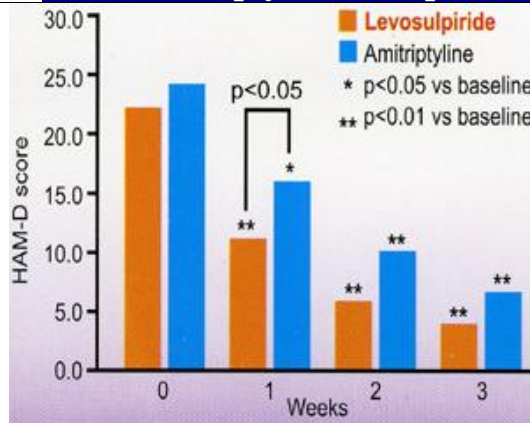
Variation in the number of SD symptoms with levo-sulpiride or placebo, before and after cross-over ( $p < 0.007$ ).

**Trial Setup:**

**No. of patients: 74 Dose: 50 mg b.i.d.**

**Result:** Levopraid 50 has proved a significantly better efficacy compared with placebo in reducing the number & severity of somatoform disorder symptoms.

**LEVOPRAID 50 Acts Faster Than Amitriptyline in Depression<sup>4</sup>**



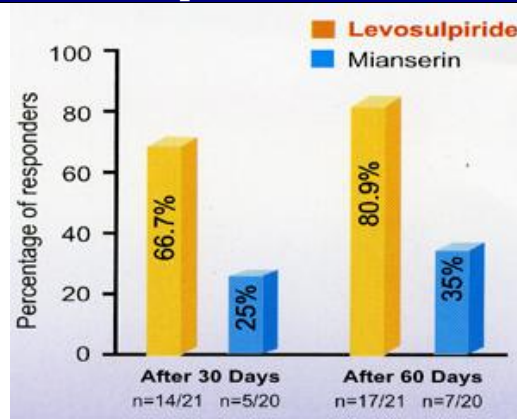
**No. of Patients: 28**

**Duration: 4 Weeks**

**Results:**

**LEVOPRAID 50** showed antidepressant activity comparable to Amitriptyline but its onset of effects was faster.

**LEVOPRAID 50 Achieves Higher Clinical Response Than Mianserin<sup>5</sup>**



**No. of Patients: 41** (21 on Levosulpiride and 20 on Mianserin) suffering from major depression or dysthymia. **Duration of Treatment: 60 days.** **Dose:** Levosulpiride 200-300 mg/day, Mianserin 90-120 mg/day

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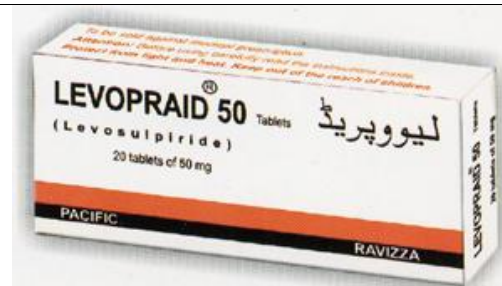
### **Safety Profile:**

The safety of Levosulpiride (LEVOPRAID 50 tablet bid) was assessed in 2145 patients with depressive disorders, over a period of 2-3 months at 60 Psychiatric centres all over Italy.

- ❖ The incidence of adverse reactions was very low
- ❖ The drop out of patients due to side effects was only 0.49%.
- ❖ No clinically noteworthy laboratory or ECG changes.<sup>3</sup>

### **Dosage:**

1 tablet of LEVOPRAID 50  
2-3 times daily.



### **Prescribing Information**

Composition: LEVOPRAID 50 tablets: Each tablet contains Levosulpiride.....50mg - LEVOPRAID 100 tablets: Each tablet contains Levosulpiride.....100 mg - Chemical classification: Levosulpiride is a substituted benzamide, chemically it is S-(-)-N(1-ethylpyrrolidine-2-yl-methyl 1-5-) sulfamoyl-benzamide. Therapeutic classification: Atypical Neuroleptic with stereoselective antidopaminergic action. Properties: The biochemical, pharmacological and clinical data obtained from the two sulpiride isomers indicate that the Antidopaminergic action, both on a central and peripheral level, is due to the levogyre enantiomer (levosulpiride). LEVOPRAID exhibits a clear antidepressive, anticenesthopathic, Uninhibiting and resocializing action. Due to its hallucinolytic and deliriolytic action, it is effective against acute and chronic schizophrenia. For depression LEVOPRAID is administered at lower dosages than those used in patients with schizophrenia. It is suggested that these low dosages involve a preferential action on the presynaptic DA-receptors, thus producing a functional increase of dopaminic transmission and stimulating motoric and psychic action. The antipsychotic effects of LEVOPRAID generated at high dosages may be due to a blocking of the post synaptic DA- receptors, although these effects are not a characteristic as those produced by classic neuroleptic agents. LEVOPRAID exerts its action at dosages which are 2-3 times lower than those of the racemic molecule, which entails a better tolerability and a reduced occurrence of collateral effects. Sedation, antimuscarinic effects, hypotension and extrapyramidal disorders are less of a problem than with most other neuroleptics. Pharmacokinetics: After oral administration, the bioavailability of L-sulpiride is about 30%. Peak-plasma concentration occurs

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after about 3 hours and it has plasma half life of about 9.7 hours. It is mostly eliminated by the kidneys in the urine. Indications: LEVOPRAID is indicated in the treatment of endogenous and reactive depressive states, Somatic disturbances, acute and chronic schizophrenia with predominant negative symptoms (After disorders). Dosage: Endogenous and reactive depressive states / somatic disturbances: For Adults 2-3 tablets of 50mg in divided doses daily. Acute and chronic schizophrenia: For Adults 2 - 3 tablets of 100mg daily. Maintenance Therapy: The dosages may be progressively lowered. When treating aged patients, the dosage must be carefully established by the physician who must consider a possible reduction in the dosage mentioned above. Contraindications: As with other neuroleptics, levosulpiride is also contraindicated in patients with hyperprolactinemic tendency, mammary dysplasias and malignant mastopathies. Precautions: LEVOPRAID is to be applied with caution in epilepsies, manic states, manic stages of manic-depressive psychoses, cases of hypertension in patients suspected to be carriers of phaeochromocytoma and in patients showing signs of cardiac insufficiency. Warnings: As with other neuroleptics, the association of levosulpiride with typical neuroleptics demands particular medical care and attention. In case of potentially fatal complex of symptoms, known as Malignant Neuroleptic Syndrome (hyperpyrexia, muscular rigidity, akinesia, vegetative disturbances, irregularities of pulse and arterial pressure, perspiration, arrhythmias, alteration of the conscious conditions, or numbness and coma). Under such circumstances, the treatment may be suspended, or should be continued if considered essential and patients must be carefully monitored. Drug interactions: As with other neuroleptics or substituted benzamide, the concomitant use of levosulpiride with therapeutic doses of sucralfate, or an antacid containing aluminium and magnesium hydroxide may reduce mean oral bioavailability of levosulpiride. Side Effects: Numbness, a sense of vertigo and asynchronisms may occur; patients under treatment must be made aware of these risks in order to avoid driving vehicles and attending to operations demanding total attention, due to their potential dangers. In very rare cases, psychomotoric excitement, neurovegetative disturbances and allergic phenomena have been observed. Isolated cases of an increase in body weight have been reported following prolonged treatment. All these effects are of a modest and reversible nature. Galactorrhoea and alterations of the libido, observed on particular occasions, are reducible to a reversible effect of levosulpiride on the functionality of the hypothalamus-pituitary-gonadic axis, which are similar to that known in many neuroleptics. Packing: LEVOPRAID 50 is available in a box of 2x10's tablets. M.R.P. Rs. 382.10. KEEP OUT OF THE REACH OF CHILDREN.

Ref:1. Scotta M et al, 1 Congresso Nazionale della Societa Italiana di Psicopatologia, Torino. 1996.  
2. international Journal of Psychiatry in Clinical Practice .Vol.7,No.3: Sep2003 .Crepaldi et al;  
1991. 4. Bocchetta et al, Acta Psychiatrica Scandinavia 1993; 88:434-9 5. Minervini Mg et al  
LEVOSULPIRIDE Nelle Syndrome Depressive: Confronto Con Mianserin Ravista Spermentable  
Freniatria 1989: CX III: 1277-88