Pharmaceutical Information

Dosage form/Description of product

Tablets	0.25 mg	0.5 mg	1 mg
Average weight	105 mg	150 mg	190 mg
Diameter	6 mm	7 mm	8 mm
Shape	round, biconvex, sugarcoated		
Colour	ochre yellow		

Incompatibilities
No known.

Storage conditions and shelf life
Fluanxol tablets should be stored at max. 25°C.

Each pack has open expiry date.

Keep out of reach of children.

Packs
0.25 mg: 50 and 100
0.5 mg: 50 and 100
1 mg: 50 and 100

Manufactured by
H. LUNDBECK A/S
DK-2500 Copenhagen, Denmark

Lundbeck

Fluanxol®
(flupentixol)

Rapid antidepressant and anxiolytic effect

Composition

Each coated tablet contains flupentixol dihydrochloride corresponding to 0.25 mg, 0.5 mg, or 1 mg flupentixol.

The tablets contain lactose.
Colour: Yellow iron oxide.

Pharmacological Information

Pharmacological effects and mode of action

Fluanxol given in daily doses of up to 3 mg possesses antidepressant, anxiolytic and activating properties which have been shown in many controlled, clinical trials.

The effect of Fluanxol can be seen promptly, i.e. during the first week of treatment and also ceases soon after discontinuation.

Pharmacokinetics

The bioavailability after oral administration of flupentixol is about 40%. Maximum serum concentration is reached in 3 to 6 hours. Flupentixol in small amounts crosses the placental barrier; flupentixol is excreted in small amounts with the milk. The metabolites are devoid of psychopharmacological activity. The excretion proceeds mainly with feces but also to some degree with the urine. The biological half-life is about 35 hours.

Clinical Information

Indications

Depression involving anxiety, asthenia, and lack of initiative.

Chronic neuroses with anxiety, depression, and inactivity. Psychosomatic disorders with asthenic reactions.

Acute and situational anxiety and tension states in which a sedative/hypnotic effect is not required, and especially when the patient is considered in danger of abusing minor tranquillizers.

Contraindications

Acute alcohol, barbiturate, and opiate poisoning, comatose states. Not recommended for excitable or overactive patients since its activating effect may lead to exaggeration of these characteristics.

Adverse effects

Occasional: Restlessness and/or insomnia.

Rare: Extrapyramidal symptoms, if recommended dosage is exceeded.

Precautions

Fluanxol should be used with caution in patients with severe hepatic disease.

If previously the patient has been treated with tranquillizers with a sedative effect these should be withdrawn gradually.

Use during pregnancy and lactation

Fluanxol should preferably not be given during pregnancy and lactation.

Drug interactions

Fluanxol in high doses may enhance the response to alcohol and the effects of barbiturates and other CNS depressants. Fluanxol should not be given concomitantly with guanethidine or similar acting compounds, since neuroleptics may block the antihypertensive effect of these compounds. Fluanxol may lower the effects of levodopa and adrenergic drugs and concomitant use of metoclopramide and piperazine increases the risk of extrapyramidal symptoms.

Dosage regimen

Adults:

Initially 1 mg daily as a single morning dose or 0.5 mg twice daily. After one week the dosage may be increased to 2 mg daily if there is inadequate clinical response. Daily dosage of more than 2 mg should be in divided doses up to a maximum of 3 mg.

Patients often respond to Fluanxol within two or three days. If no effect has been observed within one week of maximum dosage (3 mg daily) the drug should be withdrawn.

Overdosage

Symptoms: Somnolence, coma, extrapyramidal symptoms, convulsions, hypotension, shock, hypo- or hyperthermia.

Treatment: Symptomatic and supportive. Gastric lavage should be carried out as soon as possible and activated charcoal may be administered. Measures aimed at supporting the respiratory and cardiovascular systems should be instituted. Epinephrine (adrenaline) should not be used as further lowering of blood pressure may result. Convulsions may be treated with diazepam and extrapyramidal symptoms with biperiden.