

Only for the use of Medical Professionals

Adelax[®]

Flupentixol+Melitracen

Presentation

Adelax[®] Tablet: Each coated tablet contains Flupentixol 0.5mg as Dihydrochloride BP and Melitracen 10mg as Hydrochloride INN.

Description

Adelax[®] is a combination preparation of two well known and time tested molecules: *Flupentixol*-a neuroleptic with anxiolytic and antidepressant properties of its own when given in small doses and *Melitracen*-a bipolar thymoleptic with activating properties in low doses. In combination, the compounds exert antidepressant, anxiolytic and activating properties.

Maximum serum concentration is reached in about 4 hours after oral administration of both Flupentixol and Melitracen. The biological half-life of Flupentixol is about 35 hours and that of Melitracen is about 19 hours. The combination of Flupentixol and Melitracen does not seem to influence the pharmacokinetic properties of the individual compounds.

Indications

Adelax[®] is indicated for the treatment of different types of anxiety, depression and apathy. These include:

- Psychogenic depression
- Depressive neuroses
- Masked depression
- Psychosomatic affections accompanied by anxiety apathy
- Menopausal depressions
- Dysphoria and depression in alcoholics and drug addicts

Adelax[®] is also indicated for maintenance in psychogenic depressions and other psychoses.

Dosage & administration

Adults : Usually 2 tablets daily : morning and noon.

In severe cases the morning dose may be increased to 2 tablets.

Elderly patients : 1 tablet in the morning.

Maintenance dose : Usually 1 tablet in the morning.

In case of insomnia and severe restlessness additional treatment with sedative in the acute phase is recommended.

Contra-indications, warnings, etc.

Side-effects: In the recommended doses side-effects are rare. *Restlessness, insomnia, hypomania reported, rarely dizziness, tremor, visual disturbances, headache, hyperprolactinaemia, extrapyramidal symptoms* may be observed.

Contra-indications: The immediate recovery phase after myocardial infarction. Defects in bundle-branch conduction. Untreated narrow angle glaucoma. Acute alcohol, barbiturate and opiate intoxications. Flupentixol-Melitracen combination should not be given to patients who have received a MAO-inhibitor within two weeks. Not recommended for excitable or overactive patients since its activating effect may lead to exaggeration of these characteristics.

Precautions: If previously the patient has been treated with tranquilizers with sedative effect these should be withdrawn gradually.

Use in pregnancy and lactation: Flupentixol-Melitracen combination should preferably not be given during pregnancy and lactation.

Drug interactions: Flupentixol-Melitracen combination may enhance the response to alcohol, barbiturates and other CNS depressants. Simultaneous administration of MAO-inhibitors may cause hypertensive crises. Neuroleptics and thymoleptics reduce the antihypertensive effect of guanethidine and similar acting compounds and thymoleptics enhance the effects of adrenaline and noradrenaline.

Overdosage: Symptoms: In case of overdosage the symptoms of intoxications by Melitracen, especially of anticholinergic nature, dominate. More rarely extrapyramidal symptoms due to Flupentixol occur. **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) must not be used for such patients. Convulsions may be treated with diazepam and extrapyramidal symptoms with biperiden.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Package quantities

Adelax[®] Tablet: Carton of 80 tablets in blister.

Adelax[®] Tablet: Carton of 50 tablets in blister (for Export).

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