

Xolitra

Flupentixol + Melitracen

Composition

Each tablet contains Flupentixol Dihydrochloride BP equivalent to Flupentixol 0.5 mg and Melitracen Hydrochloride INN equivalent to Melitracen 10 mg.

Description

Xolitra consists of two well known and well proven compounds: 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 render a preparation with antidepressant, anxiolytic and activating properties.

Maximal serum concentration is reached in about 4 hours after oral administration of flupentixol and in about 4 hours after oral administration of 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 and Uses

Xolitra is indicated in various types of anxiety, depression and apathy. These include-

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

Contraindications

The immediate recovery phase after myocardial infarction. Defects in bundle-branch conduction. Untreated narrow angle glaucoma. Acute alcohol, barbiturate and opiate intoxications. Flupentixol-Melitracen 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.

Dosage and Administration

Adults:

Usually 2 tablets daily : In the 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 cases of insomnia or severe restlessness additional treatment with sedative in the acute phase is recommended.

Precautions

If previously the patient has been treated with tranquilizers with sedative effect these should be withdrawn gradually.

Side Effects

In the recommended doses side-effects are rare. These could be transient restlessness and insomnia.

Use in pregnancy & lactation

Flupentixol-Melitracen should preferably not be given during pregnancy and lactation.

Overdosage

Symptoms: In cases 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 Information

Storage conditions

Store in a cool and dry place away from light. Keep out of the reach of children.

Presentation and packaging

Each commercial box contains 50 tablets in blister-pack.

Manufactured By

BEACON[®]
Pharmaceuticals PLC

Bhaluka, Mymensingh, Bangladesh