



Melixol[®]

Flupenthixol and Melitracen
Psycholeptic antidepressant

COMPOSITION

Melixol[®] tablet : Each tablet contains Flupenthixol INN 0.5 mg (as di-hydrochloride) and Melitracen INN 10 mg (as hydrochloride).

PHARMACOLOGY

Melixol[®] tablet contains two ingredients, Flupenthixol INN (as di-hydrochloride) and Melitracen INN (as hydrochloride). Among the two active ingredients, Flupenthixol primarily acts as a neuroleptic drug. The antipsychotic effect of Flupenthixol is achieved by mixed blockade of dopamine D1 and D2 receptors. In the mesolimbic dopamine system of the brain, this accounts for the antipsychotic action of this drug. Flupenthixol has other effects on CNS. In the chemoreceptor trigger zone, the dopamine blockade accounts for the antiemetic effect of the drug.

Melitracen is a tricyclic antidepressant. It blocks the neuronal re-uptake of both serotonin and nor-epinephrine in the central nervous system, thereby minimizing the symptoms of depression.

INDICATION

Melixol[®] is indicated in anxiety along with depression and apathy. These includes:

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

DOSAGE AND ADMINISTRATION

Adults : In general 2 tablets per day, morning and at midday. For the severe cases, the amount of the morning dose can be increased to 2 tablets.

Elderly patients : One tablet in the morning.

Maintenance dose : 1 tablet in the morning. In cases of insomnia or severe restlessness additional treatment with a sedative in acute phase is recommended.

Children :

This tablet is not for paediatric use.

CNS PREPARATIONS

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Melixol®

CONTRAINDICATION

At the time of over-sensitiveness to Melitracen or Flupenthixol.

This tablet is contra-indicated at the time of depression of the CNS (e.g. at the time of acute intoxications to alcohol, barbiturates or opiates), state of coma, pheochromocytoma, blood dyscrasy. The administration of this is not advised in the phase of immediately consecutive recovery to a myocardial infarction, at the time of a cardiac block of any rank, disorders of cardiac conduction as well as coronary insufficiency. The concomitant administration of inhibitors of the MAO is contra-indicated.

To observe 14 days a therapeutic pause after a former treatment by inhibitors of MAO of the irreversible type.

PRECAUTION AND WARNING

The administration of this requires prudence among patients presenting an organic cerebral lesion, convulsions, urinary retention, hyperthyroid, parkinson's syndrome, serious myasthenea, advanced hepatic affection as well as cardiovascular disorders.

Because it has a stimulating effect, this is not recommended at the agitated patients. To stop the sedatives gradually if an administration took place in pre-processing.

Among depressive patients, the risk of suicide remains during the treatment, until the appearance of a marked remission of the depressive symptoms.

During the treatment, the patients having a tendency to suicide should not have access to the drug in great quantities.

As for the other psychotropic ones, this combination tablet can deteriorate the tolerance with glucose and insulin. An antidiabetic adaptation of the treatment can prove to be necessary.

Because it dilates the pupil, this tablet can cause an acute crisis of glaucoma among patients having glaucoma at closed angle or a narrowness of the irido-corneal angle.

The administration of anaesthetic buildings during a treatment by tricyclic or tetracyclic antidepressants can increase the risk of arrhythmias and hypotension. If possible a treatment by this tablet may be stopped a few days before an operation envisaged. One should inform the anaesthetist in the emergency cases where the treatment cannot be stopped in advance.

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As for all nerve sedatives, a syndrome nerve sedative (potentially fatal) can seldom occur.

Extrapyramidal disorders can occur in very rare cases, mainly at the beginning of a treatment by Flupenthixol. Potentially irreversible late dyskinesia are possible during one long-term treatment with nerve sedatives like the Flupenthixol.

To regularly control the psychological and neurological situation, the blood picture and the hepatic function of the patients under long-term treatment by Flupenthixol should be monitored.

SIDE EFFECT

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

USE IN PREGNANCY AND LACTATION

This tablet should preferably not be given during pregnancy and lactation.

STORAGE CONDITION

Melixol[®] tablet should be stored at a cool and dry place, protect from light and moisture.

HOW SUPPLIED

Melixol[®] Tablet : Each box contains 5X10's tablet in blister pack.

