

**SERNIL®  
TABLET**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

**Information about SERNIL**

SERNIL tablet for oral use contains flupentixol dihydrochloride equivalent to 0.5 mg flupentixol and melitracen hydrochloride equivalent to 10 mg melitracen.

Excipients are: Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

SERNIL is a combination of flupentixol, a neuroleptic with anxiolytic and antidepressant properties of its own when given in small doses and melitracen, a tricyclic antidepressant with activating properties in low doses.

SERNIL is a neuroleptic, anxiolytic and antidepressant indicated in the following conditions:

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

This medicine may be used to treat other conditions as well.

**The way to take SERNIL**

Take SERNIL as directed by your physician. Do not discontinue the treatment without consulting your doctor.

The usual recommended dose for adults is 2 tablets daily (one in the morning and one at noon). In severe cases the morning dose may be increased to 2 tablets.

For elderly patients, the dose is 1 tablet in the morning.

The maintenance dose is usually 1 tablet in the morning

**Duration of treatment**

The duration of treatment will be decided by your doctor. Do not discontinue therapy of your own accord even if you feel better; you may require continuous treatment for quite some time. You should be periodically reassessed to determine the need for maintenance therapy with an appropriate dose.

**In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

**In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

**Contraindications**

This drug is contra-indicated in the following conditions:

- Hypersensitivity to flupentixol and melitracen or to any of the excipients.
- Recent myocardial infarction and any degree of atrioventricular block or disorders of cardiac rhythm and coronary artery insufficiency.
- Coma, blood disorders, phaeochromocytoma.
- Untreated narrow-angle glaucoma.
- Central nervous system depression (alcohol, barbiturate and opiate intoxications).

- In combination with MAOI or in patients who have received a MAOI within 2 weeks.
- Excitable or overactive patients.

**Precautions**

- Caution should be taken when this drug is administered for patients with liver problem, a history of convulsions, diabetes, organic brain syndrome, urinary retention, thyroid gland disorders, prostatic hypertrophy, Parkinson syndrome, myasthenia gravis, cardiovascular disorders, narrow angle glaucoma and predisposing factors to venous thromboembolism.
- Close monitoring for changes in behaviour, suicidal thoughts or clinical worsening during the initial part of the treatment is recommended.
- In case of long term treatment your blood formula and liver function should be monitored regularly.
- Inform your doctor that you are taking this drug if you are going to have an operation and receive general or local anesthetics.
- You should be cautious when driving a car or operating machinery, until you are certain that you are not adversely affected by drowsiness or dizziness.
- Inform your doctor before using this medication in case of pregnancy or lactation.
- Safety and effectiveness of this drug in pediatric patients under 18 years of age have not been established.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.  
Concomitant use with a MAOI or within 14 days of discontinuing treatment with a MAOI is contraindicated.

This product may enhance the influence of alcohol, barbiturates, and CNS depressants. It is advised not to drink alcohol during treatment with this drug.

Use with caution with: lithium, adrenaline, epinephrine, isoprenaline, phenylephrine, phenylpropanolamine, anticholinergics, blood pressure lowering agents, drugs which cause drowsiness, anti-epileptic drugs, levodopa, metoclopramide, piperazine, products with a QT-prolonging effect, drugs responsible for electrolyte and fluid imbalances.

**Adverse reactions**

The most common side effects include: insomnia, restlessness, agitation, dizziness, tremor, dry mouth, constipation, blurred vision, fatigue.

Inform your doctor if any adverse effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (below 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

SERNIL, flupentixol 0.5 mg and melitracen 10 mg, pack of 100 tablets

**Issue date:** 11/2011

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