

SEDOXIL

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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1. WHAT SEDOXIL IS AND WHAT IT IS USED FOR

SEDOXIL, tablets – mexazolam 1 mg, per tablet.

The other ingredients are mannitol, maize starch, hydroxypropyl cellulose, sodium lauryl sulphate, and calcium stearate.

PHARMACEUTICAL FORM:

SEDOXIL, tablets, box with 60 tablets.

PHARMACOTHERAPEUTIC CATEGORY:

The active substance is mexazolam.

SEDOXIL is an anxiolytic agent, benzodiazepines group.

SEDOXIL is used for the management of anxiety disorder associated or not to psychoneurotic conditions.

Benzodiazepines are only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.

Marketing Authorisation Holder: BIAL– Portela & C^a, S.A., Portugal

Manufacturer: BIAL – Portela & C^a, S.A., Portugal

2. BEFORE YOU TAKE SEDOXIL

Do not take SEDOXIL:

- if you are hypersensitive (allergic) to mexazolam or to benzodiazepines;
- if you suffer from a disease called myasthenia gravis;
- if you have severe respiratory insufficiency, sleep apnoea syndrome or severe hepatic insufficiency.

Take special care with SEDOXIL:

- Benzodiazepines should be used with extreme caution in patients with a history of drug abuse and alcoholism.
- SEDOXIL should be used with caution in patients with cardiac, renal or hepatic disorders and in patients with encephalic organic disorders.

Taking SEDOXIL with food and drink:

Do not take SEDOXIL with alcohol. The sedative effect may be enhanced when SEDOXIL is used in combination with alcohol; this affects the ability to drive or use machines.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Although clinical trials in animals did not suggest any harm of mexazolam during pregnancy, its safety in humans was not established during pregnancy.

Benzodiazepines may cause congenital abnormalities when administered in the first trimester of pregnancy. If for compelling reasons SEDOXIL is administered during the late phase of pregnancy or during labour at high doses, effects on the neonate such as hypothermia, hypotonia and moderate respiratory depression can be expected.

Infants born to mothers who took benzodiazepines chronically during pregnancy may have developed physical dependence and may be at some risk for developing withdrawal symptoms in the postnatal period.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Since mexazolam may be found in the breast milk, it should not be given to breast-feeding mothers.

Driving and using machines:

Sedation, amnesia, impaired concentration and impaired muscular function resulting from the administration of SEDOXIL may adversely affect the ability to drive or use machines.

If insufficient sleep duration occurs the likelihood of impaired alertness may be increased.

Do not drive or use hazardous machine while taking this medicine.

Important information about some of the ingredients of SEDOXIL:

- SEDOXIL contains mannitol.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Take into account the association with CNS depressants. Enhancement of the central depressive effect may occur in cases of concomitant use of SEDOXIL with antipsychotic (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressant agents, narcotic analgesics, anti-epileptic products, anesthetics, and antihistamine sedatives.

In the case of narcotic analgesics enhancement of the euphoria may also occur leading to an increase in psychic dependence.

In pre-clinical studies with animals the following interactions were reported: *Drugs enhancing mexazolam effects:* chlorpromazine, haloperidol, diazepam, cyproheptadine, Aminopirine, phenobarbital, ethanol, sulpiride, trichlormethiazide and alpha-methyldopa. *Drugs antagonising mexazolam effects:* imipramine, amitriptyline and chlorpheniramine. *Drugs which have not shown interaction with mexazolam:* diphenylhydantoin, scopolamine butylbromide, gefarnate, propranolol and pindolol.

3. HOW TO TAKE SEDOXIL

Always take SEDOXIL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage should be individualised according to the age of patient and severity of symptoms.

Adults: average dose is 1 – 3 mg daily, preferably divided in three doses. A lower dosage is recommended for patients with chronic respiratory insufficiency.

Elderly patients: do not exceed 1,5 mg daily.

Children: Not for pediatric use.

If you have the impression that the effect of SEDOXIL is too strong or too weak, talk to your doctor or pharmacist.

Treatment of anxiety should be as short as possible.

The patient should be reassessed regularly and the need for continued treatment should be evaluated, especially in case the patient is symptom free.

The overall duration of treatment should be as short as possible, depending on the indication, but should not exceed 8-12 weeks in case of anxiety, including tapering off process. In certain cases extension beyond the maximum treatment period may be necessary; if so, it should not take place without reevaluation of the patient's status with special expertise.

In any case treatment should be started with the lowest recommended dose.

The patient should be checked regularly and kept under observation at the start of the treatment in order to decrease if necessary, the dose or frequency of administration to prevent overdose due to accumulation.

If you take more SEDOXIL than you should:

As with other benzodiazepines, overdose should not present a threat to life, unless combined with other CNS depressants, including alcohol.

Overdose of benzodiazepines is usually manifested by central nervous system depression, ranging from drowsiness to coma. In mild cases symptoms include drowsiness, mental confusion and lethargy, and in more serious cases, symptoms include ataxia, hypotonia, hypotension, respiratory depression, rarely coma and very rarely death.

If a large amount of SEDOXIL is taken all at once, immediately contact your doctor or an emergency service, showing them the SEDOXIL package.

If you forget to take SEDOXIL:

In case of a missing dose after more than 1 hour as scheduled do not take it. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with SEDOXIL is stopped:

SEDOXIL must be taken to the end of the prescribed course of treatment. Do not stop the treatment if you feel better. If you have any doubts, ask your doctor or pharmacist.

Dependence – Even at therapeutic doses, use of benzodiazepines may lead to the development of physical and psychic dependence upon these products. The risk of dependence increases with dose and duration of treatment, and is also greater in patients with a history of drug abuse or alcoholism. Once physical dependence has developed, abrupt termination of the drug will be accompanied by withdrawal symptoms; these may consist of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases the following symptoms may occur: derealization, depersonalization, hyperacusis, numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

When benzodiazepines with a long duration of action, as mexazolam, are being used it is important to warn against changing to a benzodiazepine with a short duration of action, as withdrawal symptoms might develop.

Rebound of anxiety - A transient syndrome, whereby the symptoms that led to treatment with a benzodiazepine recur in an enhanced aggravated form, may occur on withdrawal of treatment. It may be accompanied by other reactions including mood changes, anxiety or sleep disturbances and restlessness. Since the risk of rebound phenomena is greater after abrupt discontinuation of the drug, it is recommended that the dosage be decreased gradually.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SEDOXIL can have side effects.

The most frequent side effects of benzodiazepines are likely to be an extension of the pharmacological actions and include drowsiness during the day, numbed emotions, reduced alertness, confusion,

fatigue, headache, light-headedness, muscle weakness, ataxia or double vision. If you notice any of these symptoms, contact your doctor as soon as possible.

Pre-existing depression may recur when benzodiazepines are used.

Benzodiazepines may induce anterograde amnesia. The condition occurs most often several hours after ingesting the product and therefore to reduce the risk, patients should ensure that they would be able to have an uninterrupted sleep of 7-8 hours.

Reactions like restlessness, agitation, irritability, aggressiveness, delusions, rage, nightmares, psychoses, inappropriate behaviour and other related adverse behavioural effects are known to occur and become particularly severe with benzodiazepines. They are more likely to occur in children and the elderly.

Rarely (<0,1%) the following adverse events were reported with mexazolam: altered tongue movements, hypotension, light-headedness, nausea, vomiting, anorexia, gastric discomfort, gastric pain, abdominal pain, diarrhoea, hypersensitivity reactions (e.g. skin reactions), decreased libido, increase of alkaline phosphatase, anaemia and leukopenia. Commonly (0.1 - 5%) were reported drowsiness, vertigo, dizziness, headache, ataxia, dry mouth, weakness, increase of aspartate aminotransferase, alanine aminotransferase and gamma-glutamyl-transpeptidase.

Side effects occur predominantly at the start of therapy and usually disappear upon continued administration.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SEDOXIL

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the pack.

In order to protect from light, store in the original package.

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