

PACKAGE LEAFLET: INFORMATION FOR THE USER

Δ MENDILEX

2 mg tablets

BIPERIDEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Mendilex is and what it is used for
2. Before you take Mendilex
3. How to take Mendilex
4. Possible side effects
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1. WHAT MENDILEX IS AND WHAT IT IS USED FOR

Biperiden belongs to a group of medicines called anticholinergics, which act by blocking certain natural substances (acetylcholine). In this way it helps reduce muscle stiffness, sweating, saliva and improves the ability to walk in people with Parkinson's disease.

Anticholinergics can stop severe muscle spasms in back, neck and eyes, which are sometimes caused by psychiatric medicines. It can also reduce other unwanted effects, such as muscle rigidity/stiffness (extra pyramidal signs). It is not useful in treating problems of movement that are caused by Tardive dyskinesia and it can exacerbate them.

Mendilex is used to treat and control the symptoms of Parkinson's disease. It can also be used to control undesirable effects caused by certain medicines.

2. BEFORE YOU TAKE MENDILEX

Do not take Mendilex:

- if you are allergic (hypersensitive) to biperiden or any of the other ingredients of the medicinal product,

- if you have myasthenia gravis (a certain muscle diseases),
- if you suffer from narrow angle glaucoma,
- if you have megacolon (abnormal dilation of the colon),
- if you have bladder blockage/esophagus/stomach/intestines (such as bowel obstruction), severe ulcerative colitis and
- during acute blood loss.

Be careful with Mendilex if you have:

- prostate hypertrophy,
- epilepsy or other problems with seizures,
- heart problems (e.g., angina, heart attack, heart failure) or heart rhythm disturbances (rapid/irregular heartbeat),
- high blood pressure,
- intestinal problems (e.g., chronic constipation, ileus, ulcerative colitis),
- stomach problems (e.g., acid reflux, hernia, ulcers) and
- mental problems, mood problems (e.g., anxiety, psychosis).

This medicine may cause decreased sweating, which can lead to a high-rise in body temperature (hyperthermia). The risk of this serious unwanted effects are higher during warm days, during intense exercise and/or if you drink alcohol.

If you have signs of hyperthermia, such as mental problems, mood changes, headaches or dizziness, seek cold air conditioned shelter and/or stop exercising and seek medical help.

Safety and effectiveness in children have not been established.

Taking other medicines with Mendilex

Please tell your doctor or pharmacist about all medicines you are taking or have recently taken, including ones that you bought without a prescription.

Simultaneous use of Mendilex with the following medicines is not recommended :

- certain narcotic analgesics, such as meperidin,
- fenotiazine and other antipsychotics,
- tricyclic antidepressants,
- antiarrhythmics like quinidine salt and
- antihistamines.

Taking food and drinks

Alcohol consumption should be avoided during therapy with biperiden.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before you start to use any medicine.

During pregnancy, the biperiden should be avoided. If breast-feeding, medicine in breast milk can lead to unpleasant anti cholinergic effects in infants. Biperiden may be given in pregnancy and during lactation only if necessary.

Driving and using machines

Trigonic, a medicine with the possible influence of the psycho-physical capabilities (warning when operating motor vehicles and machinery).

Medicine strongly affects psychophysical abilities. Driving a vehicles or handling machines is forbidden during therapy with biperiden.

What you need to know about other substances contained in Mendilex

Mendilex contains lactose. If a doctor told you that you have intolerance to some sugars, before you start taking this medicine, consult your doctor.

3. HOW TO TAKE MENDILEX

Always take Mendilex as prescribed by a doctor. If you are not sure how, consult a doctor or pharmacist.

The dose is gradually increased until the optimal dose is reached.

The usual starting dose is 2 mg/day, divided into two individual doses. The dose is gradually increased until the optimal daily dose, which for a large number of patients is 3 mg to 12 mg, divided into three or four individual doses. The maximum daily dose is 16 mg.

The usual dose for adults for control of extra pyramidal disorders caused by medicines (Neuroleptics) is 2 mg, one to three times a day.

With spastic states the recommended dose is 2 mg, two to three times a day.

If you take more Mendilex than you should

An overdose with biperiden causes the typical symptoms of atropine intoxication, such as dilated pupils and hot and dry skin, facial redness, reduced secretions in the mouth and upper respiratory tract infection, fever, tachycardia, cardiac arrhythmia, decreased motility of the intestine and urinary retention, delirium, disorientation, anxiety, hallucinations, confusion, hyperactivity, ataxia, restlessness and convulsions.

If you forget to take Mendilex

In case you forget to take your medication do not take a double dose to make up for the one you missed.

Take the medicine as soon as you remember if you miss a dose. If it is almost time for your next dose, wait until then and skip the missed dose.

If you have any further questions on the use of Mendilex, talk to your doctor or to the pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mendilex may cause side effects, although not everybody gets them.

If you experience any of these side effects please stop taking medication and seek medical help:

- severe allergic reactions (rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue),
- fever,
- fast, slow, or irregular heartbeat,
- anxiety, hallucinations, confusion, restlessness, hyperactivity or unconsciousness,
- cramps and
- rash on the skin.

You are more likely to experience less serious side effects. Continue to take biperiden, and talk to your doctor if you notice one of the following symptoms:

- dry mouth, stomach discomfort,
- mydriasis or blurred vision,
- fatigue, drowsiness, dizziness,
- ataxia (lack of coordination of muscle movements),
- have movements that you cannot control, mainly the tongue, lips, jaw, hands and feet,
- impaired memory,
- difficulty urinating, constipation,
- nervousness or anxiety and
- decreased sweating.

If you notice any side effect, talk to your doctor or pharmacist.

5. HOW TO STORE MENDILEX

Keep out of reach and sight of children.

Mendilex should not be used after the expiration date stated on the carton. Expiration date refers to the last day of that month.

This product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to remove medicines that you no longer need. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Mendilex contains

- Active substance is biperiden.
- Each tablet contains biperiden hydrochloride 2 mg.
- Other substances are: lactose monohydrate; microcrystalline cellulose; magnesium stearate.

How Mendilex looks like and contents of the Pack

Mendilex tablets are white, round, biconvex tablets with breaking line on one side.

The tablets are packaged in blister pack of AL/PE films, each with 10 tablets.

The box contains 50 tablets (5 blisters) of 2 mg, with the attached instructions.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Alkaloid AD
Bulevar Aleksandar Makedonski 12, Skopje, Macedonia

Manufacturer of the medicinal product

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Bulevar Aleksandar Makedonski 12, Skopje, Macedonia