

GILEX

10 mg

Cap sules

Composition:

Each capsule contains:

Doxepin (as HCl) 10 mg

For the list of excipient see chapter 6 "further information"

GILEX

25 mg

Capsules

Each capsule contains:

Doxepin (as HCl) 25 mg

Read this package insert carefully in its entirety before using this medicine.

This leaflet contains essential information of this medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

This medicine is intended for administration to adults and children over 12 years of age.

1. What is this medicine intended for?

For the treatment of anxiety and depression.

Therapeutic Group: Doxepin is tricyclic antidepressant.

2. Before use this medicine:

Do not take this medicine if:

- You are sensitive (allergic) to doxepin, or to any other ingredient of This medicine, or to any other tricyclic antidepressant.
- You have a difficulty in passing urine.
- You have glaucoma.
- You suffer from impaired function of the liver.
- You are breastfeeding.
- You are children under 12 years of age.
- You are taking, or have taken in the last two weeks, any medicines called Monoamine Oxidase Inhibitors (MAOIs)
- You suffer from a type of mood disorder called mania.

Special warning concerning the medicine use:

Do not take this medicine without consulting a doctor before starting treatment if:

- You are pregnant or **trying to become pregnant**
- You are suffering, or have suffered in the past, from impaired function of the heart or the kidney
- You have had a heart attack recently
- You suffer from epilepsy
- You have suicidal thoughts or have attempted suicide in the past

Warnings:

This medicine may cause a special sensitivity when the patient is exposed to the sun, therefore, avoid exposure to the sun and take appropriate precautions (long clothes, a hat, protective creams, etc.).

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Elderly patients are more sensitive to the effects of this medicine.

Caution should be exercised when getting up from sitting/lying position to a standing position because of possible dizziness.

The doctor should be informed that you are taking this medicine if you are about to undergo any medical tests or a surgery (including dental surgery).

Suicides, suicidal thoughts or clinical worsening:

If you suffer from depression you may have suicidal thoughts or even harm yourself. These phenomena may increase when you start treatment with antidepressants, since it usually takes two weeks or even more until these drugs begin to act. You may be more likely to think like this if:

- You have suicidal thoughts in the past
- You are under 25 years of age. Information from clinical trials has shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behavior.

Drug interactions:

If you are taking another drug concomitantly, including non-prescription medicines and dietary supplements, or if you have just finished treatment with them, inform the attending doctor or pharmacist. This is especially important for medicines belonging to the following groups:

- Monoamine Oxidase Inhibitors (MAOIs) antidepressants. You should stop taking them two weeks before taking this medicine.
- Tricyclic antidepressants.
- Other antidepressants, barbiturates (used to treat insomnia) or other sleeping medicines or medicines for anxiety.
- Medicines to lower blood pressure.
- Cimetidine.
- Thyroid hormones (used to treat thyroid disorders)
- Sympathomimetics, such as nasal decongestants and bronchodilators (used to treat asthma)
- Chlorpromazine (used to treat mental illness)
- Sublingual nitrates (used to treat angina and heart failure).

Use of this medicine and food: Do not chew! Swallow the medicine with water.

Use of this medicine and alcohol: Do not drink wine or alcoholic beverages while under treatment with this medicine.

Pregnancy and breast-feeding: Do not take this medicine during pregnancy, or if you are planning to become pregnant unless advised by your doctor. There are reports about newborns that suffered from complications right after birth. Consult your doctor about the possible risks against the possible benefit of taking Gilex while pregnancy. Do not take this medicine if you are breast-feeding.

Driving and using machines: Use of this medicine may impair alertness and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery and in any other activity which requires alertness. Children should be cautioned against engaging in activities such as bicycle riding, playing near roads and the like. Do not drive or work with machinery until the sleeping effect of the medicine has worn off.

Important information about some of the ingredients of Gilex capsules: Gilex 10 mg contains 162.96 mg of lactose and Gilex 25 mg contains 144.27 mg of lactose. Consult your doctor if you are sensitive to lactose.

3. How should you use the medicine?

Always take this medicine exactly as instructed by the attending doctor. If you are unsure how to use this medicine, you should consult your doctor or your pharmacist.

Dosage is according to doctor's instructions only.

This medicine is not intended for administration to children under 12 years of age.

Do not exceed the recommended dosage. This medicine is to be taken at specific time intervals as determined by the attending doctor. If you are elderly these doses may be reduced.

If you are elderly and require an increased dose of the medicine your doctor may wish to see you regularly.

If you suffer from liver problems you may also be started on a low dose.

Do not chew! Swallow the medicine with water. Don't crush the capsule.

Don't take the medicine with alcoholic beverages.

You may have to take Gilex for 2-3 weeks before you start to feel better. You must keep taking Gilex to help you get better. See your doctor before your capsules run out. Even if you begin to feel better, keep taking your capsules.

Medical tests: Taking this medicine can cause abnormal blood tests results (change in blood sugar levels, lower sodium content of blood and low blood cell count). If you undergo these tests, inform the medical staff that you take this medicine.

If you have accidentally taken an overdose, or if a child has accidentally swallowed the medicine, contact immediately the doctor or proceed immediately to a hospital emergency room and bring the package of the medicine with you. Taking an overdose might be dangerous. Possible signs of an overdose: drowsiness, numbness, blurred vision, dry mouth. Possible signs of a severe overdose: loss of consciousness, reduced breathing rate, convulsions, low blood pressure, unusually fast heart beat or palpitations.

If you forget to take this medicine at the specified time take the dose as soon as you remember, but never take a double dose to compensate for a missed one. Take the next dose at the usual time and consult your doctor.

You should always consult with your doctor before you stop treatment. Your doctor may want you to reduce gradually the amount you are taking before stopping the medicine completely. This may help to prevent a recurrence of the original trouble and reduce the chance of withdrawal effects such as insomnia, irritability and excessive sweating.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side Effects:

Like all medicines, Gilex capsules use can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible events. You may not have any of them.

Suicides, suicidal thoughts or clinical worsening:

If you suffer from depression you may have suicidal thoughts or even harm yourself. These phenomena may increase when you start treatment with antidepressants, since it usually takes two weeks or even more until these drugs begin to act. You may be more likely to think like this if:

- You have suicidal thoughts in the past
- You are under 25 years of age. Information from clinical trials has shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behavior.

Bone fractures: An increased risk of bone fractures has been observed in patients taking this type of medicine.

Gilex is well tolerated. Most undesirable effects are usually mild and tend to wear off after continued treatment. However, if the side effects are troublesome, your doctor may decide to reduce your dose.

The most common side effects are:

- Drowsiness
- Dry mouth
- Constipation

These are usually mild. If they last for more than several days, check with your doctor.

Less common or rare side effects listed below. If they don't wear off after a few days or trouble you, check with your doctor.

- Dizziness (if you experience dizziness you should be particularly careful to stand up slowly)
- Sweating
- Blurred vision
- Headache
- Insomnia
- Difficulty in passing urine
- Tiredness
- Weakness
- Weight gain
- Upset stomach
- Loss of appetite
- Vomiting or diarrhea
- Mouth ulcers
- Unpleasant taste
- Fast heart beat (palpitations)
- Changes in sex drive
- Swelling of testicles
- Chills
- Flushing
- Hair loss from the scalp
- Shakiness or trembling
- Numbness in the hands or feet
- Feeling of pins and needles
- Agitation or confusion
- Ringing or buzzing in the ears

Rare side effects: The undesirable effects below are rare but they have occurred in patients taking one of the tricyclic antidepressants, however, not all have occurred with Gilex.

You should check with your doctor immediately if any of the following occur:

- Skin rash, itching, face swelling. Your skin may be more sensitive to sunlight than it is normally.
- At high doses particularly in the elderly, unwanted effects on muscles which may cause slowed movements or stiffness of arms and legs, slurred speech or odd tongue or eye movements.
- Staggering walk which may occur on a mixture of centrally acting drugs.
- Worsening of an existing mental disorder.
- Breast enlargement in both men and women, breast milk production when you are not pregnant or breast feeding.
- Worsening of asthma.
- Convulsions (fits) are unlikely unless you already suffer from these.
- Nightmares, hallucinations (seeing or hearing things that are not there), jaundice (yellow eyes or skin).
- Changes to the heart rhythm may occur very rarely.
- Blood disorders which may cause fever or chills and painful ulceration in the mouth or rectum; unusual bruising or bleeding.
- Abnormal blood tests results i.e.: change in blood sugar levels, lower sodium content of blood and low blood cell count.

Elderly patients: If you are elderly, you may be more likely to be troubled by agitation or confusion.

In the event that one of your side effects exacerbates, or you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor or pharmacist immediately.

5. How to store this medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C in a dry place.

6. Further information:

In addition to active ingredient (substance) this medicine contains also:

Gilex 10 mg: Lactose, Microcrystalline Cellulose, Colloidal Silicon Dioxide, Magnesium Stearate, Talc

Capsule composition: Gelatin, Titanium dioxide, Yellow iron oxide, Quinoline yellow, Sunset yellow FCF- FD&C yellow 6

Gilex 25 mg: Lactose, Microcrystalline Cellulose, Colloidal Silicon Dioxide, Magnesium Stearate, Talc

Capsule composition: Gelatin, Titanium dioxide, Yellow iron oxide, Patent blue V, Erythrosin-FD&C Red 3

What does the medicine look like and what is the content of the package?

Gilex 10 mg: Yellow-orange capsules. 30 capsules in box

Gilex 25 mg: Yellow-blue capsules. 30 capsules in box

Holder and manufacturer:

Rekah Pharmaceutical Industry Ltd. 30 Hamelacha St. Holon, Israel.

This leaflet was checked and approved in April 2014

License number: Gilex 10 mg: 033-55-22651-00

Gilex 25 mg: 033-54-22652-00

For simplicity and easier to read, this leaflet is formulated male, however, the medicine is intended for members of both sex.