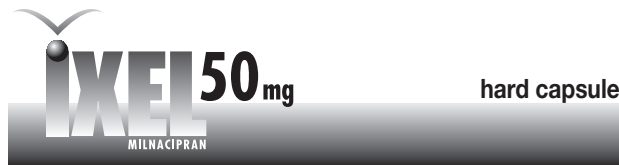


Package Leaflet: Information for the patient



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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What IXEL 50 mg, hard capsule is and what it is used for?
2. What you need to know before you take IXEL 50 mg, hard capsule?
3. How to take IXEL 50 mg, hard capsule ?
4. Possible side effects
5. How to store IXEL 50 mg, hard capsule ?
6. Contents of the pack and other information

1. What IXEL 50 mg, hard capsule IS AND WHAT IT IS USED FOR ?
IXEL 50 mg, hard capsule belongs to a group of medicines known as antidepressants. It is used in the treatment of depressive states in adult. It may take 1-3 weeks to take effect.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IXEL 50 mg, hard capsule

- Do not take IXEL 50 mg, hard capsule:**
- If you are allergic to milnacipran or any of the other ingredients of this medicine (listed in section 6),
 - In combination with another medicine known as an irreversible monoamine oxidase inhibitor (MAOI) (iproniazide), (See Other medicines and IXEL),
 - If you are breast-feeding,
 - If you have uncontrolled hypertension, severe or unstable coronary heart disease.

Warnings and precautions

Talk to your doctor or, pharmacist or nurse before taking IXEL

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
 - If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour 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 or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents under 18 years of age
IXEL 50 mg, hard capsule should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe IXEL 50 mg, hard capsule for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed IXEL 50 mg, hard capsule for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking IXEL 50 mg, hard capsule. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of IXEL 50 mg, hard capsule in this age group have not yet been demonstrated.

- Talk to your doctor, pharmacist or nurse before taking IXEL :
- If you have renal failure : the daily dose may be adjusted by your doctor,
 - If you have enlargement of the prostate (prostate adenoma) or difficulty to urinate,

- If you have high blood pressure (hypertension) or heart disease,
- If you have vision disorders with high pressure of liquids inside the eye (narrow-angle glaucoma),
- If you have epilepsy or a history of epilepsy,

During the treatment, talk to your doctor, pharmacist or nurse

- If you have sleep disorders or nervousness at the start of treatment,
- If you have jaundice (yellowing of your skin and the whites of your eyes).

Other medicines and IXEL

Tell your doctor or your pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor should decide whether you can take IXEL, hard capsule with other medicines.

Do not start or stop taking any medicines, including those bought without a prescription and herbal remedies, before checking with your doctor

- Irreversible monoamine oxidase inhibitors such as iproniazide (used to treat depression) must not be taken with IXEL, hard capsule. You must wait at least 14 days after you have stop taking an MAOI before you can take IXEL. Also, you need to wait at least 7 days after you stop taking IXEL before you take a MAOI.

- Serotonin syndrome.

When IXEL is taken in combination with other medicines, this may lead to the so called “serotonin syndrome”. For Information about the symptoms of this potentially life-threatening serotonin syndrome, see section 4 under ‘Possible side effects’. This syndrome may be caused when IXEL is used in combination with other medicines such as:

- irreversible MAOI such as iproniazide,
- medicines containing moclobemide, which is a reversible MAOI (used to treat depression),
- medicines containing linezolid, an antibiotic (used to treat infections),
- products containing methylene blue,
- medicines to treat depression for instance SNRI, SSRIs, tricyclics, or medicines containing lithium,
- products containing tryptophan (used for problems such as sleep and depression),
- products containing St. John’s Wort (*Hypericum perforatum*) a herbal treatment used to treat mild depression),
- medicines containing tramadol or pethidine (pain killer).

Certain other medicines may also interact with IXEL 50 mg, hard capsule. Except if you have a doctor recommendation, you should not take this medicine in combination with:

- some medicine with cardiovascular effects (injectionsof alpha and beta sympathomimetics).

Tell your doctor or your pharmacist if you are taking

- adrenalin (used in case of serious allergic shock) as the dose has to be adjusted when used together with IXEL,
- oral anticoagulants, drugs which have an effect on platelet function, e.g. NSAIDs and aspirin, or other drugs that may increase the risk of bleeding,
- digoxin, medicine to treat heart failure and irregular heart beats or heart rhythm.

Taking IXEL 50 mg, hard capsule with food drink and alcohol
The consumption of alcoholic drinks or medicines containing alcohol is not recommended.
IXEL 50 mg, hard capsule should be taken with a glass of water, preferably during the meal.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
It is not recommended to take this medicine during pregnancy. If you discover that you are pregnant during treatment, consult your doctor, as only he/she can decide whether or not treatment should be continued.
If you are taking IXEL 50 mg, hard capsule until delivery, your baby could present immediately or soon after delivery reversible symptoms linked to a withdrawal syndrome or exposure to milnacipran. In that case, a clinical surveillance should be performed.

Breast feeding
This medicine may pass in the mother’s milk. Therefore, the breast-feeding is contraindicated.

Driving and using machines
Particular caution is advised in vehicle drivers and machine operators, because of the risk of dizziness, especially at the beginning of the treatment.

3. HOW TO TAKE IXEL 50 mg, hard capsule ?

Posology
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dose
The usual dose is 1 hard capsule in the morning and 1 hard capsule in the evening, preferably during the meal.

If you have the impression that the effect of IXEL 50 mg, hard capsule is too strong or too weak, talk to your doctor or your pharmacist.

Method and route of administration
Oral route.
Swallow the hard capsule with a glass of water during the meal.

Duration
Treatment will usually last for several months.
Do not stop treatment yourself even if you are feeling better. If necessary, treatment must be stopped gradually in accordance with your doctor’s instructions (see section If you stop taking IXEL and Possible side effects).

If you take more IXEL 50 mg, hard capsule than you should:
You must contact immediately your doctor or go immediately to the nearest hospital.

If you forget to take IXEL 50 mg, hard capsule: Do not take a double dose to make up for a forgotten hard capsule.

If you stop taking using IXEL
Do not stop taking IXEL unless you are instructed to do so by your doctor. Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually. Most of the withdrawal reactions are mild and self-limiting in nature.

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

4. POSSIBLE SIDE EFFECTS
Like all medicines, IXEL 50 mg, hard capsule can cause side effects, although not everybody gets them.
Side effects can occur especially in the first week or the first two weeks of treatment with milnacipran.

You should see your doctor immediately if you experience symptoms, such as:

- If you get a rash or allergic reaction such as itching, swollen lips/ tongue or wheezing/shortness of breath, stop taking the capsules straight away and tell your doctor immediately
- If you experience sudden weakness or numbness of the face, arms or legs, especially on one side, or instances of slurred speech (symptoms of strokes).
- If you experience heart problems such as pain in the chest (tightness, pressure, or squeezing).
- If you experience a whole of symptoms related to a serotonin excess in the brain (serotonin syndrome), due to an important effect of IXEL 50 mg, hard capsule, occur with high fever, nausea, excessive sweating, anxiety, hot flush, muscle twitching or tremor, palpitations and agitation. This syndrome is noted especially if you are being treated with other medicines at the same time.

The following side effects are very common (affecting more than 1 user in 10)

- Nausea, headache.

The following side effects are common side effects (affecting less than 1 user in 100)

- Agitation, anxiety, eating disorder, sleep disorder, suicidal behaviour,
- Migraine, shaking, dizziness, modification of sensitivity, somnolence,
- Feeling your heart beat (palpitations), faster heart beat (tachycardia), blood pressure increase, hot flush,
- Abdominal pain, diarrhoea, constipation, dry mouth, indigestion, vomiting,
- Itching, rash, excessive sweating,
- Muscle pain,
- Inability to pass urine, abnormally frequent urination (pollakiuria),
- Difficulties with erection, ejaculation, testicular pain,
- Fatigue.

The following side effects are uncommon (affecting 1 to 10 users in 1,000)

- Increased level of lipids in the blood, decreased weight,
- Feelings panic, feeling confused, delusion, strange visions or sounds (hallucinations), having overactive behaviour or thoughts (mania), libido decrease, abnormal dreams, suicidal thought,
- Memory impairment, feeling of restless (akathisia), balance disorders, modification of taste, syncope,
- Blurred vision, dry eye, eye pain, visual acuity reduced, dilation of pupils (mydriasis),
- Feeling of dizziness or ‘spinning’(vertigo), ringing in ears,
- Heart problems, such as low blood pressure, conduction disorders,
- Low blood pressure, poor blood circulation which makes the toes and fingers numb and pale (Raynaud’s syndrome), orthostatic hypotensionBreathing difficulties, cough, dry nose, pharyngeal disorders,
- Gastro intestinal disorders as gastritis, stomatitis, abdominal discomfort, ulcer, haemorrhoids,
- Disturbed liver function tests.
- Skin disease (dermatosis), skin allergy (urticaria), inflammation of the skin (dermatitis),

- Muscle pain or muscle stiffness,
- Urinary disorders such as miction disorders, urinary retention, incontinence , possibility of red-colored urine,
- Some women may having irregular, heavy periods or no monthly period,
- Prostatic disorder,
- Feeling abnormal, fever, pain.

The following side effects are rare (affecting less than 1 users in 1,000)

- Inappropriate secretion of a hormone that controls urine volume (inappropriate antidiuretic hormone secretion),
- Psychotic disorder,
- Unvoluntary movements (dyskinesia), parkinsonism (medical term that could include many symptoms such as increase in saliva secretion, musculoskeletal stiffness, reduced or impaired body movements, no expression on the face, muscle tightness, shaking),
- Angina pectoris,
- Hepatitis, hepatocellular injury,
- Being sensitive to sun (photosensitivity reaction).

The following side effects have been reported, however precise frequency cannot be identified and therefore how often these occur is classed as not known:

- A reduction in the level of sodium in the blood (hyponatremia),
- Bleeding of the skin and mucous membranes,
- Convulsions especially in patients with a history of epilepsy,
- Aggression,
- Cytolitic hepatitis,
- Stevens-Johnson syndrome (a serious generalised illness with blistering of the skin and the mucous membranes).

Some symptoms can also be caused by your depression.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side affects you can help provide more information on the safety of this medicine.

5. HOW TO STORE IXEL 50 mg, hard capsule ?

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not use IXEL 50 mg, hard capsule after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What IXEL 50 mg, hard capsule contains ?
The active substance is:
Milnacipran hydrochloride. 50.00 mg
The other ingredients are:
Calcium hydrogen phosphate dihydrate, carmellose calcium, povidone K30, anhydrous colloidal silica, magnesium stearate, talc.
Ink: Shellac, Propylene glycol (E1520), Iron oxide black (E172), Ammonium hydroxide, Potassium hydroxide.
The capsule shells contain:
Cap (pink) : titanium dioxide (E171), red yellow iron oxide (E172), yellow iron oxide (E172), gelatine.
Body (rust-coloured) : titanium dioxide (E171), red yellow iron oxide (E172), yellow iron oxide (E172), gelatine.

What IXEL 50 mg, hard capsule looks like and contents of the pack
The 50 mg hard capsule is pink and rust-coloured and is imprinted with “Ixel 50”. This medicine is supplied in box containing either 14, 28, 56 or 112 hard capsules. Not all pack sizes may be marketed

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