

IXEL 50 mg, hard capsule
Milnacipran hydrochloride

Framed

Read all of this leaflet carefully before taking this medicine because it contains important information for you.

- Keep this leaflet. You might need to read it again.

- If you have any further questions, ask your doctor, pharmacist or nurse.

- This medicine has been prescribed. Do not give this to anyone else. 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, pharmacist or nurse. This also applies to any side effects that are not mentioned in this leaflet. See section 4.

What does this booklet contain ?

1. What is IXEL 50 mg capsule and in which cases it is used?
2. What should I know before taking IXEL 50 mg capsule?
3. How to take IXEL 50 mg capsule?
4. What are the possible side effects?
5. How to store IXEL 50 mg capsule?
6. Contents of the pack and other information.

1. WHAT IS IXEL 50 mg hard capsule AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: ANTIDEPRESSANT, OTHER ANTIDEPRESSANTS, ATC code: N06AX17

IXEL 50 mg hard capsules belong to a class of medicines called antidepressants.

It is recommended in the treatment of depressive states in adults. Its action is manifested only after a certain delay which can vary from 1 to 3 weeks.

2. BEFORE YOU TAKE IXEL 50 mg, capsule?

Do not take IXEL 50 mg capsule:

- If you are allergic (hypersensitive) to milnacipran or any of the other ingredients of this medicine listed in section 6,

- In combination with other medications: MAOIs (monoamine oxidase inhibitors) irreversible (iproniazid) (see "Other medicines and IXEL 50 mg capsule)

- If you are breastfeeding.

- If you have uncontrolled hypertension, severe or unstable coronary artery disease

Warnings and Precautions

Thoughts of suicide and worsening of your depression or anxiety disorder

If you suffer from depression and / or anxiety disorders, you may sometimes have thoughts of harming (assaulting yourself) or suicide. These manifestations may be increased at the start of treatment with an antidepressant, as this type of medication does not work immediately but only after 2 weeks or more of treatment.

You are more likely to have this type of manifestation in the following cases:

- If you have had suicidal thoughts or self-harm in the past.
- If you are a young adult. Clinical studies have shown that the risk of suicidal behavior is increased in adults under 25 years of age with psychiatric illness treated with antidepressants.

If you have thoughts of killing or harming yourself, contact your doctor or go straight to the hospital.

You can get help from a friend or relative, telling them that you are depressed or have an anxiety disorder, and asking them to read this leaflet. You can ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about a change in your behavior. Medicines like IXEL 25 mg hard capsules (called SSRIs / SNRIs) could cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms continued after stopping treatment.

Tell your doctor if:

- Insomnia or nervousness at the beginning of treatment,
- Jaundice occurrence (yellowing of your skin and the whites of your eyes)
- Kidney failure: your doctor may need to change your daily dose
- To increase the volume of the prostate (benign prostatic hyperplasia) or difficulty urinating,
- High blood pressure (hypertension) or heart disease,
- problems related to an increase in the pressure of fluids in the eye (narrow-angle glaucoma),
- Epilepsy or a history of epilepsy.

IF IN DOUBT, DO NOT HESITATE TO ASK FOR THE ADVICE OF YOUR DOCTOR OR YOUR PHARMACIST.

Children and adolescents

Use in children and adolescents under 18 years

IXEL 50 mg hard capsules should usually not be used in children and adolescents under 18 years of age. It is also important to know that patients under the age of 18 have an increased risk of side effects, such as suicide attempt, suicidal thoughts and hostile behavior (mainly aggression, oppositional behavior and anger) when treated by this class of drugs. However, your doctor may decide to prescribe IXEL 50 mg hard capsules to patients under 18 years of age if he / she decides it is in the patient's best interests. If your doctor has prescribed IXEL 50 mg hard capsules for a patient under the age of 18 and you want to discuss this, please contact them. You should tell your doctor if any of the symptoms listed above appear or worsen while taking IXEL 50 mg hard capsules by a patient under 18 years of age. You should also be aware that the long-term safety with regard to growth, maturation and cognitive and behavioral development of IXEL 50 mg hard capsules has not yet been established in this age group.

Other medicines and IXEL 50 mg, capsule

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor will tell you if you can take IXEL 50 mg hard capsules with other medicines.

Do not start or stop any medication, including those available without a prescription, as well as natural and herbal remedies, until you have checked the compatibility with your doctor or pharmacist.

You should not take this medicine at the same time as:

– irreversible MAOIs such as iproniazid (used in depression) should not be taken with IXEL 50 mg hard capsules. After stopping an MAOI, take at least 14 days before taking IXEL 50 mg hard capsules. In addition, you must wait at least 7 days after stopping IXEL 50 mg, capsule before you can take an MAOI.

• Serotonin syndrome:

When IXEL 50 mg hard capsules are taken in combination with other medicines, it can cause "serotonin syndrome". For information on the symptoms of this potentially life-threatening syndrome, see section 4. "What are possible side effects? "

This syndrome may occur during treatment with IXEL 50 mg hard capsules when it is combined with certain other medicines, such as:

- irreversible MAOIs such as iproniazid
- Medicines containing moclobemide, a selective MAOI-A (used to treat depression).
- medicines containing linezolid, an antibiotic (used to treat infections).
- medicines containing tramadol or pethidine (used to relieve pain).
- products containing St. John's Wort (also called *Hypericum perforatum*, a herbal medicine used in the treatment of mild depression).
- medicines containing methylene blue

- other antidepressants

Some other medicines may interact with IXEL 50 mg hard capsules.

You should generally not take this medicine, unless your doctor tells you otherwise, at the same time as:

- Some drugs acting on the cardiovascular system (APHA and beta sympathomimetic by injection),

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, talk to your doctor or pharmacist.

IXEL 50 mg, capsule with food, drink and alcohol

The absorption of alcoholic beverages or drugs containing alcohol is not recommended.

IXEL 50 mg, capsule should be taken with a glass of water, preferably with a meal.

Pregnancy, breastfeeding and fertility

Pregnancy

It is best not to take this medicine during pregnancy or in women of childbearing potential not using contraception. If you discover that you are pregnant during treatment, consult your doctor as only he can judge the need for continued treatment.

If you take IXEL 50 mg hard capsules until you give birth, your baby may have reversible symptoms immediately or soon after due to sudden stopping of exposure to milnacipran (withdrawal syndrome) or to 'milnacipran impregnation. In this case, clinical monitoring should be ensured.

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

Feeding with milk

Breast-feeding is contraindicated due to poor passage of the drug into breast milk.

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

Fertility

Fertility is affected by milnacipran in animals.

There are no data available regarding the impact of milnacipran on human fertility.

Driving and using machines

Be careful if you drive vehicles or use machines. Possible risks of dizziness may appear at the start of treatment.

IXEL 50 mg hard capsule contains

Not applicable.

3. HOW TO TAKE IXEL 50 mg capsule?

Dosage

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

The usual dose is 1 capsule in the morning and 1 capsule in the evening, preferably with a meal.

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

Administration mode

Oral route.

Swallow the capsule with a glass of water during a meal.

Duration of treatment

Do not stop your treatment without medical advice, even if you feel better.

If necessary, this treatment should be stopped gradually according to your doctor's instructions (see sections "If you stop taking IXEL 50 mg hard capsules" and "what are the possible side effects").

If you take more IXEL 50 mg, capsule than you should

Immediately consult your doctor or pharmacist.

Seek immediate medical assistance.

If you forget to take IXEL 50 mg hard capsule

Do not take a double dose to make up for the dose you forgot to take.

If you stop taking IXEL 50 mg hard capsules

Do not stop your treatment unless your doctor tells you to. Withdrawal symptoms may occur when treatment is stopped, it is advisable to reduce the dose gradually. Most of the withdrawal symptoms are mild and go away on their own.

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

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects observed during treatment with milnacipran are especially noted during the first or even the first two weeks of treatment.

You should see your doctor immediately if you experience the following symptoms:

- If you develop a rash or allergic reaction such as itching, swelling of the lips and / or tongue or wheezing and / or shortness of breath, stop immediately taking the capsules and contact your doctor immediately
- If you experience sudden weakness or numbness (e) of the face, arm or leg, especially on one side, or episodes of speech disorders (symptoms of stroke).
- If you have heart problems such as chest pain (contraction of sensation, tightness, squeezing).
- If you have a set of symptoms related to an excess of serotonin in the brain (serotonin syndrome) due to a significant effect IXEL 50 mg capsule, manifested by high fever, nausea, excessive sweating, anxiety, hot flashes, muscle twitching or tremors, palpitations and restlessness. This syndrome is observed in particular in patients who simultaneously receive other drugs;

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

- Nausea, headache

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

- Agitation, anxiety, eating disorders, sleep disorders, suicidal behavior
- Headache, dizziness, tremors, changes in sensitivity, drowsiness
- Perception of heart beats (palpitations), fast heart beat (tachycardia), increased blood pressure, flushing
- Abdominal pain, diarrhea, constipation, dry mouth, indigestion, vomiting
- Itching, rash, excessive sweating
- Muscle pain
- Inability to urinate, frequent urination abnormally (urinary frequency)
- Erectile dysfunction, ejaculation, testicular pain
- Fatigue

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

- Increased levels of blood lipids, weight loss
- Feelings of panic, confusion, delirium, strange visions or sounds (hallucinations), overactive behavior or thoughts (mania), decreased libido, abnormal dreams, suicidal thoughts
- Poor memory, sensation of restlessness (akathisia), balance disorders, taste changes, syncope
- Blurred vision, dry eye, eye pain, decreased visual acuity, pupil dilation (mydriasis)
- Sensation of dizziness or spinning (vertigo), whistling or ringing in the ears
- Heart problems, such as low blood pressure, conduction abnormalities
- Low blood pressure, poor circulation makes toes and fingers numb and pale (Raynaud's syndrome), orthostatic hypotension
- Difficulty in breathing, cough, dry nose and throat disorders
- Gastrointestinal disorders such as gastritis, stomatitis, abdominal discomfort, ulcers, hemorrhoids
- Liver function abnormalities.

- Skin disease (dermatitis), allergic skin reactions (hives), skin inflammation (dermatitis)
- Pain or muscle stiffness
- Urinary disorders such as disorders of micturition, urinary retention, incontinence, possibility of staining red urine
- Some patients may have irregular menstrual bleeding or a lack of rules
- Disorders of the prostate
- Feeling abnormal, fever, pain

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

- Inappropriate secretion of a hormone that controls urine volume (syndrome of inappropriate secretion of antidiuretic hormone)
- Psychotic Disorder
- Involuntary movements (dyskinesia), parkinsonism (medical term that can include many symptoms, such as increased secretion of saliva, musculoskeletal stiffness, reduced or abnormal movements of the body, lack of facial expression, muscle twitching, tremor)
- Angina (angina)
- Hepatitis, hepatocellular damage
- Sun sensitivity (photosensitivity reaction)

The following side effects have been reported, but the precise frequency cannot be established and is therefore classified as 'not known':

- Reduced sodium levels in the blood (hyponatremia);
- Bleeding of the skin and mucous membranes;
- Seizures, especially in patients with a history of epilepsy;
- Aggressiveness;
- Cytolytic hepatitis;
- Stevens-Johnson syndrome (serious illness with a generalized rash affecting the skin and mucous membranes);

- Cardiomyopathy Takotsubo (cardiomyopathy stress).

Some symptoms can also be part of your depression.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for Medicines and Health Products Safety (ANSM) and network of Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE IXEL 50 mg capsule?

Keep this medication out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiration date refers to the last day of that month.

Do not store above 30 ° C.

Do not throw away any medicine 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. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What IXEL 50 mg, capsule contains

- The active substance is:

Milnacipran hydrochloride	50, 00 mg
Quantity corresponding to milnacipran base	43.55 mg

For a capsule.

- The other ingredients are:

Calcium hydrogen phosphate dihydrate, calcium carmellose, povidone K 30, colloidal anhydrous silica, magnesium stearate, talc.

Composition of the capsule shell

Head (pink color) : titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172), gelatin.

Body (rust color) : titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172), gelatin.

What IXEL 50 mg, hard capsule looks like and contents of the pack

This medication is in the form of a capsule in a box of 14, 28, 56 and 112 capsules.

Not all presentations may be marketed.

Marketing authorization holder

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