

JONCIA® 25, 50, 100 mg capsules

Milnacipran hydrochloride

What is in this leaflet

This leaflet answers some common questions about Joncia®.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Joncia® against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Joncia® is used for

Joncia® is used to manage fibromyalgia.

Fibromyalgia is a health problem involving muscle and joint pain, tenderness, tiredness, sleep problems and a number of symptoms such as morning stiffness,

mood disturbances and cognition problems.

Joncia® is a kind of medicine called a serotonin-noradrenaline reuptake inhibitor which has the ability to increase the levels of the biochemicals, serotonin and noradrenaline thereby improving the problems experienced with fibromyalgia syndrome.

Your doctor may have prescribed Joncia® for another purpose.

Ask your doctor if you have any questions about why Joncia® has been prescribed for you.

This medicine is available only on a doctor's prescription.

Before you take Joncia®

When you must not take it

You must not take Joncia® if you are taking medicine to treat depression.

Joncia® is not used to treat depression, but it acts like medicines that are used to treat depression (antidepressants) and other psychiatric

disorders. If you are taking medicine to treat another psychiatric disorder you should discuss this with your doctor before you take Joncia®.

If you take Joncia® with medicines to treat depression, the potentially life-threatening condition of serotonin syndrome may occur. Serotonin syndrome may include agitation, hallucinations, coma, changes in blood pressure, fast heart rate, increased body temperature, incoordination, nausea and vomiting.

Do not take Joncia® if you have an allergy to Joncia® or any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Joncia® if you have severe problems with your heart, a high risk of serious arrhythmia (changes in the rate or

rhythm of your heart beat), uncontrolled high blood pressure or severe or unstable heart disease.

Joncia® can increase blood pressure and heart rate which may make your condition worse.

Do not take Joncia® if you have glaucoma.

Do not take Joncia® if you are having injections of adrenaline or noradrenaline.

Taking milnacipran with this kind of medicine may cause high blood pressure and possibly change the rhythm or rate of your heart beat.

Ask your doctor or pharmacist if you are not sure if you have been taking or have been given one of these medicines.

Do not take Joncia® if you are breastfeeding.

Small amounts of the active ingredient in Joncia® may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not take Joncia® after the expiry date printed on the pack. The expiry date refers to the last day of that month.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Joncia® if the packaging is torn or shows signs of tampering.

If your medicine has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Joncia®, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney disease;
- liver disease;
- glaucoma or high pressure of the fluids inside your eye;
- an enlarged prostate or difficulty urinating;
- epilepsy (fits or convulsions) or a history of epilepsy;
- high blood pressure or heart disease;
- bleeding problems;

Tell your doctor if you suffer from depression or have or have had suicidal thoughts.

Symptoms of depression may include thoughts of harming yourself or committing suicide. It is

the experience with depression that these suicidal thoughts or actions may increase in the early stages of recovering from your depression. Joncia® has anti-depressant effects, although it is not used to treat depression.

Therefore, during the first few weeks or more of treatment with Joncia®, thoughts of suicide may get worse.

You should tell your doctor if you suffer from depression or have or have had suicidal thoughts so that you will receive careful monitoring during your treatment with Joncia®.

Tell your doctor if you are pregnant or intend to become pregnant.

Taking Joncia® during pregnancy is not recommended. If you discover that you are pregnant during treatment, tell your doctor. Your doctor will discuss the risks and benefits of using Joncia® when pregnant and decide whether or not treatment should be continued.

Tell your doctor if you drink a lot of alcohol.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Joncia® may interfere with each other. These include:

- MAO inhibitors, medicines used to treat depression;
- serotonin reuptake inhibitors, medicines used to treat depression;
- St John's wort, a herbal product used to treat depression;
- injections of adrenaline or noradrenaline;
- digoxin, a medicine used to treat heart failure;
- clonidine, a medicine used to treat high blood pressure;
- medicines used to treat migraine belonging to a group known as triptans eg. sumatriptan;
- medicines which have an effect on blood clotting such as NSAIDs and aspirin, or other medicines that may increase the risk of bleeding;
- some medicines used to treat Parkinson's disease.
- medicines which affect the central nervous system.
- diuretics, medicines used to treat swelling of the ankles, feet or

legs or high blood pressure.

- lithium, a medicine used to treat mood swings and some types of depression.
- antipsychotic medicines, used to treat certain mental and emotional conditions.
- dopamine agonists, medicines typically used for treating Parkinson's disease.
- tryptophan, an amino acid found in protein-based foods which can increase the levels of serotonin in the brain.

These medicines may be affected by Joncia®, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking Joncia®.

Avoid drinking alcohol or taking medicines which contain alcohol while taking Joncia®.

Alcohol may interfere with the way Joncia® works or how well it works.

If you are 65 years or older, you should be especially careful while taking Joncia®. Report

any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

The safety and effectiveness of Joncia® in children and adolescents under the age of 18 years have not been established. Use in children and adolescents aged under 18 years is not recommended.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Joncia®.

How to take Joncia®

Take Joncia® exactly as your doctor has prescribed.

How much to take

Your doctor will decide what dose you will receive.

Your treatment with Joncia® has to be started gradually. Your doctor will prescribe a dosage schedule for the start of your treatment.

After this initiation period, the usual dose is one 50 mg capsule in the morning and one 50 mg capsule in the evening, preferably during meals.

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

If you feel that Joncia® is not having enough of an effect or is having too strong an effect, talk to your doctor or pharmacist.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist for help.

How to take it

Swallow Joncia® with a glass of water preferably during meals.

How long to take it

Continue taking your medicine for as long as your doctor tells you. Treatment will usually last for several months.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not double a dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints

If you take too much (overdose)

Immediately contact your doctor or the Poisons Information Centre (In Australia telephone 131 126. In New Zealand telephone 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Joncia®.

You may need urgent medical attention.

If you stop taking it

Do not stop taking Joncia® without the advice of your doctor even if you feel better. If your doctor decides that you no longer need to take Joncia®, your doctor will reduce your dose gradually over a period of no less than two weeks before stopping treatment altogether. Suddenly stopping Joncia® may lead to headache, dizziness, sleepiness, diarrhoea,

vomiting, anxiety disorders and pain (withdrawal symptoms).

While you are taking Joncia®

Things you must do

You must tell your doctor if you are experiencing any distressing thoughts or feelings at any time while you are taking Joncia®.

If you are suffering from depression, you must tell your doctor immediately if you feel that your depression is getting worse or if you are having suicidal feelings or thoughts of harming yourself while you are taking Joncia®.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Joncia®.

Tell any other doctors, dentists and pharmacists who treat you that you are taking Joncia®.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Joncia®.

If you become pregnant while taking Joncia®, tell your doctor immediately.

Things you must not do

Do not stop taking Joncia® without the advice of your doctor. Suddenly stopping Joncia® may cause withdrawal symptoms.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Do not take Joncia® to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Joncia® affects you. Joncia® may reduce physical ability and alertness in some people.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Joncia®.

Like other medicines, Joncia® can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- nausea
- constipation
- excessive sweating
- hot flushes
- loss of appetite
- weight loss
- agitation
- anxiety
- depression
- problems sleeping
- dizziness
- migraine
- shaking or tremor
- change in taste
- increase in skin sensitivity
- stomach pain or discomfort
- diarrhoea
- dry mouth
- indigestion
- vomiting
- itching, rash
- muscle ache, pain or tenderness
- pain passing urine
- problems with erection, ejaculation or pain in the testicles
- fatigue
- memory problems
- palpitations (fast or irregular heart beat)

- fast heart rate
- high blood pressure
- chest pain
- swelling

These are the more common side effects of Joncia®.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Contact your doctor or mental health professional immediately or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your anxiety or depression;
- thoughts or talk of death or suicide;
- thoughts or talk of self-harm or harm to others;
- any recent attempts of self-harm or suicide;
- an extreme increase in activity and talking (mania);
- increase in agitation or restlessness;
- panic attacks;
- increase in aggressive behavior, irritability or any other unusual changes

in behavior or mood.

All mentions of suicide or violence must be taken seriously.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- difficulty breathing
- chest pain
- palpitations, fast or irregular heart beat
- rash, itching or hives on the skin
- swelling of the feet and ankles, face, lips, tongue or other parts of the body.
- severe agitation, confusion, hallucinations, inability to walk, fainting or seizure.

These are very serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

After using Joncia®

Storage

Your Joncia® capsules both in the blister pack or in the bottle, should be stored in a dry place where the temperature stays below 30°C.

Keep your capsules in their original pack/container until it is time to take them.

Do not store Joncia® or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Joncia®, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules left over.

Product description

What it looks like

The 25 mg capsules are yellow and white with "PFM 25" imprinted in black.

The 50 mg capsules are orange and white with "PFM 50" imprinted in black.

The 100 mg capsules are orange and yellow with "PFM 100" imprinted in black.

The 25, 50 and 100 mg capsules are supplied in blister packs of 14, 28, or 56 capsules.

Ingredients

Active ingredient:

- milnacipran hydrochloride

Other ingredients:

- calcium hydrogen phosphate
- carmellose calcium
- povidone K30
- silica hydrophobic-colloidal
- magnesium stearate
- talc-purified

The capsule shell for the 25 mg and 100 mg strengths contain:

- titanium dioxide (E171)
- quinoline yellow (E104)
- sunset yellow FCF (E110)
- gelatin

The capsule shell for the 50 mg strength contains:

- titanium dioxide (E171)

- sunset yellow FCF (E110)
- gelatin

The capsules are marked with food grade ink.

Distributor

Joncia® is supplied in Australia by:

Pierre Fabre Australia Pty Limited
Suite 601, 504 Pacific Highway, St Leonards, NSW 2065

Australian Registration Number:

25 mg: AUST R 176508
50 mg: AUST R 176513
100 mg: AUST R 176515

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