**Package leaflet: Information for the patient**

**Mildronate 500 mg hard capsules**
meldonium dihydrate

**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. See section 4.

**What is in this leaflet**


## 1. What Mildronate is and what it is used for

Mildronate contains the active substance meldonium dihydrate (it will be referred to as meldonium throughout the leaflet). Meldonium is a structural analogue of gamma-butyrobetaine (GBB), substance that can be found in each cell of the body.
Under the conditions of poor cardiac (heart) blood flow, Mildronate widens the blood vessels, positively affects metabolism of the heart muscle and restores the balance between oxygen delivery and its consumption in the cells. In the case of heart failure, Mildronate improves the ability of heart muscle to contract and increases the tolerance to physical overload.
Mildronate can be used as supplementary treatment for mild long-term heart failure in adults.

## 2. What you need to know before you take Mildronate

**Do not take Mildronate**
- if you are allergic to meldonium dihydrate or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Talk to your doctor before taking Mildronate:
- if you have chronic kidney or liver diseases.

Anti-doping warning
Athletes must be aware that this medicinal product may cause a positive reaction to “anti-doping tests”.

**Children**
Mildronate is not to be used by children because it may not be safe or effective.

**Other medicines and Mildronate**
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
If prescribed by a doctor, Mildronate can be used in combination with these cardiovascular system affecting medicines:

- antianginal medicines (used to treat angina),
- anticoagulants (blood thinners),
- antiarrhythmics (used to treat heart rhythm disorders),
- cardiac glycosides (used for treating heart failure),
- diuretics (help to reduce the amount of water in your body).

Mildronate may intensify the actions of several cardiovascular agents, such as:
- glyceryl trinitrate,
- nifedipine,
- beta-adrenoblockers,
- hypotensive agents,
- peripheral vasodilators.

Your doctor will take it into consideration when prescribing you the treatment with Mildronate as doses may be reduced.

**Mildronate with food**
Food slightly delays the absorption of this medicine but does not reduce its effect.

**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.
Mildronate is not recommended during pregnancy, as safety in pregnant women has not been studied.
Do not breast-feed if you are using meldonium.

**Driving and using machines**
Mildronate has no influence on the ability to drive and use machines.

## 3. How to take Mildronate

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Take the capsules by mouth. The capsules should be swallowed whole with water.
- Mildronate can be taken with food, preferably in the morning. Administration with food is recommended to avoid gastrointestinal disturbances.

Adults
The recommended dose is 500-1000 mg of meldonium dihydrate (1 – 2 capsules) daily. The daily dose of 1000 mg can be divided into two single doses. The maximum daily dose is 1000 mg. The length of treatment varies from 4 to 6 weeks.

Elderly
Elderly patients with liver and/or kidney impairment may require lower doses (see "*Warnings and precautions"*).

Patients with liver and/or kidney disorders
In patients with liver and/or kidney disorders reduced doses should be used (see "*Warnings and precautions"*).

Talk to your doctor if the effect of Mildronate is too strong or too weak.

**Use in children**
This medicine is not to be used by children.

**If you take more Mildronate than you should**
This medicine is of low toxicity and causes no severe side effects. If hypotension (decreased blood pressure) occurs, headache, dizziness, increased heart rate or weakness may be observed.
If you take more Mildronate than you should, contact your doctor immediately.

**If you forget to take Mildronate**
If you forget to take Mildronate, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Continue to take this medicine as prescribed. Do not take a double dose to make up for a forgotten dose.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Usually Mildronate is well tolerated.

*Common* (may affect up to 1 in 10 people):
- allergic reactions (blush, rash, itching, swelling),
- headache,
- indigestion (stomach discomfort, nausea, vomiting, bitter taste in mouth).

*Very rare* (may affect up to 1 in 10 000 people):
- increased heart rate,
- decreased blood pressure.

*Not known* (frequency cannot be estimated from the available data):
- eosinophilia (increased number of white blood cells called eosinophils),
- agitation,
- weakness.

The leading and concomitant diseases can cause other possible side effects, such as proteinuria (presence of higher amount of protein in the urine), liver impairment due to inappropriate diet and mood changes. The relationship between these effects and using meldonium is hardly possible.

**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 HPRA Pharmacovigilance Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Mildronate

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

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

Do not store above 25 °C.
Store in the original package in order to protect from moisture.

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. Contents of the pack and other information

**What Mildronate contains**

- The active substance is meldonium dihydrate. Each hard capsule contains 500 mg of meldonium dihydrate (equivalent to 401.14 mg of meldonium).
- The other ingredients are:
  Capsule contents: potato starch (dried), silicon dioxide, calcium stearate.
  Capsule shell: titanium dioxide (E171), gelatin.

**What Mildronate looks like and contents of the pack**

Mildronate are white hard capsules. Mildronate is available in blisters of 20 or 60 hard capsules. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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**This medicine is authorised in the Member States of the European Economic Area under the following names:**

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|---|---|
| Austria | Mildronate 500 mg Hartkapseln |
| Finland | Myldrox 500 mg kovat kapselit |
| Ireland | Mildronate 500 mg hard capsules |
| Norway | Mildronate |

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