

# MIRON TABLETS

Midodrine Hydrochloride 2.5mg, 5mg, 10mg

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## What Miron is used for

Miron is a medicine is used to treat severe forms of low blood pressure in adults when other treatments have not worked.

## How Miron works

Miron containing Midodrine HCl which is belongs to a group of medicines called adrenergic agents.

It works by raising your blood pressure.

## Before you use Miron

### – When you must not use it

Do not take this medicine:

- if you have high blood pressure
- if you have kidney disease
- if you have difficulty passing urine
- if you have hormonal disorders caused by a rare tumour in the adrenal gland, which sits near the kidney (phaeochromocytoma)
- if you have an overactive thyroid gland (thyrotoxicosis)

If any of the above applies to you, tell your doctor or pharmacist before taking Miron.

### – Before you start to use it

Talk to your doctor before taking Miron if you have or have been told you have high blood pressure when you lie down.

If this applies to you then:

Regular monitoring of your blood pressure will be required when you are lying down and standing up as there may be a risk of your blood pressure rising when you lie down, for example, at night. If your blood pressure rises when you lie down and reducing the

dose does not correct this problem, then treatment with this medicine must be stopped.

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

- elevated pressure in the eye (glaucoma) or poor vision because of damage to the eye caused by diabetes
- slow pulse

Your doctor will perform some tests such as checking your kidney function and blood pressure before you start using this medicine.

## Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Using this medicine while pregnant or breastfeeding is not recommended.

## Do not give this medicine to children and adolescents under the age of 18.

The safety and efficacy of Miron in children has not been established

### – Taking other medicines

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

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

- Vasoconstrictors (medicines that narrow blood vessels)
- MAO-inhibitors (medicines used to treat depression)
- Hormones for the thyroid (used when the thyroid is not working properly)
- Dihydroergotamine (medicine used to treat migraines)
- Prazosin (medicines used to treat heart disease)
- Corticosteroids preparations such as fludrocortisone acetate (an anti-inflammatory medicine)
- Digitalis preparations (medicines used to treat heart disease)
- Medicines that may slow down the heart rate
- Promethazine (medicine used to treat allergies and help with vomiting)
- Quinidine (medicine used to change the way the heart beats)

These medicines may be affected by Miron or may affect how well it works.

Some may enhance or block the effects of midodrine or affect the heartbeat. Others will require that decrease your salt intake. You may need different amounts of your medicines, or you may need to take different medicines.

If you are taking medicines which directly or indirectly reduce your heart rate, your doctor will closely monitor you while you are taking Miron.

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

## How to use Miron

### – How much to use

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

The recommended dose is 10 mg 3 times daily.

Swallow the tablets whole with a full glass of water. The tablets may be taken with food.

### – When to use it

## Take your medicine at about the same times each day.

Taking it at the same times each day will have the best effect. It will also help you remember when to take it.

Avoid taking the medicine in the late evening. The last daily dose should be taken at least 4 hours before your bedtime.

Keep your head elevated when you lie down at night. This reduces the potential risk of rise in your blood pressure.

### – How long to use it

## Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### – If you forget to use it

If you forget to take a dose, take it as soon as you remember and then carry on as before. If you do not take your

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tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

– *If you use too much (overdose)*

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. Symptoms of an overdose may include:

- high blood pressure
- goose bumps and feeling cold
- slow heart beat
- difficulty passing urine

**While you are using it**

– *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Miron.

Tell your doctor immediately if you become pregnant while taking this medication.

– *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Miron to anyone else, even if they have the same symptoms or condition as you.

– *Things to be careful of*

**Be careful driving or operating machinery until you know how Miron affects you.**

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Side Effects**

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

Some side effects can be serious and need immediate medical attention:

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

- high blood pressure
- goosebumps
- urge to urinate, difficulty urinating
- tingling and itching of the skin and scalp

- heart burn
- vomiting
- dizziness
- anxiety, feelings of confusion

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [www.npra.gov.my](http://www.npra.gov.my) (Consumers → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)).

**Storage and Disposal of Miron**

– *Storage*

Keep out of the reach and sight of children.

Store below 25°C.

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

– *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

– *What it looks like*

Miron 2.5mg - White to off-white, round, scored tablets debossed with 2.5 above the score on one side of the tablet and N on the other side.

Miron 5mg- White to off-white, round, scored tablets debossed with 5 above the score on one side of the tablet and N on the other side.

Miron 10mg - White to off-white, round, scored tablets debossed with 10 above the score on one side of the tablet and N on the other side.

– *Ingredients*

– *Active ingredient(s)*

Miron 2.5mg – Each tablet contains 2.5mg of Midodrine Hydrochloride.

Miron 5mg – Each tablet contains 5mg of Midodrine Hydrochloride.

Miron 10mg – Each tablet contains 10mg of Midodrine Hydrochloride.

– Inactive ingredient

- Colloidal silicon dioxide
- Croscarmellose sodium
- Magnesium stearate
- Microcrystalline cellulose
- Pregelatinized starch (corn)
- Sodium lauryl sulfate

– *MAL numbers*

MALXXXXXXXXXX

**Manufacturers**

Novugen Pharma Sdn. Bhd.  
No. 27, Jalan Lengku Teknologi 2,  
Taman Teknologi Enstek Fasa 1,  
71760 Bandar Baru Enstek,  
Negeri Sembilan, Malaysia.

**Product Registration Holder**

Novugen Pharma Sdn. Bhd.  
No. 3, Jalan Jururancang U1/21,  
Hicom Glenmarie Industrial Park,  
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Selangor, Malaysia.

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