

PATIENT INFORMATION LEAFLET

Mirabegron Extended-Release Tablet
(25/50 mg)

MIGRON 25/50 ER

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 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.

What is in this leaflet

1. What MIGRON is and what it is used for
2. What you need to know before you take MIGRON
3. How to take MIGRON
4. Possible side effects
5. How to store MIGRON
6. Contents of the pack and other information

1. What MIGRON is and what it is used for

Mirabegron contains the active substance mirabegron. It is a bladder muscle relaxant (a so called beta 3-adrenoceptor agonist), which reduces the activity of an overactive bladder and treats the related symptoms.

Mirabegron is used to treat the symptoms of an overactive bladder in adults such as:

- ❖ suddenly needing to empty your bladder
- ❖ having to empty your bladder more than usual
- ❖ not being able to control when to empty your bladder

2. What you need to know before you take MIGRON

Do not take MIGRON

- ❖ if you are allergic to Mirabegron or any of the other ingredients of this medicine
- ❖ if you suffer from very high uncontrolled blood pressure

If any of the above applies to you, do not take MIGRON and talk to your doctor.

Warnings and precautions:

Talk to your doctor before taking Mirabegron.

Take special care with Mirabegron and tell your doctor if you:

- ❖ if you have trouble emptying your bladder or you have a weak urine stream or if you take other medicines for the

treatment of overactive bladder such as anticholinergic medicines.

- ❖ if you have kidney or liver problems. Your doctor may need to reduce your dose or may tell you not to take Mirabegron, especially if you are taking other medicines such as itraconazole, ketoconazole (fungal infections), ritonavir (HIV/AIDS) or clarithromycin (bacterial infections).

Other medicines and MIGRON

Tell your doctor if you are taking, or have recently taken, or might take any other medicines. Mirabegron can be taken with or without food and drinks, at any time of the day.

Pregnancy and breast-feeding

- ❖ Mirabegron is not recommended for use during pregnancy.
- ❖ Tell your doctor if you are pregnant or planning to become pregnant.
- ❖ If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.
- ❖ It is likely that this medicine passes into your breast milk. You and your doctor should decide if you should take Mirabegron or breast-feed. You should not do both.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Mirabegron is unlikely to affect your ability to drive or use machines. However, sometimes Mirabegron may cause dizziness and tiredness, especially on the first day of treatment, and this may have an effect on driving and use of machines.

3. How to take MIGRON

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 one 50 mg tablet by mouth once daily.

If you have kidney or liver problems, your doctor may need to reduce your dose to one 25 mg tablet by mouth once daily. You should take this medicine with liquids and swallow the tablet whole. Do not crush or chew the tablet.

Use in children and adolescents

Mirabegron is only for adults and should not be taken by children and adolescents up to 18 years.

If you forget to take Mirabegron

If you forget to take your medicine, take the missed dose as soon as you remember. If it is less than 6 hours before your next scheduled dose, skip the dose and continue to take your medicine at the usual time.

Do not take a double dose to make up for a forgotten dose. If you

miss several doses, tell your doctor and follow the advice given to you.

If you stop taking Mirabegron

Do not stop treatment with Mirabegron early if you do not see an immediate effect. Your bladder might need some time to adapt. You should continue taking your tablets. Do not stop taking them when your bladder condition improves. Stopping treatment may result in recurrence of symptoms of overactive bladder.

Do not stop taking Mirabegron without talking to your doctor first, as your overactive bladder symptoms may come back.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects mostly occur at the start of treatment and usually disappear within a few days with continued treatment.

The following side effects have been reported:

Common: may affect up to 1 in 10 people

- ❖ Increased Heart Rate
- ❖ Urinary Tract Infection
- ❖ Nausea
- ❖ Constipation
- ❖ Dizziness
- ❖ Diarrhoea

Uncommon: may affect up to 1 in 100 people

- ❖ Bladder Infection
- ❖ Palpitations
- ❖ Vaginal Infection
- ❖ Indigestion
- ❖ Increased Blood Pressure
- ❖ Gastritis

Rare side effects: may affect up to 1 in 1,000 people

- ❖ Swelling of the eyelid (Eyelid oedema)
- ❖ Swelling of the lip (Lip oedema)
- ❖ Swelling of the deeper layers of the skin caused by a build-up of fluid, which can affect any part of the body including the face, tongue or throat and may cause difficulty in breathing (Angioedema)
- ❖ Small purple spots on the skin (Purpura)
- ❖ Inflammation of small blood vessels mainly affecting the skin (Leukocytoclastic Vasculitis)

- ❖ Inability to completely empty the bladder (Urinary retention)

Very rare side effects: may affect up to 1 in 10,000 people

- ❖ Hypertensive crisis

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store MIGRON

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.

This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via waste water. 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 MIGRON 25/50 ER contains

The active ingredient is Mirabegron.

MIGRON 25 ER

Each film-coated extended-release tablet contains:

Mirabegron 25 mg

Colours: Iron Oxide Red, Iron Oxide Yellow & Titanium Dioxide

MIGRON 50 ER

Each film-coated extended-release tablet contains:

Mirabegron 50 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

What MIGRON 25/50 ER looks like and contents of the pack

MIGRON 25 ER tablets are red, oval and biconvex film-coated tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton.

MIGRON 50 ER tablets are yellow, oval, biconvex film-coated tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton.



Manufactured by :
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