

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S3**VESIREL 25 prolonged-release tablets****VESIREL 50 prolonged-release tablets****Mirabegron****Sugar free.****Read all of this leaflet carefully before you start taking VESIREL**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VESIREL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What VESIREL is and what it is used for

VESIREL contains the active substance mirabegron.

It belongs to a group of medicine called urologicals (urinary antispasmodics). It is a bladder relaxant which reduces the activity of an overactive bladder and helps to treat the related

symptoms.

VESIREL is used to treat symptoms related to an overactive bladder such as:

- Sudden need to empty the bladder (urgency).
- Increased urinary frequency (increased micturition).
- Not being able to control when to empty your bladder (urgency incontinence).

2. What you need to know before you take VESIREL

Do not take VESIREL:

- If you are hypersensitive (allergic) to mirabegron or to any of the other ingredients of VESIREL listed in section 6 of this leaflet.
- If you have severe liver problems (severe hepatic impairment).
- If you have severe kidney problems (end-stage renal impairment).
- If you have uncontrolled high blood pressure.

Warnings and precautions

Talk to your doctor before taking VESIREL:

- If you have liver or kidney problems. Your doctor may need to reduce the dose or tell you not to take VESIREL.
- If you have a heart rhythm abnormality (QT prolongation) or are on medicine known to cause this.
- If you have high blood pressure. VESIREL may cause blood pressure to increase or worsen your blood pressure if you have a history thereof, therefore, it is recommended that your doctor check your blood pressure while you are taking VESIREL.
- If you have a blockage in your bladder or urinary tract (characterised by difficulty starting to pass urine, a weak urine stream, or a feeling that your bladder is not empty), or if you are taking medicine for an overactive bladder (OAB) (antimuscarinic medicine), VESIREL may increase your risk of being unable to pass urine.

Children and adolescents

VESIREL is not recommended for children and adolescents aged under 18 years as the safety and effectiveness is not known in this age group.

Other medicines and VESIREL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you:

- Use digoxin (medicine used for heart failure or abnormal heart rhythm). Your doctor needs to monitor blood levels of VESIREL and will adjust the digoxin dose when needed.
- Use desipramine, imipramine or clomipramine (medicines used for depression), thioridazine, haloperidol or risperidone (medicines used for mental illness) or medicine such as propafenone or flecainide for abnormal heart rhythm. These specific medicines may require dose adjustment by a doctor.
- Have kidney or liver problems and are using medicine such as itraconazole, ketoconazole (medicines used for fungal infections), ritonavir (medicine used for human immunodeficiency virus (HIV) infection (AIDS)) and clarithromycin (medicine used for bacterial infections). Your doctor may adjust the dose if necessary.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking VESIREL.

Do not take VESIREL if you are pregnant or breastfeeding your baby.

Driving and using machines

VESIREL may cause side effects such as dizziness, drowsiness (somnolence) and blurred vision, which may have an influence on your ability to drive and use machines.

It is not always possible to predict to what extent VESIREL may interfere with your daily activities, such as driving, riding, flying, sailing or operating machines/equipment. You should ensure that you do not engage in these activities until you are aware of the extent to which VESIREL affects you.

3. How to take VESIREL

Do not share medicines prescribed for you with any other person.

Always take VESIREL exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 50 mg VESIREL once daily.

If you have any kidney or liver problems, your doctor may need to reduce your dose to 25 mg once daily.

VESIREL should be taken with liquids, swallowed whole. Do not chew, divide or crush the tablets.

VESIREL may be taken with or without food.

Your doctor will tell you how long your treatment with VESIREL will last. If you have the impression that the effect of VESIREL is too strong or too weak, tell your doctor or pharmacist.

If you take more VESIREL than you should

If you take too many tablets you may be more likely to have side effects, such as forceful heart beating (palpitations), increased pulse rate and increased blood pressure.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to VESIREL

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose and then continue with your normal schedule. Do not take a double

dose to make up for a forgotten dose.

If you stop taking VESIREL

Continue to take VESIREL for as long as your doctor prescribes it.

You should not stop taking VESIREL without talking to your doctor first.

4. Possible side effects

VESIREL can have side effects.

Not all side effects reported for VESIREL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VESIREL, please consult your health care provider for advice.

If any of the following happens, stop taking VESIREL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash, hives or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to VESIREL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Swelling of the deeper layers of the skin (angioedema) may cause a build-up of fluids, which can affect any part of the body including the face, tongue or throat, resulting in difficulty in breathing.
- If you experience sudden, migraine-like (throbbing) headaches. This may be a sign of severely elevated blood pressure (hypertensive crisis).

These are all very serious side effects. If you have them, you may have had a serious reaction to

VESIREL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Urinary tract infection.
- Headache.
- Dizziness.
- Tachycardia.
- Nausea.
- Constipation.
- Diarrhoea.

Less frequent side effects:

- Vaginal infections.
- Bladder infections (cystitis).
- Insomnia.
- Confusional state.
- Drowsiness.
- Blurred vision.
- Swelling of eyelid (eyelid oedema).
- Increased heartbeat (palpitations).
- Irregular and often rapid heart rate (atrial fibrillation).
- Indigestion (dyspepsia).
- Infection of the stomach (gastritis).
- Swelling of the lip (lip oedema).
- Itching, hives or rash (urticaria, rash, macular rash, papular rash, pruritus).
- Inflammation of small blood vessels mainly affecting the skin (leukocytoclastic vasculitis).
- Small blood spots on the skin (purpura).

- Swelling of the deeper layers of the skin (angioedema).
- Joint swelling.
- Difficulty urinating and completely emptying the bladder (urinary retention).
- Vaginal itching, discharge and inflammation (vulvovaginal pruritus).
- Blood pressure increase.
- Increased liver enzymes (GGT, AST and ALT).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VESIREL. By reporting side effects, you can help provide more information on the safety of VESIREL.

5. How to store VESIREL

- Store at or below 25 °C
- HDPE container: Keep in the original container until required for use.
- Blister pack: Keep the blister strips in the original carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton, blister or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VESIREL contains:

The active substance is mirabegron.

Each prolonged-release tablet contains 25 mg or 50 mg mirabegron.

The other ingredients are:

Polyethylene glycol, hydroxypropyl cellulose, polyethylene oxide, magnesium stearate.

VESIREL 25 contains Opadry Brown

(consisting of hypromellose, iron oxide yellow, titanium dioxide, macrogol and iron oxide red).

VESIREL 50 contains Opadry Yellow

(consisting of hypromellose, iron oxide yellow, titanium dioxide, macrogol, iron oxide red).

What VESIREL looks like and contents of the pack

VESIREL 25: Brown, oval, biconvex, bevel-edged, film-coated tablets, debossed with “25” on one side and “M” on the other side. Tablets’ surface may have a rough film coating.

VESIREL 50: Yellow, oval, biconvex, bevel-edged, film-coated tablets, debossed with “50” on one side and “M” on the other side. Tablets’ surface may have a rough film coating.

White opaque HDPE bottle with white child-resistant polypropylene cap and 1 g silica gel canister.

Or

OPA/PVC/aluminium blister strips containing 10 tablets per blister strip.

Pack sizes: 30 or 90 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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