APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

VESIFIN 5 mg Film-coated tablets

VESIFIN 10 mg Film-coated tablets

Solifenacin succinate

VESIFIN contains sugar (lactose monohydrate 137,50 mg per 5 mg tablet and 132,50 mg per 10 mg tablet)

Read all of this leaflet carefully before you start taking VESIFIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- VESIFIN 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 VESIFIN is and what it is used for

VESIFIN contains a medicine called solifenacin succinate.

The active substance of VESIFIN belongs to the group of anticholinergics.

VESIFIN is used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

2. What you need to know before you take VESIFIN

Do not take VESIFIN:

- if you are hypersensitive (allergic) to solifenacin succinate or any of the other ingredients of VESIFIN (see section 6)
- if you have an inability to pass water or to empty your bladder completely (urinary retention)
- if you suffer from increased pressure in the eyes, with gradual loss of eyesight (glaucoma)
- if you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- if you have a severe stomach or bowel condition (toxic megacolon)
- if you are undergoing kidney dialysis
- if you have severe liver disease

- if you suffer from severe kidney disease or moderate liver disease and at the same time are being treated with medicines that may decrease the removal of VESIFIN from the body (for example, ketoconazole)
- if you have been diagnosed with a prolonged QT interval (a measurement made on an electrocardiogram used to assess some of the electrical properties of the heart)
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with VESIFIN:

- if you have other underlying diseases (for example heart failure or kidney disease) which may also lead to the urge to frequently urinate. Your doctor should address these conditions first before treatment with VESIFIN
- if you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine. Risk of accumulation of urine in the bladder (urinary retention) is much higher
- if you have some obstruction of the digestive system (constipation)
- if you are at risk of your digestive system slowing down (stomach and bowel movements)
- if you suffer from severe kidney disease
- if you have moderate liver disease
- if you are taking medicines which decreases the rate of breakdown of VESIFIN by the body for example ketoconazole
- if you have a stomach tear (hiatus hernia) or heartburn
- if you have a nervous disorder (autonomic neuropathy)

- if you have a condition called QT syndrome or Torsades de pointes, which are conditions associated with changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat.

Skin allergy that results in swelling of the tissue just below the skin (angioedema) with obstruction of the airway has been reported. If this occurs, you should stop taking VESIFIN and inform your doctor immediately.
Potentially life-threatening allergic reactions (anaphylactic reactions) have been reported. If you experience any allergic reaction, you should stop taking VESIFIN and inform your doctor immediately.

VESIFIN will only reach its complete effect after 4 weeks at the earliest.

Children and adolescents

Safety in children has not been established, therefore VESIFIN is not recommended for children under 18 years.

Other medicines and VESIFIN

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

- bisphosphonates (such as alendronate, risedronate, ibandronate, zoledronic acid, used to treat bone problems and osteoporosis)

- amantadine (used as an anti-viral or Parkinson's disease), some anti-histamines, phenothiazine (for psychiatric disorders), and tricyclic antidepressants as they can reduce the effect of VESIFIN
- metoclopramide (used to treat nausea and vomiting), domperidone and cisapride (to treat heartburn), which make the digestive system work faster, as VESIFIN can reduce their effect
- ketoconazole, itraconazole (used to treat fungal infections), ritonavir, nelfinavir (used to treat human immunodeficiency virus (HIV) infection), verapamil and diltiazem (used to treat high blood pressure and angina (chest pain)), which decrease the rate at which VESIFIN is broken down by the body. If you have severe kidney disease you should not take these medicines with VESIFIN (see section 2)
- rifampicin (used to treat tuberculosis (TB)), phenytoin and carbamazepine (used to treat epilepsy), as they increase the rate at which VESIFIN is broken down by the body.

Tell your doctor if you are taking or planning on taking any other anticholinergic medicines as he/she may advise you to wait 7 days after taking VESIFIN before taking any other anticholinergic medicines.

VESIFIN with food and drink

VESIFIN can be taken with or without food.

Pregnancy breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using VESIFIN.

VESIFIN is contraindicated in pregnancy and during breastfeeding.

Driving and using machines

VESIFIN may cause blurred vision, sleepiness, a general feeling of tiredness (somnolence and fatigue), dizziness or possibly
hallucinations (perceiving things that are not there). If you suffer from these side effects, do not drive or operate machinery, as it may affect these activities.
It is not always possible to predict to what extent VESIFIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VESIFIN affects them.

VESIFIN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Contains lactose monohydrate 137,50 mg per 5 mg tablet and 132,50 mg per 10 mg tablet. This should be taken into account in patients with diabetes mellitus.

3. How to take VESIFIN

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

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

The usual dose for VESIFIN is 5 mg per day. Your doctor may increase your dose to 10 mg per day if needed.

Your doctor will determine the correct dose for you based on your kidney function, liver function or any other medicines that you are taking at the same time.

You should swallow the whole tablet with some liquid. It can be taken with or without food.

Your doctor will tell you how long your treatment with VESIFIN will last. Do not stop treatment early because your symptoms may return.

If you have the impression that the effect of VESIFIN is too strong or too weak, tell your doctor or pharmacist.

If you take more VESIFIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- headache, dry mouth, dizziness, drowsiness and blurred vision.

If you forget to take VESIFIN

It is important that you do not miss any doses. If you miss a dose of VESIFIN, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule once daily. Do not take a double dose to make up for forgotten individual doses.

If you stop taking VESIFIN

Do not stop taking VESIFIN unless your doctor tells you to do so. If you have further questions on the use of VESIFIN, ask your doctor or pharmacist.

4. Possible side effects

VESIFIN can have side effects.

Not all side effects reported for VESIFIN are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using VESIFIN, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

- yellowing of the skin and eyes, also called jaundice
- chest pain
- angina
- changes in the way your heart beats e.g. if you notice it beating faster or slower, irregular heartbeat or changes in the electrical activity of your heart (electrocardiogram (ECG))
- difficulty in breathing
- less urine than is normal for you
- hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious, confusion or delirium
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite)
- angioedema (skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing)
- partial or complete obstruction in the bowel (faecal impaction) or the colon, (lodging of a large amount of hardened stool in the large intestine)
- allergic rash, reddening of patches of the skin (erythema multiforme) with symptoms including red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- blurred vision
- dry mouth, constipation, nausea, heartburn (dyspepsia), stomach pain.

Less frequent side effects:

- bladder infection, inflammation of the bladder due to infection (cystitis)
- sleepiness, impaired sense of taste (dysgeusia)
- dry eyes
- dry nasal passages
- reflux disease (gastro-oesophageal reflux), dry throat
- dry skin
- difficulty in passing urine
- tiredness, accumulation of fluid in the lower legs (oedema)
- dizziness and headache
- vomiting
- itching of the skin (pruritus), rash or hives (urticaria)
- fatigue, accumulation of fluid in the lower legs or hands (peripheral oedema).

The following side effects have been reported but the frequency for them to occur is not known:

- Itching, rash, skin or mouth rash that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring which may be painful, extreme reddening and peeling of the skin
- decreased appetite, high levels of blood potassium which can cause abnormal heart rhythm
- disturbed state of mind characterised by restlessness, illusions and confusion (delirium)
- increased pressure in the eyes (glaucoma)
- voice disorder
- a painful obstruction of the ileum or other part of the intestine, stomach discomfort
- liver disorder
- muscular weakness
- kidney disorder.

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, pharmacist or nurse. 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 VESIFIN.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store VESIFIN

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from light and moisture.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VESIFIN contains

The active substance is solifenacin succinate.

Each VESIFIN 5 mg film-coated tablet contains 5 mg solifenacin succinate.

Each VESIFIN 10 mg film-coated tablet contains 10 mg solifenacin succinate.

The other ingredients are

Ferric oxide red, hypromellose, lactose monohydrate, magnesium stearate, povidone, talc, titanium dioxide, triacetin.

What VESIFIN looks like and contents of the pack

VESIFIN 5 mg is a white to brown white, round, slightly convex film-coated tablet with bevelled edges.

VESIFIN 10 mg is a pinkish white, round, slightly convex film-coated tablet with bevelled edges.

VESIFIN tablets are available PVC/PVDC - Aluminium blister packs of 30 tablets each.

Each blister strip contains 10 tablets, with three blisters per pack.

Holder of Certificate of Registration

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