Package leaflet: Information for the user

Vesitirim™ 10mg film-coated tablets
(solifenacin succinate)

Your medicine is available using the above name but will be referred to as Vesitirim throughout this leaflet.

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 Vesitirim is and what it is used for

The active substance of Vesitirim belongs to the group of anticholinergics. These medicines are 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.

Vesitirim is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

2. What you need to know before you take Vesitirim

Do not take Vesitirim
- if you have an inability to pass water or to empty your bladder completely (urinary retention)
- if you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- if you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- if you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma)
- if you are allergic to solifenacin or any of the other ingredients of this medicine (listed in section 6)
- 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 Vesitirim from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Vesitirim starts.

Warnings and precautions
Talk to your doctor or pharmacist before taking Vesitirim
- if you have trouble emptying your bladder (= bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). 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). Your doctor will have informed you if this is the case.
- if you suffer from severe kidney disease.
- if you have moderate liver disease.
- if you have a stomach tear (hiatus hernia) or heartburn.
- if you have a nervous disorder (autonomic neuropathy).

Children and adolescents
Vesitirim is not to be used in children or adolescents under 18 years.

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Vesitirim starts.

Before starting Vesitirim, your doctor will assess whether there are other causes for your need to pass urine frequently (for example heart failure (insufficient pumping power of the heart) or kidney disease). If you have a urinary tract infection, your doctor will prescribe you an antibiotic (a treatment against particular bacterial infections).

Other medicines and Vesitirim
Please tell your doctor or pharmacist if you are taking or have recently taken or might take other medicines.

It is especially important to inform your doctor if you are taking:
- other anticholinergic medicines, effects and side effects of both medications can be enhanced.
- cholinergics as they can reduce the effect of Vesitirim.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Vesitirim can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, intraconazole, verapamil and diltiazem, which decrease the rate at which Vesitirim is broken down by the body.
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which Vesitirim is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

Vesitirim with food and drink
Vesitirim can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding
You should not use Vesitirim if you are pregnant unless clearly necessary. Do not use Vesitirim if you are breast-feeding as solifenacin may get into your breast milk.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Vesitirim may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

Vesitirim contains lactose monohydrate. If you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption you should not use this medicine.

3. How to take Vesitirim

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

You should swallow the whole tablet with some liquid. It can be taken with or without food, according to your preference.
Do not crush the tablets.

The usual dose is 5mg per day, unless your doctor told you to take 10mg per day.

If you take more Vesitirim than you should
If you have taken too much Vesitirim or if a child has accidentally taken Vesitirim, contact your doctor or pharmacist immediately.

Symptoms of overdose may include: headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

If you forget to take Vesitirim
If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose.
Never take more than one dose per day. If you are in doubt, always consult your doctor or pharmacist.

If you stop taking Vesitirim
If you stop taking Vesitirim, your symptoms of overactive bladder may return or worsen. Always consult your doctor, if you are considering stopping the treatment.

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

4. Possible side effects

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

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor or pharmacist immediately

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) has been reported in some patients on solifenacin succinate (Vesitirim). If angioedema occurs, solifenacin succinate (Vesitirim) should be discontinued immediately and appropriate therapy and/or measures should be taken.

Vesitirim may cause the following other side effects:

Very common (may affect more than 1 in 10 people)
- dry mouth

Common (may affect up to 1 in 10 people)
- blurred vision
- constipation, nausea, indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, and heartburn (dyspepsia), stomach discomfort

Uncommon (may affect up to 1 in 100 people)
- urinary tract infection, bladder infection
- sleepiness
- impaired sense of taste (dysgeusia)
- dry (irritated) 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)

Rare (may affect up to 1 in 1,000 people)
- lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- build up of urine in the bladder due to inability to empty the bladder (urinary retention)
- dizziness, headache
- vomiting
- itching, rash

Very rare (may affect up to 1 in 10,000 people)
- hallucinations, confusion
- allergic rash

Not known (frequency cannot be estimated from the available data)
- decreased appetite, high levels of blood potassium which can cause abnormal heart rhythm
- increased pressure in the eyes
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat
- voice disorder
- liver disorder
- muscle weakness
- renal disorder

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. You can also report side effects directly via
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vesitirim

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date (EXP) which is marked on the carton and the blister strip. This refers to the last day of that month.
This medicinal product does not require any special storage conditions.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.
Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.

6. Contents of the pack and other information

What Vesitirim contains
The active ingredient is solifenacin succinate.
Each tablet contains 10mg solifenacin succinate, corresponding to 7.5mg solifenacin.

The tablets also contain: maize starch, lactose, hypromellose (E464) and magnesium stearate.

The film coating contains: macrogol, talc, titanium dioxide (E171), hypromellose (E464) and red ferric oxide (E172).

What Vesitirim looks like and contents of the pack
Each 10mg tablet is a round, light pink tablet marked with the  logo and "151" on the same side.

Your medicine is available in blister packs containing 30, 50 or 90 film-coated tablets.
Not all pack sizes may be marketed.

Manufacturer
Manufactured by: Astellas Pharma Europe BV, Elisabethhof 19, 2353 EW Leiderdorp, The Netherlands
or
Astellas Pharma Europe BV, Hogemaat 2, 7942 JG Meppel, The Netherlands
or
Astellas Pharma Europe BV, Sylviusweg 62, 2333 BE Leiden, The Netherlands

Repackaged by: Cast Healthcare Ltd, Unit E
The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK or IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

PPA Holder: IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

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Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Norway, Poland, Portugal, Sweden, Slovenia, Slovakia, Spain and United Kingdom: Vesicare
Italy: Vesiker
Germany: Vesikur
Ireland: Vesitirim

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