Package leaflet: Information for the user

Vesicare™ 1mg/ml oral suspension

(solifenacin succinate)

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.

The name of your medicine is Vesicare 1mg/ml oral suspension but will be referred to as Vesicare throughout this leaflet.

What is in this leaflet

1. What Vesicare is and what it is used for

The active substance of Vesicare 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.

Vesicare is used to:
- treat the symptoms of a condition called overactive bladder in adults.
  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.

- treat a condition called neurogenic detrusor overactivity in children aged 2 to 18 years. Neurogenic detrusor overactivity is a condition in which involuntary bladder contractions occur due to a condition that you are born with or injury to the nerves, which control the bladder. If left untreated, neurogenic detrusor overactivity may lead to damage to your bladder and/or kidneys. Vesicare is used to increase the amount of urine your bladder can hold and reduce urine leakage.

2. What you need to know before you take Vesicare

Do not take Vesicare
- if you have an inability to pass water or to empty your bladder completely (urinary retention) and you do not practice clean intermittent catheterization (CIC);
- 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 Vesicare 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 Vesicare starts.

Warnings and precautions
Talk to your doctor or pharmacist before taking Vesicare
- if you have trouble emptying your bladder (= bladder obstruction) or have difficulty in passing urine (e.g., a thin urine flow) and you do not practice clean intermittent catheterization (CIC). In such a case the risk of accumulation of urine in your 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 any condition which results in alterations of your heart rhythm, especially an abnormality known as QT prolongation;
- 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).

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

Before starting Vesicare, 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).

Children and adolescents
Vesicare is not to be used in children under 2 years of age for treatment of neurogenic detrusor overactivity.

Vesicare is not to be used in children under 18 years of age for treatment of overactive bladder.

Other medicines and Vesicare
Tell your doctor or pharmacist if you are taking, have recently taken or might take any 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 Vesicare.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Vesicare can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which Vesicare is broken down by the body.
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which Vesicare is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

Vesicare with food and drink
Vesicare oral suspension should not be taken together with food and/or drinks other than water. Take a glass of water after you have taken a dose. See section 3. If you have accidently taken the suspension with food and/or drinks, you might experience a bitter taste and a feeling of numbness in your mouth.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use Vesicare if you are pregnant unless clearly necessary.

Do not use Vesicare if you are breast-feeding as solifenacin may get into your breast milk.

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

Vesicare oral suspension contains benzoic acid: This medicine contains 0.015mg benzoic acid in each ml, which is equivalent to 0.15mg/10ml.

Vesicare oral suspension contains ethanol: Ethanol originates from the natural orange flavour. This medicine contains 48.4mg of alcohol (ethanol) per maximum dose of 10ml Vesicare oral suspension. The amount of ethanol in 10ml Vesicare oral suspension is equivalent to 1ml beer (4% w/v) or less than 1ml wine (10% w/v). The small amount of alcohol in this medicine will not have any noticeable effects.

Vesicare oral suspension contains methyl parahydroxybenzoate and propyl parahydroxybenzoate: This may cause an allergic reaction (possibly delayed). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Vesicare oral suspension contains propylene glycol: This medicine contains 20mg propylene glycol in each ml, which is equivalent to 200mg/10ml.

Vesicare oral suspension contains sodium hydroxide: This medicine contains less than 1mmol sodium (23mg) per ml, that is to say essentially 'sodium-free'.

If you get Vesicare oral suspension in your eyes: rinse and clean your eyes thoroughly with water.

3. How to take Vesicare

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

Take this medicine by mouth, once daily. You can take this medicine before or after a meal. Drink a glass of water after you have taken a Vesicare dose. Do not take this medicine together with food and/or other drinks. If you have accidently taken the suspension with food and/or other drinks, you might experience a bitter taste and a feeling of numbness in your mouth.

<u>Adults with overactive bladder</u>
Your doctor will determine the appropriate dose for you. Use the oral syringe and bottle adaptor provided with Vesicare oral suspension to measure and administer the dose. If you need to take a dose of 10mg (10ml) per day, then you will need to use the syringe twice to administer the total amount of each dose. Rinse the tip of the oral syringe with warm water prior to reuse.

<u>Children and adolescents (age 2 to 18 years) with neurogenic detrusor overactivity</u>
Your doctor will tell you which dose you/your child should take. Your doctor will calculate the correct dose for a patient depending on his or her body weight. You should carefully follow their instructions.

Use the oral syringe and bottle adaptor provided with Vesicare oral suspension to measure and administer the dose. If you need to take a dose greater than 5mg (5ml) per day, then you will need to use the syringe twice to administer the total amount of each dose. Rinse the tip of the oral syringe with warm water prior to reuse.

How to take the Vesicare dose using an oral syringe
Use the oral syringe and adaptor provided with Vesicare oral suspension to measure the correct dose.

<u>Preparation for the first use of a bottle of Vesicare oral suspension</u>
1. Wash your hands carefully.
2. Open the carton and remove the bottle, syringe, and adaptor.
3. Place the bottle on a flat surface and remove the cap.
4. Firmly press the adaptor into the neck of the bottle.
5. Ensure that the top of the adaptor is flush with the top of the bottle neck.
6. The adaptor should remain in the neck of the bottle until the end of the 28-day shelf life period.
7. Replace the cap on the bottle.

<u>Before each oral administration</u>
1. Wash your hands carefully.
2. Shake the Vesicare oral suspension bottle at least 20 times.
3. Remove the bottle cap and ensure the adaptor is present in the bottle neck. Insert the oral syringe tip into central opening of the bottle adaptor until it is firmly in place.
4. Carefully invert the bottle and syringe ensuring the adaptor remains in place.

5. Pull back the plunger of the syringe slowly to withdraw the amount prescribed by your doctor from the inverted bottle.
6. Discard the overage if too much medicine has been accidently withdrawn.
7. Ensure that there are no air bubbles in the syringe. If an air bubble appears, push the plunger upwards to remove a potential bubble.
8. Leave the syringe in place and turn the bottle upright and ensure the plunger of the syringe does not move. Gently remove the syringe from the adaptor. The adaptor should remain in place.
9. Confirm the appropriate dose has been measured. Place the syringe in the mouth and gently push the plunger down to administer the medication to the patient.
10. After completion of dosing; close the bottle with the cap.
11. Wash the syringe with warm water. Allow to dry.

Note: If the patient requires a dose >5ml rinse the tip of the syringe with warm water prior to reuse.

Cleaning of the oral syringe
After use, clean the oral syringe with warm water only.

The oral syringe can be used throughout the 28-day shelf life after first opening (see section 5).

If you take more Vesicare than you should
If you have taken too much Vesicare or if a child has accidentally taken Vesicare, 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 Vesicare
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 Vesicare
If you stop taking Vesicare, your symptoms of your underlying bladder disease 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Vesicare and seek medical help immediately if you notice any of the following side effects:
If you experience an allergic attack (a sudden and rapid side effect consisting of generalized itching, hives, swelling, difficulty breathing and/or other allergic reactions, called anaphylaxis), or a severe skin reaction (e.g., blistering and peeling of the skin).
If you experience an 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). Angioedema has been reported in some patients on Vesicare.

Vesicare 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, 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 heart beat
- voice disorder
- liver disorder
- muscle weakness
- renal disorder

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Vesicare

Keep out of the sight and reach of children.
Store the oral syringe under clean and dry conditions and protect from sunlight and heat.
Store in the original bottle in order to protect from light.
This product does not require any special temperature storage conditions.
After first opening of the bottle, the suspension can be stored for 28 days.
Discard any remaining medicine 28 days after opening the bottle.
Do not use the suspension after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
If the suspension becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Remember if your doctor tells you to stop using this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
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.

6. Contents of the pack and other information

What Vesicare contains
The active ingredient in the vesicare is solifenacin succinate.
Each ml oral suspension contains 1mg solifenacin succinate, equivalent to 0.75mg solifenacin.

The other ingredients are polacrilin potassium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), simethicone emulsion 30% (consisting of simethicone, polyethylene glycol sorbitan tristearate (E436), methylcellulose (E461), polyethylene glycol stearate, glycerides, xanthan gum (E415), benzoic acid (E210), sorbic acid (E200), sulphuric acid (E513) and water), carbomer, xylitol (E967), acesulfame potassium (E950), natural orange flavour (consisting of orange essential oils, natural flavouring substances, ethanol, propylene glycol (E1520), butylated hydroxyanisol (E320) and water), sodium hydroxide, purified water.

What Vesicare looks like and contents of the pack
Vesicare oral suspension is a white to off-white coloured aqueous, homogeneous suspension with an orange flavour.

It is available in amber polyethylene terephthalate (PET) bottle of 150 ml with a child resistant and high density polyethylene-polypropylene cap.

Devices for dosing and administration are packed in the carton: 5ml oral syringe and press-in bottle neck adaptor.

Manufactured by: Delpharm Meppel B.V., Hogemaat 2, 7942 JG Meppel, The Netherlands.

Procured from within the EU & repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Vesicare™ 1mg/ml oral suspension; PL 18799/4272

POM

Leaflet date: 23.12.2025

Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

Package leaflet: Information for the user

Solifenacin succinate 1mg/ml oral suspension

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- 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.

The name of your medicine is Solifenacin succinate 1mg/ml oral suspension but will be referred to as Solifenacin throughout this leaflet.

What is in this leaflet

1. What Solifenacin is and what it is used for

The active substance of Solifenacin 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.

Solifenacin is used to:
- treat the symptoms of a condition called overactive bladder in adults.
  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.

- treat a condition called neurogenic detrusor overactivity in children aged 2 to 18 years. Neurogenic detrusor overactivity is a condition in which involuntary bladder contractions occur due to a condition that you are born with or injury to the nerves, which control the bladder. If left untreated, neurogenic detrusor overactivity may lead to damage to your bladder and/or kidneys. Solifenacin is used to increase the amount of urine your bladder can hold and reduce urine leakage.

2. What you need to know before you take Solifenacin

Do not take Solifenacin
- if you have an inability to pass water or to empty your bladder completely (urinary retention) and you do not practice clean intermittent catheterization (CIC);
- 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 Solifenacin 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 Solifenacin starts.

Warnings and precautions
Talk to your doctor or pharmacist before taking Solifenacin
- if you have trouble emptying your bladder (= bladder obstruction) or have difficulty in passing urine (e.g., a thin urine flow) and you do not practice clean intermittent catheterization (CIC). In such a case the risk of accumulation of urine in your 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 any condition which results in alterations of your heart rhythm, especially an abnormality known as QT prolongation;
- if you suffer from severe kidney disease;
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- if you have a nervous disorder (autonomic neuropathy).

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

Before starting Solifenacin, 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).

Children and adolescents
Solifenacin is not to be used in children under 2 years of age for treatment of neurogenic detrusor overactivity.

Solifenacin is not to be used in children under 18 years of age for treatment of overactive bladder.

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

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

Solifenacin with food and drink
Solifenacin oral suspension should not be taken together with food and/or drinks other than water. Take a glass of water after you have taken a dose. See section 3. If you have accidently taken the suspension with food and/or drinks, you might experience a bitter taste and a feeling of numbness in your mouth.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use Solifenacin if you are pregnant unless clearly necessary.

Do not use Solifenacin if you are breast-feeding as solifenacin may get into your breast milk.

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

Solifenacin oral suspension contains benzoic acid: This medicine contains 0.015mg benzoic acid in each ml, which is equivalent to 0.15mg/10ml.

Solifenacin oral suspension contains ethanol: Ethanol originates from the natural orange flavour. This medicine contains 48.4mg of alcohol (ethanol) per maximum dose of 10ml Solifenacin oral suspension. The amount of ethanol in 10ml Solifenacin oral suspension is equivalent to 1ml beer (4% w/v) or less than 1ml wine (10% w/v). The small amount of alcohol in this medicine will not have any noticeable effects.

Solifenacin oral suspension contains methyl parahydroxybenzoate and propyl parahydroxybenzoate: This may cause an allergic reaction (possibly delayed). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Solifenacin oral suspension contains propylene glycol: This medicine contains 20mg propylene glycol in each ml, which is equivalent to 200mg/10ml.

Solifenacin oral suspension contains sodium hydroxide: This medicine contains less than 1 mmol sodium (23mg) per ml, that is to say essentially ‘sodium-free’.

If you get Solifenacin oral suspension in your eyes: rinse and clean your eyes thoroughly with water.

3. How to take Solifenacin

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

Take this medicine by mouth, once daily. You can take this medicine before or after a meal. Drink a glass of water after you have taken a Solifenacin dose. Do not take this medicine together with food and/or other drinks. If you have accidently taken the suspension with food and/or other drinks, you might experience a bitter taste and a feeling of numbness in your mouth.

<u>Adults with overactive bladder</u>
Your doctor will determine the appropriate dose for you. Use the oral syringe and bottle adaptor provided with Solifenacin oral suspension to measure and administer the dose. If you need to take a dose of 10 mg (10 ml) per day, then you will need to use the syringe twice to administer the total amount of each dose. Rinse the tip of the oral syringe with warm water prior to reuse.

<u>Children and adolescents (age 2 to 18 years) with neurogenic detrusor overactivity</u>
Your doctor will tell you which dose you/your child should take. Your doctor will calculate the correct dose for a patient depending on his or her body weight. You should carefully follow their instructions.

Use the oral syringe and bottle adaptor provided with Solifenacin oral suspension to measure and administer the dose. If you need to take a dose greater than 5mg (5ml) per day, then you will need to use the syringe twice to administer the total amount of each dose. Rinse the tip of the oral syringe with warm water prior to reuse.

How to take the Solifenacin dose using an oral syringe
Use the oral syringe and adaptor provided with Solifenacin oral suspension to measure the correct dose.

<u>Preparation for the first use of a bottle of Solifenacin oral suspension</u>
1. Wash your hands carefully.
2. Open the carton and remove the bottle, syringe, and adaptor.
3. Place the bottle on a flat surface and remove the cap.
4. Firmly press the adaptor into the neck of the bottle.
5. Ensure that the top of the adaptor is flush with the top of the bottle neck.
6. The adaptor should remain in the neck of the bottle until the end of the 28-day shelf life period.
7. Replace the cap on the bottle.

<u>Before each oral administration</u>
1. Wash your hands carefully.
2. Shake the Solifenacin oral suspension bottle at least 20 times.
3. Remove the bottle cap and ensure the adaptor is present in the bottle neck. Insert the oral syringe tip into central opening of the bottle adaptor until it is firmly in place.
4. Carefully invert the bottle and syringe ensuring the adaptor remains in place.

5. Pull back the plunger of the syringe slowly to withdraw the amount prescribed by your doctor from the inverted bottle.
6. Discard the overage if too much medicine has been accidently withdrawn.
7. Ensure that there are no air bubbles in the syringe. If an air bubble appears, push the plunger upwards to remove a potential bubble.
8. Leave the syringe in place and turn the bottle upright and ensure the plunger of the syringe does not move. Gently remove the syringe from the adaptor. The adaptor should remain in place.
9. Confirm the appropriate dose has been measured. Place the syringe in the mouth and gently push the plunger down to administer the medication to the patient.
10. After completion of dosing; close the bottle with the cap.
11. Wash the syringe with warm water. Allow to dry.

Note: If the patient requires a dose >5ml rinse the tip of the syringe with warm water prior to reuse.

Cleaning of the oral syringe
After use, clean the oral syringe with warm water only.

The oral syringe can be used throughout the 28-day shelf life after first opening (see section 5).

If you take more Solifenacin than you should
If you have taken too much Solifenacin or if a child has accidentally taken Solifenacin, 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 Solifenacin
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 Solifenacin
If you stop taking Solifenacin, your symptoms of your underlying bladder disease 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Solifenacin and seek medical help immediately if you notice any of the following side effects:
If you experience an allergic attack (a sudden and rapid side effect consisting of generalized itching, hives, swelling, difficulty breathing and/or other allergic reactions, called anaphylaxis), or a severe skin reaction (e.g., blistering and peeling of the skin).
If you experience an 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). Angioedema has been reported in some patients on Solifenacin.

Solifenacin 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, 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
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Reporting of side effects
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5. How to store Solifenacin

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Store the oral syringe under clean and dry conditions and protect from sunlight and heat.
Store in the original bottle in order to protect from light.
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Remember if your doctor tells you to stop using this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
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.

6. Contents of the pack and other information

What Solifenacin contains
The active ingredient is solifenacin succinate.
Each ml oral suspension contains 1mg solifenacin succinate, equivalent to 0.75mg solifenacin.

The other ingredients are polacrilin potassium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), simethicone emulsion 30% (consisting of simethicone, polyethylene glycol sorbitan tristearate (E436), methylcellulose (E461), polyethylene glycol stearate, glycerides, xanthan gum (E415), benzoic acid (E210), sorbic acid (E200), sulphuric acid (E513) and water), carbomer, xylitol (E967), acesulfame potassium (E950), natural orange flavour (consisting of orange essential oils, natural flavouring substances, ethanol, propylene glycol (E1520), butylated hydroxyanisol (E320) and water), sodium hydroxide, purified water.

What Solifenacin looks like and contents of the pack
Solifenacin oral suspension is a white to off-white coloured aqueous, homogeneous suspension with an orange flavour.

It is available in amber polyethylene terephthalate (PET) bottle of 150 ml with a child resistant and high density polyethylene-polypropylene cap.

Devices for dosing and administration are packed in the carton: 5ml oral syringe and press-in bottle neck adaptor.

Manufactured by: Delpharm Meppel B.V., Hogemaat 2, 7942 JG Meppel, The Netherlands.

Procured from within the EU & repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Solifenacin succinate 1mg/ml oral suspension; PL 18799/4272

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