Solifenacin succinate 5mg film-coated tablets
Solifenacin succinate 10mg film-coated tablets

If you experience an allergic attack, or a severe side effect (e.g. tingling and puckering of the skin), you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

4. POSSIBLE SIDE EFFECTS

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 you think are side effects of this medicine, 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
- This medicine and what it is for
- What you need to know before you take this medicine
- How to take this medicine
- Possible side effects
- Contents of the pack and other information

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

The active substance solifenacin succinate belongs to the group of drugs called anticholinergics. These medicines are used to reduce the activity of the bladder muscle. This enables you to wait longer before going to the bathroom and increases the amount of urine that can be held by your bladder.

This medicine is used to treat the symptoms of overactive bladder in adults. The symptoms of overactive bladder include:

- having a strong, sudden urge to pass urine
- not being able to stop passing urine

Symptoms often include:

- headaches
- dizziness
- drowsiness
- blurred vision

Side effects and what to do if you get them

1. WHAT YOU NEED TO KNOW BEFORE YOU TAKE THIS MEDICINE

Do not take this medicine
- If you have an itchy mouth or throat, or if you want or need to stop taking this medicine immediately.
- If you have a severe stomach or bowel condition (including constipation) or if you cannot pass urine.
- If you have a stomach or bowel condition that cannot usually be passed or if you have an allergic reaction to this medicine.
- If you have severe liver disease.
- If you have severe kidney disease.
- If you have a nervous disorder (e.g. Parkinson’s disease). Your doctor will have informed you if this is the case.

If you forget to take a dose
- If you forget to take a dose at the usual time.
- If you are feeling unwell or if you have a sick feeling (nausea).

If you take too much of this medicine
- If you take more solifenacin succinate than you should.

What is this medicine and what it is for
- This medicine contains solifenacin succinate.
- Solifenacin succinate tablets are used to treat the symptoms of overactive bladder (OAB) in adults.

The active substance solifenacin succinate belongs to the group of drugs called anticholinergics. These medicines are used to reduce the activity of the bladder muscle. This enables you to wait longer before going to the bathroom and increases the amount of urine that can be held by your bladder.

Children and adolescents
- This medicine should not be used in children or adolescents under 18 years.

Other medicines and solifenacin succinate
tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

It is especially important to inform your doctor if you are taking:

- angiotensin-converting enzyme (ACE) inhibitors (e.g. enalapril, captopril), because these medicines may increase the risk of side effects such as a fluid retention.

- other anticholinergic medicines (e.g. tolterodine, darifenacin), because they too may increase the risk of side effects.

- other antispasmodic medicines (e.g. dicyclomine), because they too may increase the risk of side effects.

Warnings and precautions
- Do not use this medicine.
- Do not use this medicine if you have kidney problems.
- Do not use this medicine if you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, lactase deficiency or fructose intolerance.
- Do not use this medicine if you are allergic to any of its ingredients.
- Do not use this medicine if you are breast-feeding as solifenacin succinate may get into your breast milk.
- Do not use this medicine if you are pregnant unless clearly necessary.
- Do not use this medicine if you are breast-feeding as solifenacin succinate may get into your breast milk.
- Do not use this medicine if you are pregnant unless clearly necessary.

Driving and using machines
- This medicine may cause blurred vision and sometimes sleepiness or tiredness. If any of these side effects develops, do not drive or operate machinery.

This medicine contains lactose.
- If you have been told by your doctor that you have galactose intolerance, you should consider whether you should use this medicine.
- You should not use this medicine.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.

In some cases, solifenacin succinate tablets may be used in children aged 12 years and over, and in adolescents aged 16 years and over.

In elderly patients, solifenacin succinate tablets should be used with caution, and only at the lowest possible dose.

If you are pregnant or breast-feeding when you start taking this medicine, you must inform your doctor or pharmacist immediately.

If you are taking this medicine and you start taking other medicines, you must inform your doctor or pharmacist immediately.
This medicine 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 pain, burning, nausea, and heartburn (dyspepsia), Stomach discomfort

**Uncommon** (may affect up to 1 in 100 people)
- urinary tract infection, bladder infection
- sleeplessness, impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastric-oesophageal reflux), dry throat
- dry skin
- reflux disease (gastric-oesophageal reflux), dry throat
- constipation, nausea, indigestion with symptoms such as abdominal pain, burning, nausea, and heartburn (dyspepsia), stomach discomfort

**Rare** (may affect up to 1 in 1,000 people)
- urinary tract infection, bladder infection
- sleepiness, impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastric-oesophageal reflux), dry throat
- dry skin
- difficulty in passing urine
- tiredness, accumulation of fluid in the lower legs (oedema)

**Very rare** (may affect up to 1 in 10,000 people)
- hallucinations, confusion
- allergic rash
- blurred vision
- constipation, nausea, indigestion with symptoms such as abdominal pain, burning, nausea, and heartburn (dyspepsia), Stomach discomfort
- urinary tract infection, bladder infection
- sleeplessness, impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastric-oesophageal reflux), dry throat
- dry skin
- difficulty in passing urine
- tiredness, accumulation of fluid in the lower legs (oedema)

**Not known** (frequency cannot be estimated from the available data)
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your pulse and fast heartbeat
- 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 website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE THIS MEDICINE

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 after EXPI.

There are no special precautions for storage.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What this medicine contains
The active substance is solifenacin succinate.

The other ingredients are maize starch, lactose monohydrate, hypromellose, magnesium stearate, silicon dioxide (talc), propyl gallate, polyethylene glycol 4000, titanium dioxide (E171) and iron oxide red (E172).

5 mg tablets only: iron oxide yellow (E172).

What this medicine looks like and contents of the pack

Solifenacin succinate film-coated tablets are available in two strengths.

5 mg tablets are pink coloured, round, biconvex, film-coated tablets marked with “5” on one side. 10 mg tablets are red-brown coloured, round, biconvex, film-coated tablets marked with “10” on one side.

Available in pack sizes of 10, 20, 30, 50, 90, 100 film-coated tablets in blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aspire Pharma Limited
Unit 4, Rothesbrooke Court
Bodford Road
Peterfield
Gu32 3QL

United Kingdom

Manufacturer(s)

Delcato Pharmaceutical Limited
17 Athion Street
Ergates Industrial Area
Engales, Lefkosia (Nicosia)
Cyprus

Or

Medica International a.s.
Production plant Bolatice
Průmyslova 601/16
247 23 Bolatice
Czech Republic

This leaflet was last revised in 08/2018.

1010466 - P1.6
<table>
<thead>
<tr>
<th>Packaging Information:</th>
<th>Colour: Pantone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name: Solifenacin</td>
<td>PMS Black</td>
</tr>
<tr>
<td>PN: PL 35533/0139-0140</td>
<td></td>
</tr>
<tr>
<td>Dimensions: 165X480MM</td>
<td></td>
</tr>
<tr>
<td>Type: leaflet</td>
<td></td>
</tr>
<tr>
<td>Version No: 1.6</td>
<td></td>
</tr>
<tr>
<td>Date amended: 20.12.18</td>
<td></td>
</tr>
<tr>
<td>Font: Helvetica LT Pro</td>
<td></td>
</tr>
<tr>
<td>Average font size: 8</td>
<td></td>
</tr>
<tr>
<td>Reason for change Initial Artwork</td>
<td></td>
</tr>
<tr>
<td>Software: Adobe Indesign CS6</td>
<td></td>
</tr>
<tr>
<td>Created by: TP</td>
<td></td>
</tr>
</tbody>
</table>