Package leaflet: Information for the user

Emselex 7.5 mg prolonged-release tablets
Darifenacin

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk 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 Emselex is and what it is used for
2. What you need to know before you take Emselex
3. How to take Emselex
4. Possible side effects
5. How to store Emselex
6. Contents of the pack and other information

1. What Emselex is and what it is used for

How Emselex works
Emselex reduces the activity of an overactive bladder. This enables you to wait longer before you go to the toilet and it increases the amount of urine that your bladder can hold.

What Emselex can be used for
Emselex belongs to a class of medicines which relax the muscles of the bladder. It is used in adults for the treatment of the symptoms of overactive bladder conditions - such as a sudden urge to rush to the toilet, needing to go to the toilet frequently and/or not getting to the toilet in time and wetting yourself (urge incontinence).

2. What you need to know before you take Emselex

Do not take Emselex
- if you are allergic to darifenacin or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from urinary retention (inability to empty your bladder).
- if you have gastric retention (problems emptying the contents of the stomach).
- if you suffer from uncontrolled narrow-angle glaucoma (high pressure in the eyes that is not being adequately treated).
- if you have myasthenia gravis (a disease marked by unusual tiredness and weakness of selected muscles).
- if you have severe ulcerative colitis or toxic megacolon (acute dilation of the colon due to complication of infection or inflammation).
- if you have severe liver problems.
- if you are taking medicines that strongly decrease the activity of some liver enzymes such as ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g. rheumatoid arthritis or atopic dermatitis), verapamil (a medicine used to lower blood pressure, to correct heart rhythm or to treat angina pectoris), antifungal medicines (e.g. ketoconazole and itraconazole) and some antiviral medicines (e.g. ritonavir) – see paragraph “Other medicines and Emselex”.

Warnings and precautions
Talk to your doctor before taking Emselex

- if you have autonomic neuropathy (damage to the nerves that communicate between the brain and internal organs, muscles, skin, and blood vessels to regulate vital functions, including the heart rate, blood pressure and bowel function) – your doctor will have told you if you have this.
- if you have a condition where one or more organs in your abdomen has moved up into your chest through a hole in your diaphragm, causing you to get heartburn and belch a lot.
- if you have difficulties in passing urine and a weak stream of urine.
- if you have severe constipation (less than or equal to 2 bowel movements per week).
- if you have a digestive motility disorder.
- if you have an obstructive gastrointestinal disorder (any obstruction of the passage of intestinal or gastric contents, such as narrowing of the pylorus, the lower part of the stomach) – your doctor will have told you if you have this.
- if you are taking medicinal products that can cause or worsen inflammation of the oesophagus such as oral bisphosphonates (a class of medicinal products that prevent the loss of bone mass and are used to treat osteoporosis).
- if you are receiving treatment for narrow-angle glaucoma.
- if you have liver problems.
- if you have urinary tract infection or other kidney problems.
- if you have an overactive muscle that controls the emptying of the bladder which may cause accidental passing of urine (a condition called detrusor hyperreflexia) – your doctor will tell you if you are suffering from this condition.
- if you have heart diseases.

If any of these apply to you, tell your doctor before you take Emselex.

During treatment with Emselex, tell your doctor straight away and stop taking Emselex if you experience swelling of the face, lips, tongue and/or throat (signs of angioedema).

Children and adolescents
Emselex is not recommended for use in children and adolescents (<18 years).

Other medicines and Emselex
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is particularly important if you are taking any of the following as your doctor may need to adjust your dose of Emselex and/or the other medicine:

- certain antibiotics (e.g. erythromycin, clarithromycin, telithromycin and rifampicin),
- antifungal medicines (e.g. ketoconazole and itraconazole - see paragraph “Do not take Emselex”, fluconazole, terbinafine),
- medicines used to reduce the activity of the immune system, for example, after organ transplantation (e.g. ciclosporin - see paragraph “Do not take Emselex”),
- antiviral medicines (e.g. ritonavir - see paragraph “Do not take Emselex”),
- antipsychotic medicines (e.g. thioridazine),
- certain antidepressants (e.g. imipramine and paroxetine),
- certain anticonvulsants (carbamazepine, barbiturates),
- certain medicines used to treat heart problems (e.g. verapamil - see paragraph “Do not take Emselex”, flecainide, digoxin and quinidine),
- certain medicines used for the treatment of stomach problems (e.g. cimetidine),
- other antimuscarinic medicines (e.g. tolterodine, oxybutynin and flavoxate).

Please also inform your doctor if you are taking products containing St John’s wort.

Emselex with food and drink
Eating food has no effect on Emselex. Grapefruit juice may interact with Emselex. Tell your doctor if you are taking grapefruit juice regularly.

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 for advice before taking this medicine.
Emselex is not recommended during pregnancy.
Emselex should be taken with caution while breast-feeding.

Driving and using machines
Emselex may cause effects such as dizziness, blurred vision, trouble sleeping or drowsiness. If you have any of these symptoms whilst taking Emselex, consult your doctor for advice on changing the dose or considering an alternative treatment. You should not drive or use machines if you are affected by these symptoms. For Emselex, these side effects have been reported to be uncommon (see section 4).

3. How to take Emselex

Always take Emselex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of Emselex is too strong or too weak, talk to your doctor or pharmacist.

How much Emselex to take
The recommended starting dose, including for patients aged over 65 years, is 7.5 mg daily. Depending on your response to Emselex, your doctor may increase your dose to 15 mg daily, two weeks after starting therapy.

These doses are suitable for people with mild liver problems or people with kidney problems.

Take Emselex tablets once a day with liquid, at about the same time each day.

The tablet may be taken with or without food. Swallow the tablet whole. Do not chew, split or crush it.

If you take more Emselex than you should
If you have taken more tablets than you have been told to take, or if someone else accidentally takes your tablets, go to your doctor or hospital for advice immediately. When seeking medical advice, make sure that you take this leaflet and your remaining tablets with you to show them to the doctor. People who have taken an overdose may have dry mouth, constipation, headache, indigestion and nasal dryness. Overdose with Emselex may lead to severe symptoms requiring emergency treatment in hospital.

If you forget to take Emselex
If you forget to take Emselex at the usual time, take it as soon as you remember, unless it is the time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Emselex
Your doctor will tell you how long your treatment with Emselex will last. Do not stop treatment early because you do not see an immediate effect. Your bladder will need some time to adapt. Finish the course of treatment prescribed by your doctor. If you have not noticed any effect by then, discuss it with your doctor.

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. The side effects caused by Emselex are usually mild and temporary.

Some side effects could be serious
Not known (frequency cannot be estimated from the available data)
Serious allergic reactions including swelling, mainly of the face and neck (angioedema).

Other side effects
Very common (may affect more than 1 in 10 people)
Dry mouth, constipation.

Common (may affect up to 1 in 10 people)
Headache, abdominal pain, indigestion, feeling sick, dry eyes, nasal dryness.

Uncommon (may affect up to 1 in 100 people)
Fatigue, accidental injury, facial swelling, high blood pressure, diarrhoea, flatulence, ulceration of the mucous membrane of the mouth, increased liver enzymes (this shows abnormal functioning of the liver), swelling including swelling of the hands, ankles or feet, dizziness, sleeplessness, drowsiness, abnormal thinking, runny nose (rhinitis), cough, shortness of breath, dry skin, itching, rash, sweating, visual disturbance including blurred vision, taste disturbance, urinary tract disorder or infection, impotence, discharge and itching in the vagina, bladder pain, inability to empty your bladder.

Not known (frequency cannot be estimated from the available data)
Confusion, depressed mood/mood altered, hallucination, muscle spasms.

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 national reporting system:

Yellow Card Scheme
Website: 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 Emselex

- 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 and blister. The expiry date refers to the last day of that month.
- Keep the blister packs in the outer carton in order to protect from light.
- Do not use if the pack is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Emselex contains
- The active substance is darifenacin. Each tablet contains 7.5 mg darifenacin (as hydrobromide).
- The other ingredients are calcium hydrogen phosphate (anhydrous), hypromellose, magnesium stearate, polyethylene glycol, titanium dioxide (E171) and talc.

What Emselex looks like and contents of the pack
Emselex 7.5 mg prolonged-release tablets are round, convex white tablets and are debossed with “DF” on one side and “7.5” on the other.

The tablets are available in blister packs containing 7, 14, 28, 49, 56 or 98 tablets or in multipacks containing 140 (10x14) tablets. Not all pack sizes may be available in your country.

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu