Summary Public Assessment Report

non-generics

Dulsevia 90 mg hard gastro-resistant capsules
Duloxetine hydrochloride

SK/H/0155/003/DC

Date: December 2017

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Invented name of product: Dulsevia 90 mg hard gastro-resistant capsule

Active substance/common name, pharmaceutical form and strength: Dulsevia, hard gastro-resistant capsule, 90 mg

This is a summary of the public assessment report (PAR) for Dulsevia 90 mg. It explains how Dulsevia 90 mg was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Dulsevia 90 mg.

For practical information about using Dulsevia 90 mg, patients should read the package leaflet or contact their doctor or pharmacist.

What is Dulsevia 90 mg and what is it used for?
Dulsevia 90 mg is a 'hybrid generic medicine'. This means that it is similar to a reference medicine containing the same active substance, but 90 mg capsule strength represents a different strength compared to the reference medicinal product (30 mg and 60 mg).
The company has provided additional own data to demonstrate the safety and efficacy of Dulsevia 90 mg regarding this difference from the reference medicine.

The reference medicine for Dulsevia 90 mg is Ariclaim 30 mg, 60 mg gastro-resistant capsule.
Dulsevia 90 mg is used in adults to treat depression and generalised anxiety disorder (chronic feeling of anxiety or nervousness).

How does Dulsevia 90 mg work?
Dulsevia 90 mg contains the active substance duloxetine. Dulsevia 90 mg increases the levels of serotonin and noradrenaline in the nervous system.

How is Dulsevia 90 mg used?
The pharmaceutical form of Dulsevia 90 mg is hard gastro-resistant capsule and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

For depression:
The usual dose of duloxetine is 60 mg once a day, but your doctor will prescribe the dose that is right for you.

For generalised anxiety disorder:
The usual starting dose of duloxetine is 30 mg once a day after which most patients will receive 60 mg once a day, but your doctor will prescribe the dose that is right for you. The dose may be adjusted up to 120 mg a day based on your response duloxetine.

The medicine can only be obtained with a prescription.

What benefits of Dulsevia 90 mg have been shown in studies?
Because Dulsevia 90 mg is a hybrid application and is considered to be therapeutically equivalent, to the reference product Ariclaim, their benefits and risks are taken as being the same as those of the reference medicine Because Dulsevia 90 mg is a hybrid application of Ariclaim, clinical studies have been provided for Dulsevia 90 mg to show efficacy for the difference of Dulsevia 90 mg from the reference product.

What are the possible side effects from X?
The most common side effects with Dulsevia 90 mg (which may affect more than 1 in 10 people) are headache, feeling sleepy, feeling sick (nausea) and dry mouth.
The most common side effects with Dulsevia 90 mg (which may affect up to 1 in 10 people) are:
- lack of appetite
- trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty or failure to experience orgasm, unusual dreams
- dizziness, feeling sluggish, tremor, numbness, including numbness, pricking or tingling of the
skin
- blurred eyesight
- tinnitus (hearing sound in the ear when there is no external sound)
- feeling the heart pumping in the chest,
- increased blood pressure, flushing
- increased yawning
- constipation, diarrhoea, stomach pain, being sick (vomiting), heartburn or indigestion, breaking
wind
- increased sweating, (itchy) rash
- muscle pain, muscle spasm
- painful urination, frequent urination
- problems getting an erection, changes in ejaculation
- falls (mostly in elderly people), fatigue
- weight loss
For the full list of all side effects reported with Dulsevia 90 mg, see section 4 of the package leaflet.

Do not take Dulsevia 90 mg if you:
- are allergic to duloxetine or any of the other ingredients of this medicine
- have liver disease
- have severe kidney disease
- are taking or have taken within the last 14 days, another medicine known as a monoamine oxidase inhibitor (MAOI) (see "Other medicines and <Invented name>")
- are taking fluvoxamine which is usually used to treat depression, ciprofloxacin or enoxacin which are used to treat some infections
- are taking other medicines containing duloxetine (see "Other medicines and <Invented name>")
For the full list of restrictions, see the package leaflet.

Why is Dulsevia 90 mg approved?
The State Institute for Drug Control decided that Dulsevia 90 mg's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Dulsevia 90 mg?
A risk management plan has been developed to ensure that Dulsevia 90 mg is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Dulsevia 90 mg, including the appropriate precautions to be followed by healthcare professionals and patients.
Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Dulsevia 90 mg
The marketing authorisation for Dulsevia 90 mg was granted on 02.11.2017.
The full PAR for Dulsevia 90 mg can be found on the ŠÚKL website. For more information about treatment with Dulsevia 90 mg, read the package leaflet or contact your doctor or pharmacist.
This summary was last updated in December 2017.