Summary Public Assessment Report

Generics

Sertraline Medreg 50 mg, 100 mg
sertraline hydrochloride

SK/H/0297/001-002/DC

Date: 11.06.2024

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Generics

Sertraline Medreg 50 mg
Sertraline Medreg 100 mg

Sertraline hydrochloride/Sertraline, film-coated tablets 50 and 100 mg

This is a summary of the public assessment report (PAR) for Sertraline Medreg. It explains how Sertraline Medreg 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 Sertraline Medreg.

For practical information about using Sertraline Medreg, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sertraline Medreg and what is it used for?

Sertraline Medreg is a 'generic medicine'. This means that Sertraline Medreg is similar to a 'reference medicine' already authorised in the European Union (EU) called Zoloft.

Sertraline Medreg is used in the treatment of:
- depression and prevention of recurrence of depression (in adults)
- social anxiety disorder (in adults)
- post-traumatic stress disorder (PTSD) (in adults)
- panic disorder (in adults)
- obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old)

You should ask your doctor if you are unsure why you have been given Sertraline Medreg.

How does Sertraline Medreg work?

Sertraline Medreg contains the active substance sertraline. Sertraline Medreg belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level.

How is Sertraline Medreg used?

The pharmaceutical form of Sertraline Medreg is film-coated tablets 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.

The medicine can only be obtained with a prescription.

What benefits of Sertraline Medreg have been shown in studies?

Because Sertraline Medreg is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Zoloft. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.
The company provided data from the published literature on sertraline.

What are the possible side effects of Sertraline Medreg?

Because Sertraline Medreg is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is Sertraline Medreg approved?

It was concluded that, in accordance with EU requirements, Sertraline Medreg has been shown to have comparable quality and to be comparable to reference medicine. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Zoloft, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Sertraline Medreg?

A risk management plan has been developed to ensure that Sertraline Medreg 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 Sertraline Medreg, 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 Sertraline Medreg

The marketing authorisation for Sertraline Medreg was granted on 11.06.2024.

The full PAR for Sertraline Medreg can be found on the website https://www.sukl.sk. For more information about treatment with Sertraline Medreg, read the package leaflet (*sukl.sk*) or contact your doctor or pharmacist.

This summary was last updated in 06/2024.