

Summary Public Assessment Report

Sertraline Orifarm (sertraline hydrochloride)

SE/H/2168/01/DC

Summary Public Assessment Report

Sertraline Orifarm
sertraline hydrochloride

Film-coated tablet, 25 mg

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

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

What is Sertraline Orifarm and what is it used for?

Sertraline Orifarm is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Zoloft 25 mg.

Sertraline Orifarm 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).

How does Sertraline Orifarm work?

Sertraline Orifarm contains the active substance sertraline. Sertraline is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRIs); these medicines are used to treat depression and/or anxiety disorders.

Depression is a clinical illness with symptoms like feeling sad, unable to sleep properly or to enjoy life as you used to.

OCD and panic disorders are illnesses linked to anxiety with symptoms like being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

PTSD is a condition that can occur after a very emotionally traumatic experience and has some symptoms that are similar to depression and anxiety. Social anxiety disorder (social phobia) is an illness linked to anxiety. It is characterised by feelings of intense anxiety or distress in social situations (for example: talking to strangers, speaking in front of groups of people, eating or drinking in front of others or worrying that you might behave in an embarrassing manner).

How is Sertraline Orifarm used?

The pharmaceutical form of Sertraline Orifarm is a tablet for oral use.

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

The medicine can only be obtained with a prescription in Sweden.

What benefits of Sertraline Orifarm have been shown in studies?

No additional studies were needed as Sertraline Orifarm is a generic medicine considered to be bioequivalent to the reference medicine, Zoloft 25 mg.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Sertraline Orifarm?

Because Sertraline Orifarm is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Sertraline Orifarm approved?

It was concluded that, in accordance with EU requirements, Sertraline Orifarm has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Zoloft 25 mg. Therefore, the Swedish Medical Products Agency decided that, as for Zoloft 25 mg, the benefits are greater than its risks and recommended that it can be approved for use.

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

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

The full PAR for Sertraline Orifarm can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Sertraline Orifarm, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-06.