Summary Public Assessment Report

Generics

Zigilex ODT
Azithromycin

DK/H/2437/001-002/DC

2 March 2016

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Azithromycin orodispersible tablets 20 mg and 100 mg

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

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

What is Zigilex ODT and what is it used for?
Zigilex ODT is a 'generic medicine'. This means that Zigilex ODT is similar to a 'reference medicine' already authorised in the European Union (EU) called Sumamed.
Zigilex ODT is used in the treatment of infections caused by certain bacteria, which include:

- Upper respiratory tract infections – sinusitis, pharyngitis, tonsillitis
- Lower respiratory tract infections - bronchitis, mild to moderately severe community-acquired pneumonia (infection of the lung acquired outside a hospital or long-term care facility)
- Middle ear infections
- Mild to moderate severe skin and soft tissue infections, e.g. folliculitis (infection of the hair follicles in the skin), cellulitis (infection of the deeper layers of the skin and the underlying tissue)**,** erysipelas (infection of the upper layer of the skin)
- Infectious diseases caused by microorganisms called *Chlamydia trachomatis*, such as uncomplicated infection of the tube that carries urine from the bladder out of the body (urethra) or the neck of the womb (cervix).

How does Zigilex ODT work?
Zigilex ODT is one of a group of antibiotics called macrolides. Macrolides work by binding to a specific subunit of ribosomes (sites of protein synthesis) in susceptible bacteria, thereby inhibiting the formation of bacterial proteins.

How is Zigilex ODT used?
The pharmaceutical form of Zigilex ODT is orodispersible tablets and the route of administration is oral.

Zigilex ODT should be placed in the mouth, on the tongue, where it will disperse quickly in saliva. Alternatively, orodispersible tablet can be also dispersed in the spoon of water before administration. In both cases Zigilex ODT should be swallowed immadiately with a glass of water. Since the orodispersible tablet is fragile, it should be taken immediately after opening the blister.

Zigilex ODT is generally used for children under 45 kg of weight. It may also be used in adults and older children who have difficulty with swallowing.

The recommended dose in children is 10 mg for each kg of bodyweight, given as a single daily dose for 3 days.

The recommended dose in adults and in children over 45 kg is 500 mg taken as a single dose, for 3 days. The same total dose 1500 mg can also be given over a period of 5 days with 500 mg on the first day and then 250 mg on days 2 to 5.

For some diseases such as infections caused by *Chlamydia* the dose is 1 g daily taken as a single dose.

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.

What benefits of Zigilex ODT have been shown in studies?
Because Zigilex ODT is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Sumamed. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Zigilex ODT?
Because Zigilex ODT 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 Zigilex ODT approved?
It was concluded that, in accordance with EU requirements, Zigilex ODT has been shown to have comparable quality and to be bioequivalent to Sumamed. Therefore, the member states involved in the procedure concluded that, as for Sumamed, 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 Zigilex ODT?
A risk management plan has been developed to ensure that Zigilex ODT 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 Zigilex ODT, 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 Zigilex ODT
The marketing authorisation for Zigilex ODT was granted on 10 December 2015.

The full PAR and the package leaflet for Zigilex ODT can be found on the website http://mri.medagencies.org/Human/. For more information about treatment with Zigilex ODT, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 03-2016.