

Summary Public Assessment Report

Optinate Septimum (risedronate sodium)

SE/H/192/07/DC

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Optinate Septimum
(risedronate sodium)

Gastro-resistant tablet, 35 mg

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

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

What is Optinate Septimum and what is it used for?

Optinate Septimum is used in treatment of osteoporosis in postmenopausal women at increased risk of fractures. It reduces the risk of spinal and hip fractures.

How does Optinate Septimum work?

Optinate Septimum belongs to a group of non-hormonal medicines called bisphosphonates which are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone.

Postmenopausal osteoporosis is a condition occurring in women after the menopause where the bones become weaker, more fragile and more likely to break after a fall or strain. Osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis-related fractures can also cause back pain, height loss and a curved back. Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

How is Optinate Septimum used?

The pharmaceutical form of Optinate Septimum is gastro-resistant 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.

What benefits of Optinate Septimum have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Optinate Septimum is effective in treating osteoporosis in postmenopausal women at increased risk of fractures.

What are the possible side effects of Optinate Septimum?

For the full list of all side effects reported with Optinate Septimum, see section 4 of the package leaflet.

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

Why is Optinate Septimum approved?

This medicine contains the same active substances as the already authorised Optinate 5 mg film-coated tablet but is given by a new formulation and strength. The company has provided additional own data to demonstrate the safety and efficacy of the new formulation and strength regarding the difference from Optinate 5 mg film-coated tablet.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Optinate Septimum benefits are greater than its risks and recommended that it be approved for use.

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What measures are being taken to ensure the safe and effective use of Optinate Septimum?

A risk management plan has been developed to ensure that Optinate Septimum 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 Optinate Septimum, 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 Optinate Septimum

The marketing authorisation for Optinate Septimum was granted on 2016-11-28 in Sweden.

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

This summary was last updated in 2016-11.