LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Zeimem
# (dimethyl fumarate)

# SE/H/2488/01-02/DC

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# Summary Public Assessment Report

Zeimem
dimethyl fumarate

Gastro-resistant capsule, hard, 120 mg, 240 mg

This is a summary of the public assessment report (PAR) for Zeimem. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Zeimem and what is it used for?**

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Tecfidera.

Zeimem is used to treat relapsing-remitting multiple sclerosis (MS) in patients aged 13 years and older. MS is a long-term condition that affects the central nervous system (CNS), including the brain and the spinal cord. Relapsing-remitting MS is characterised by repeated attacks (relapses) of nervous system symptoms. Symptoms vary from patient to patient, but typically include walking difficulties, feeling off balance and visual difficulties (e.g. blurred or double vision). These symptoms may disappear completely when the relapse is over, but some problems may remain.

**How does Zeimem work?**

Zeimem seems to work by stopping the body's defence system from damaging your brain and spinal cord. This may also help to delay future worsening of your MS.

**How is Zeimem used?**
The pharmaceutical form is gastro-resistant capsule, hard 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 Zeimem have been shown in studies?**

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Tecfidera. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects from Zeimem?**

Because the product 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 Zeimem approved?**

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Tecfidera, 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 Zeimem?**
A risk management plan has been developed to ensure that the product 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, 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.

For more details, please see the full PAR for Zeimem on the following website: MRI - Home.

**Other information about Zeimem**
The full PAR for Zeimem can be found on the following website: MRI - Home. For more information about treatment with Zeimem, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-06.