EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Keppra

levetiracetam

Table of contents

AUTHORISED
This medicine is authorised for use in the European Union.

Overview

This is a summary of the European public assessment report (EPAR) for Keppra. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Keppra.

What is Keppra?

Keppra is a medicine that contains the active substance levetiracetam. It is available as tablets (250 mg, 500 mg, 750 mg and 1,000 mg), as an oral solution (100 mg/ml), and as a concentrate that is made up into a solution for infusion (drip into a vein, 100 mg/ml).

What is Keppra used for?

Keppra can be used on its own in patients from 16 years of age with newly diagnosed epilepsy, to treat partial-onset seizures (fits) with or without secondary generalisation. This is a type of epilepsy where too much electrical activity in one side of the brain causes symptoms such as sudden, jerky movements of one part of the body, distorted

hearing, sense of smell or vision, numbness, or a sudden sense of fear. Secondary generalisation occurs when the overactivity later reaches the whole brain.

Keppra can also be used as an add-on to other anti-epileptic medicines to treat:

- partial-onset seizures with or without generalisation in patients from one month of age;
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in patients from 12 years of age with juvenile myoclonic epilepsy;
- primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients from 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

The medicine can only be obtained with a prescription.

How is Keppra used?

When Keppra is used on its own, the starting dose is 250 mg twice a day, increasing two weeks later to 500 mg twice a day. The dose can be further increased at two-week intervals according to the patient's response, to a maximum dose of 1,500 mg twice a day.

When Keppra is added to another anti-epileptic treatment, the starting dose in patients over 12 years weighing more than 50 kg is 500 mg twice a day. The daily dose can be increased up to 1,500 mg twice a day. In patients aged between six months and 17 years weighing less than 50 kg, the starting dose is 10 mg per kilogram body weight twice a day, which can be increased up to 30 mg/kg twice a day. The oral solution is recommended when starting treatment in children under six years old or weighing less than 25 kg. In babies aged between one and six months, the starting dose is 7 mg/kg twice a day, using the oral solution. This can be increased up to 21 mg/kg twice a day.

Lower doses are used in patients who have problems with their kidneys (such as older patients).

Keppra tablets are swallowed with liquid. The oral solution may be mixed in a glass of water before it is taken. Keppra can be given as an infusion using the same doses at the same frequency when using the tablets or the oral solution is not possible. The use of the infusion should be temporary.

How does Keppra work?

The active substance in Keppra, levetiracetam, is an anti-epileptic medicine. Epilepsy is caused by excessive electrical activity in the brain. The exact way in which levetiracetam works is still unclear but it seems to interfere with a protein called synaptic vesicle protein 2A, which is found in the spaces between nerves and is involved in the release of chemical messengers from nerve cells. This helps Keppra to stabilise electrical activity in the brain and prevent seizures.

How has Keppra been studied?

Keppra used on its own has been studied in 579 patients with partial-onset seizures aged 16 years and over, who received either Keppra or carbamazepine (another anti-epileptic medicine) for up to two years. The study measured how many patients remained free of seizures for six months once they had reached their effective dose.

Keppra has also been studied as an add-on treatment:

- in partial-onset seizures, it has been studied in three main studies in a total of 904 patients aged 16 years and over. In these studies, Keppra at doses of 1,000, 2,000 or 3,000 mg per day, was compared with placebo (a dummy treatment) over 12 to 14 weeks. All of the patients were taking at least one other anti-epileptic medicine. Keppra has also been compared with placebo in 314 patients aged between one month and 17 years;
- in myoclonic seizures, Keppra was studied in 122 patients aged 12 years and over, who received either Keppra or placebo in addition to their normal anti-epileptic medicine for up to 30 weeks;
- in primary generalised tonic-clonic seizures, Keppra was compared with placebo in 164 patients aged four years or over. The patient's treatment was continued for 20 weeks once they were taking their full dose.

In all of these studies, the main measure of effectiveness was the change in the number of seizures before and during treatment.

What benefit has Keppra shown during the studies?

Keppra was as effective as carbamazepine in keeping patients free of seizures when taken on its own for partial onset seizures. In both groups, 73% of the patients experienced no seizures for six months once on an adequate dose.
As an add-on treatment, Keppra was more effective than placebo:

- for partial-onset seizures, placebo treatment reduced the weekly number of seizures by 6 to 7%, while the reduction with Keppra at a dose of 1,000 mg per

day was between 18 and 33%, depending on the study. With Keppra at a dose of 2,000 mg, the reduction was 27%, and with 3,000 mg, it was around 39%. Keppra was also more effective than placebo in children;

- for myoclonic seizures, the number of seizure days per week was halved in 58% of the patients receiving Keppra and in 23% of the patients receiving placebo;
- for tonic-clonic seizures, the number of seizures fell by an average of 28% in the patients receiving placebo, compared with 57% in those receiving Keppra. However, there were too few patients aged below 12 years to support the use of Keppra for this type of seizure in this age group.

What is the risk associated with Keppra?

The most common side effects with Keppra (seen in more than 1 patient in 10) are nasopharyngitis (inflammation of the nose and throat), somnolence (sleepiness), and headache. For the full list of all side effects reported with Keppra, see the package leaflet.

Keppra must not be used in people who are hypersensitive (allergic) to levetiracetam, to other pyrrolidone derivatives (medicines with a similar structure to levetiracetam), or to any of the other ingredients.

Why has Keppra been approved?

The CHMP decided that Keppra's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Keppra

The European Commission granted a marketing authorisation valid throughout the European Union for Keppra on 29 September 2000.

For more information about treatment with Keppra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

Keppra : EPAR - Summary for the public (PDF/89.71 KB)

First published: 18/09/2009
Last updated: 03/10/2013

Available languages (21)

More detail is available in the summary of product characteristics

This EPAR was last updated on 03/07/2019

Authorisation details

Name

Keppra

Agency product number

EMEA/H/C/000277

Active substance

Levetiracetam

International non-proprietary name (INN) or common name

Levetiracetam

Therapeutic area (MeSH)

Epilepsy

Anatomical therapeutic chemical (ATC) code

N03AX14

Marketing-authorisation holder

UCB Pharma SA

Revision

44

Date of issue of marketing authorisation valid throughout the European Union

29/09/2000

Contact address

Allée de la Recherche 60
B-1070 Bruxelles
Belgium

Product information

28/03/2019 Keppra - EMEA/H/C/000277 - WS/1451

Keppra : EPAR - Product Information (PDF/2.33 MB)

First published: 18/09/2009
Last updated: 03/07/2019

Available languages (24)

Contents

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

Keppra : EPAR - All Authorised presentations (PDF/23.55 KB)

First published: 18/09/2009
Last updated: 06/02/2013

Available languages (23)

Pharmacotherapeutic group

Anti epileptics

Therapeutic indication

Keppra is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy.

Keppra is indicated as adjunctive therapy:

- in the treatment of partial-onset seizures with or without secondary generalisation in adults, children and infants from one month of age with epilepsy;
- in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy;
- in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy.

Assessment history

Changes since initial authorisation of medicine

Keppra : EPAR - Procedural steps taken and scientific information after authorisation (PDF/359.94 KB)

First published: 18/09/2009
Last updated: 03/07/2019

Keppra-H-C-277-P46-0085 : EPAR - Assessment Report (PDF/794.35 KB)

First published: 06/01/2017
Last updated: 06/01/2017
EMA/CHMP/769369/2016

Keppra-H-C-PSUSA-1846-201511 : EPAR - Scientific Conclusion (PDF/70.61 KB)

First published: 16/11/2016
Last updated: 16/11/2016
EMA/677040/2016

Keppra-H-C-P46-0083 : EPAR - Assessment Report (PDF/270.9 KB)

Adopted

First published: 03/08/2016
Last updated: 03/08/2016
EMA/489130/2016

Keppra-H-C-277-P46-0079 : EPAR - Assessment Report (PDF/2.07 MB)

Adopted

First published: 17/03/2016
Last updated: 17/03/2016
EMA/859605/2015

Keppra-H-C-277-P46-0080: EPAR - Assessment Report - Variation (PDF/913.35 KB)

Adopted

First published: 16/02/2016
Last updated: 16/02/2016
EMA/CHMP/133443/2016

Keppra-H-C-277-P46-0078 : EPAR - Assessment report (PDF/2.28 MB)

Adopted

First published: 30/07/2015
Last updated: 30/07/2015
EMA/348791/2015

Keppra-H-C-277-P46-0077: EPAR - Assessment report (PDF/309.71 KB)

Adopted

First published: 05/06/2015
Last updated: 05/06/2015
EMA/CHMP/382391/2015

Keppra-H-C-277-P46-0072-0075 : EPAR - Scientific Discussion - Variation (PDF/2.09 MB)

Adopted

First published: 01/08/2014
Last updated: 01/08/2014
EMA/408255/2014

Keppra-H-C-277-PSUV-0140 : EPAR - Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation (PDF/74.53 KB)

Adopted

First published: 03/10/2013
Last updated: 03/10/2013
EMA/573970/2013

Keppra-H-C-277-P46-0062 : EPAR - Assessment Report (PDF/525.73 KB)

Adopted

First published: 05/04/2013
Last updated: 05/04/2013
EMA/163062/2013

Keppra-H-C-277-P46-0060 : EPAR - Assessment Report (PDF/184.92 KB)

Adopted

First published: 05/04/2013
Last updated: 05/04/2013
EMA/163052/2013

Keppra-H-C-277-P46-0065 : EPAR - Assessment Report (PDF/240.69 KB)

Adopted

First published: 21/03/2013
Last updated: 21/03/2013
EMA/163119/2013

Keppra-H-C-277-P45-0052: EPAR - Assessment Report (PDF/84.92 KB)

Adopted

First published: 05/11/2012
Last updated: 05/11/2012
EMA/639978/2012

CHMP post-authorisation summary of positive opinion for Keppra on 23 July 2009 (PDF/33.35 KB)

Adopted

First published: 24/07/2009
Last updated: 24/07/2009
EMEA/CHMP/417760/2009

Keppra-H-C-277-II-0071 : EPAR - Scientific Discussion - Variation (PDF/191.52 KB)

Adopted

First published: 13/02/2007
Last updated: 13/02/2007

Keppra-H-C-277-II-0063 : EPAR - Scientific Discussion - Variation (PDF/239.07 KB)

Adopted

First published: 12/09/2006
Last updated: 12/09/2006

Keppra-H-C-277-X-0046 : EPAR - Scientific Discussion - Extension (PDF/285.47 KB)

Adopted

First published: 12/09/2006
Last updated: 12/09/2006

Keppra-H-C-277-II-0044 : EPAR - Scientific Discussion - Variation (PDF/624.74 KB)

Adopted

First published: 09/12/2005
Last updated: 09/12/2005

Keppra : EPAR - Steps taken after authorisation when a cutoff date has been used (PDF/98.46 KB)

First published: 21/10/2005
Last updated: 21/10/2005

Initial marketing-authorisation documents

Keppra : EPAR - Procedural steps taken before authorisation (PDF/86.29 KB)

First published: 21/10/2005
Last updated: 21/10/2005

Keppra : EPAR - Scientific Discussion (PDF/262.11 KB)

First published: 21/10/2005
Last updated: 21/10/2005

News

- EMA recommends measures to ensure safe use of Keppra oral solution
  14/10/2016

Preventing medication errors

Keppra: EMA recommends measures to ensure safe use of oral solution (PDF/97.1 KB)

First published: 14/10/2016
Last updated: 14/10/2016
EMA/668736/2016

Keppra: Product Information as approved by the CHMP on 13 October 2016, pending endorsement by the European Commission (PDF/25.7 KB)

First published: 14/10/2016
Last updated: 14/10/2016

CONTACT

Visiting and delivery address
Refer to:
How to find us

Tel: +31 (0)88 781 6000

European Union agencies network

An agency of the European Union