

Changes to the Product information as approved by the CHMP on 13 October 2016, pending endorsement by the European Commission

Annex III

Amendments to relevant sections of the Product Information

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The existing product information shall be amended (insertion, replacement or deletion of the text as appropriate) to reflect the agreed wording as provided below.

Package leaflet

[The following texts should be added to or replace existing texts, as appropriate:]

3 – How to take Keppra

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Keppra must be taken twice a day, once in the morning and once in the evening, at about the same time each day. Take the oral solution following your doctor's instructions.

Monotherapy

Dose in adults and adolescents from ~~(16 years of age)~~:

Measure the appropriate dosage using the 10 ml syringe included in the package for patients 4 years and above.

General dose: ~~between 10 ml (1000 mg) and 30 ml (3,000 mg) each day, divided in 2 intakes per day. Keppra is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500mg) and 15 ml (1500mg).~~

When you will first start taking Keppra, your doctor will prescribe you a **lower dose** during 2 weeks before giving you the lowest general dose.

Add-on therapy

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:

Measure the appropriate dosage using the 10 ml syringe included in the package for patients of 4 years and above.

General dose: ~~between 10 ml (1,000 mg) and 30 ml (3,000 mg) each day, divided in 2 intakes per day.~~

Keppra is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500mg) and 15 ml (1500mg).

Dose in children 6 months and older ~~weighing less than 50 Kg~~ ~~Dose in infants (6 to 23 months), children (2 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:~~

Your doctor will prescribe the most appropriate pharmaceutical form of Keppra according to the age, weight and dose.

For children 6 months to 4 years, measure the appropriate dosage using the 3 ml syringe included in the package.

For children above 4 years, measure the appropriate dosage using the 10 ml syringe included in the package.

General dose: Keppra is taken twice daily, in two equally divided doses, each individual dose being measured between 0.1 ml (10mg) and 0.3 ml (30mg), per kg bodyweight of the child. (see table below for dose examples).

~~Your doctor will prescribe the most appropriate pharmaceutical form of Keppra according to the age, weight and dose.~~

~~General dose: between 0.2 ml (20 mg) and 0.6 ml (60 mg) per kg bodyweight each day, divided in 2 intakes per day.~~

~~The exact quantity of oral solution formulation should be delivered using the syringe provided in the cardboard box.~~

Dose in children 6 months and older ~~weighing less than 50 kg:~~

Weight	Starting dose: 0.1 ml/kg twice daily	Maximum dose: 0.3 ml/kg twice daily
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6 kg	0.6 ml twice daily	1.8 ml twice daily
8 kg	0.8 ml twice daily	2.4 ml twice daily
10 kg	1 ml twice daily	3 ml twice daily
15 kg	1.5 ml twice daily	4.5 ml twice daily
20 kg	2 ml twice daily	6 ml twice daily
25 kg	2.5 ml twice daily	7.5 ml twice daily
From 50 kg	5 ml twice daily	15 ml twice daily

Dose in infants (1 month to less than 6 months):

For infants 1 month to less than 6 months, measure the appropriate dosage using the **1 ml** syringe included in the package.

General dose: Keppra is taken twice daily, in two equally divided doses, each individual dose being measured between 0.07 ml (7mg) and 0.21 ml (21mg), per kg bodyweight of the infant. (see table below for dose examples).

General dose: between 0.14 ml (14 mg) and 0.42 ml (42 mg) per kg bodyweight each day, divided in 2 intakes per day. The exact quantity of oral solution formulation should be delivered using the syringe provided in the cardboard box.

Dose in infants (1 month to less than 6 months):

Weight	Starting dose: 0.07 ml/kg twice daily	Maximum dose: 0.21 ml/kg twice daily
4 kg	0.3 ml twice daily	0.85 ml twice daily
5 kg	0.35 ml twice daily	1.05 ml twice daily
6 kg	0.45 ml twice daily	1.25 ml twice daily
7 kg	0.5 ml twice daily	1.5 ml twice daily

Method of administration:

After measuring the correct dose with an appropriate syringe, Keppra oral solution may be diluted in a glass of water or baby's bottle.