

PACKAGE LEAFLET: INFORMATION FOR THE USER

Carnitor[®] 30% paediatric oral solution

(levocarnitine)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Carnitor 30% paediatric oral solution but will be referred to as Carnitor throughout this leaflet.

What is in this leaflet

1. What Carnitor is and what it is used for
2. What you need to know before you give your child Carnitor
3. How to give your child Carnitor
4. Possible side effects
5. How to store Carnitor
6. Contents of the pack and other information

1. What Carnitor is and what it is used for

Carnitor contains levocarnitine which is a type of protein. It is used to treat primary and secondary levocarnitine deficiency in children less than 12 years of age, infants and newborns.

Carnitine deficiency occurs when the body has a shortage of levocarnitine. Carnitor makes up for the body's lack of levocarnitine and helps give the body more energy.

2. What you need to know before you give your child Carnitor

Do not give your child Carnitor:

- if your child is allergic to Carnitor or any of the other ingredients of this medicine (listed in section 6).

If this applies to your child, do not give them Carnitor.

Warnings and precautions

Talk to your doctor before giving your child Carnitor if:

- your child has severe kidney problems or kidney disease and is having dialysis,
- your child is diabetic and taking insulin, or any other drug to treat their diabetes,
- your child is diabetic or is on a diet to reduce calorie intake,
- your child is taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting,
- your child has an intolerance to some sugars.

If any of the above apply to your child, talk to your doctor or pharmacist.

Other medicines and Carnitor

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Tell your doctor if your child is taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting. Your doctor may need to change how often your child is tested to see how fast their blood clots.

Carnitor contains sorbitol, sucrose, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217) and sodium

This product contains 100mg sorbitol in each ml of solution. Sorbitol is a source of fructose. If your doctor has told you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This product contains sucrose. If you have been told by the doctor that your child has an intolerance to some sugars, contact your doctor before giving your child this medicinal product.

Carnitor contains sodium methyl hydroxybenzoate (E219) and sodium propyl hydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1mmol sodium (23mg) per 1ml of oral solution, that is to say essentially 'Sodium-free'.

This medicine contains 26.04mg of alcohol (ethanol) per 5ml which is equivalent to 0.66% (v/v). The amount per 5ml dose of this medicine is equivalent to less than 1ml of beer. The small amount of alcohol contained in this medicine does not produce any noticeable effect.

3. How to give your child Carnitor

Always give your child this medicine exactly as your doctor has told you.

How much Carnitor should you give to your child

Your doctor will carefully calculate the amount of Carnitor that your child should take and may vary it depending on their response to the treatment. Your doctor may take blood and urine samples to check the amount of the drug in your child's body.

Method of administration

Carnitor is for oral use. It can be drunk directly or diluted further with water or fruit juices.

Primary and secondary carnitine deficiency

The usual dose of Carnitor is up to 200mg per kg of your child's bodyweight per day. This should be taken over 2-4 doses. Higher doses of up to 400mg per kg of bodyweight per day may be necessary. Your doctor will tell you exactly how much medicine to give your child and when to give it.

If you give your child more Carnitor than you should

If you give your child too much Carnitor, contact your doctor or immediately go to the nearest hospital casualty department.

If you forget to give your child Carnitor

Do not give your child a double dose to make up for a forgotten dose. Simply continue with the next dose as planned.

If your child stops taking Carnitor

Do not stop giving your child this medicine without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects are:

- Mild stomach upsets such as stomach cramps or diarrhoea, or your child may feel or be sick for a short time.
- Drug-related body odour. Your doctor may reduce your child's dose to help lessen or stop the odour.
- For children also taking anticoagulant medicine, such as warfarin, tests may show their blood is taking longer than usual to clot.

Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Carnitor

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Do not take Carnitor after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.

If the solution becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Carnitor contains

The active ingredient in Carnitor is levocarnitine. Each ml contains 300mg of levocarnitine. The other ingredients are sucrose, sorbitol solution 70% (E420) (non-crystallizing), sodium propyl parahydroxybenzoate (E217), sodium methyl parahydroxybenzoate (E219), cherry flavour (contains ethanol), black cherry flavour (contains ethanol) and purified water.

What Carnitor looks like and the contents of the pack

Carnitor is a colourless or slightly yellow solution. It comes in 20ml amber glass bottles with plastic child proof caps and one measuring spoon.

Manufactured by: Alfasigma S.p.A., Via Pontina km 30,400, 00071 Pomezia RM, Italy.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Carnitor® 30% paediatric oral solution;
PL 18799/2927**

Leaflet date: 20.04.2023

POM

Carnitor is the registered trademark of Alfasigma S.p.A.

**Blind or partially sighted?
Is this leaflet hard to see or read?**

Call 0208 515 3763 to obtain the leaflet in a format suitable for you.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Levocarnitine 30% paediatric oral solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Levocarnitine 30% paediatric oral solution but will be referred to as Levocarnitine throughout this leaflet.

What is in this leaflet

1. What Levocarnitine is and what it is used for
2. What you need to know before you give your child Levocarnitine
3. How to give your child Levocarnitine
4. Possible side effects
5. How to store Levocarnitine
6. Contents of the pack and other information

1. What Levocarnitine is and what it is used for

Levocarnitine contains levocarnitine which is a type of protein. It is used to treat primary and secondary levocarnitine deficiency in children less than 12 years of age, infants and newborns.

Levocarnitine deficiency occurs when the body has a shortage of levocarnitine. Levocarnitine makes up for the body's lack of levocarnitine and helps give the body more energy.

2. What you need to know before you give your child Levocarnitine

Do not give your child Levocarnitine:

- if your child is allergic to levocarnitine or any of the other ingredients of this medicine (listed in section 6).

If this applies to your child, do not give them Levocarnitine.

Warnings and precautions

Talk to your doctor before giving your child Levocarnitine if:

- your child has severe kidney problems or kidney disease and is having dialysis,
- your child is diabetic and taking insulin, or any other drug to treat their diabetes,
- your child is diabetic or is on a diet to reduce calorie intake,
- your child is taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting,
- your child has an intolerance to some sugars.

If any of the above apply to your child, talk to your doctor or pharmacist.

Other medicines and Levocarnitine

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Tell your doctor if your child is taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting. Your doctor may need to change how often your child is tested to see how fast their blood clots.

Levocarnitine contains sorbitol, sucrose, sodium methyl para-hydroxybenzoate (E219), sodium propyl para-hydroxybenzoate (E217) and sodium

This product contains 100mg sorbitol in each ml of solution. Sorbitol is a source of fructose. If your doctor has told you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This product contains sucrose. If you have been told by the doctor that your child has an intolerance to some sugars, contact your doctor before giving your child this medicinal product.

Levocarnitine contains sodium methyl para-hydroxybenzoate (E219) and sodium propyl para-hydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1mmol sodium (23mg) per 1ml of oral solution, that is to say essentially 'Sodium-free'.

This medicine contains 26.04mg of alcohol (ethanol) per 5ml which is equivalent to 0.66% (v/v). The amount per 5ml dose of this medicine is equivalent to less than 1ml of beer. The small amount of alcohol contained in this medicine does not produce any noticeable effect.

3. How to give your child Levocarnitine

Always give your child this medicine exactly as your doctor has told you.

How much Levocarnitine should you give to your child

Your doctor will carefully calculate the amount of Levocarnitine that your child should take and may vary it depending on their response to the treatment. Your doctor may take blood and urine samples to check the amount of the drug in your child's body.

Method of administration

Levocarnitine is for oral use. It can be drunk directly or diluted further with water or fruit juices.

Primary and secondary carnitine deficiency

The usual dose of Levocarnitine is up to 200mg per kg of your child's bodyweight per day. This should be taken over 2-4 doses. Higher doses of up to 400mg per kg of bodyweight per day may be necessary. Your doctor will tell you exactly how much medicine to give your child and when to give it.

If you give your child more Levocarnitine than you should

If you give your child too much Levocarnitine, contact your doctor or immediately go to the nearest hospital casualty department.

If you forget to give your child Levocarnitine

Do not give your child a double dose to make up for a forgotten dose. Simply continue with the next dose as planned.

If your child stops taking Levocarnitine

Do not stop giving your child this medicine to your child without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects are:

- Mild stomach upsets such as stomach cramps or diarrhoea, or your child may feel or be sick for a short time.
- Drug-related body odour. Your doctor may reduce your child's dose to help lessen or stop the odour.
- For children also taking anticoagulant medicine, such as warfarin, tests may show their blood is taking longer than usual to clot.

Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Levocarnitine

Keep out of the sight and reach of children.
Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Do not take Levocarnitine after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.

If the solution becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Levocarnitine contains

The active ingredient in Levocarnitine is levocarnitine. Each ml contains 300mg of levocarnitine. The other ingredients are sucrose, sorbitol solution 70% (E420) (non-crystallizing), sodium propyl para-hydroxybenzoate (E217), sodium methyl para-hydroxybenzoate (E219), cherry flavour (contains ethanol), black cherry flavour (contains ethanol) and purified water.

What Levocarnitine looks like and the contents of the pack

Levocarnitine is a colourless or slightly yellow solution. It comes in 20ml amber glass bottles with plastic child proof caps and one measuring spoon.

Manufactured by: Alfasigma S.p.A., Via Pontina km 30,400, 00071 Pomezia RM, Italy.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Levocarnitine 30% paediatric oral solution;
PL 18799/2927**

Leaflet date: 20.04.2023

POM

**Blind or partially sighted?
Is this leaflet hard to see or read?**

Call 0208 515 3763 to obtain the leaflet in a format suitable for you.