

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

**KUVAN®**  
**sapropterin dihydrochloride tablets**

Read this carefully before you start taking Kuvan and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Kuvan.

**What is Kuvan used for?**

Kuvan is used in combination with a diet low in phenylalanine (Phe). It works to lower blood Phe levels in patients who have high blood Phe levels from a type of Phenylketonuria (PKU).

In PKU, an enzyme called phenylalanine hydroxylase (PAH) does not work or is not present in your body. Normally, PAH helps to break down Phe from your food. When PAH does not work properly or is missing, it can cause high Phe levels in the blood of most patients. High blood Phe levels are toxic to the brain.

**How does Kuvan work?**

Kuvan activates the enzyme PAH to help lower the blood Phe levels in some patients with PKU.

It is not possible to know whether or not Kuvan will work for you until you start taking it.

**What are the ingredients in Kuvan?**

Medicinal ingredients: sapropterin dihydrochloride

Non-medicinal ingredients: Ascorbic acid, crospovidone, dibasic calcium phosphate, D-mannitol, riboflavin, and sodium stearyl fumarate.

**Kuvan comes in the following dosage forms:**

Tablets: 100 mg

**Do not use Kuvan if:**

You or your child has ever had an allergic reaction (for example a rash or itchiness) to sapropterin dihydrochloride or any ingredient in this medicine.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Kuvan. Talk about any health conditions or problems you may have, including if you:**

- Have a fever
- Are pregnant or planning to become pregnant
- Are breast feeding or planning to breast feed
- Have liver or kidney problems
- Have burning sensation or pain in your upper abdomen/stomach
- Have too much or constant activity (hyperactivity, such as fidgeting, moving around too much, or talking too much)
- Have seizures or fits
- Have poor nutrition or have a loss of appetite
- Are taking levodopa, a drug used to treat Parkinson's Disease
- Are taking drugs that affect how your body uses the B vitamin folate (e.g., methotrexate, used for cancer treatment and to treat some immune system disorders) because these drugs could affect how Kuvan works in your body
- Are taking medicines for erectile dysfunction like Viagra (sildenafil), Levitra (vardenafil), or Cialis (tadalafil)
- Are taking any medicines that may lower your blood pressure (e.g., glyceryl trinitrate (GTN), isosorbide dinitrate (ISDN), sodium nitroprusside (SNP), molsidomin, minoxidil)

**Other warnings you should know about:**

Kuvan should be prescribed by a doctor experienced in treating PKU. Your doctor and/or healthcare professional will regularly measure your blood Phe and provide counseling on your diet. This is to ensure your blood Phe levels stay in the desirable range. Patients with PKU who are taking Kuvan should also use a diet low in Phe. Your overall protein intake will also be monitored. This is because high blood Phe levels with PKU can cause severe brain damage.

Some infants under 1 year of age and children under the age of 7 may experience low blood Phe levels.

Not all patients with PKU respond to treatment with Kuvan. Your doctor will continue to monitor your blood Phe levels during your treatment with Kuvan. This is to make sure that your blood Phe levels are not too high or too low.

Kuvan has not been studied in patients less than 1 month of age or 65 years and older. It is not known how they will respond to treatment with Kuvan.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Kuvan:**

- Levodopa (used to treat Parkinson's disease)
- Medicines for the treatment of cancer (e.g. methotrexate)
- Medicines for treatment of bacterial infections (e.g. trimethoprim)
- Medicines that may lower your blood pressure (e.g. glyceryl trinitrate (GTN), isosorbide dinitrate (ISDN), sodium nitroprusside (SNP), molsidomin, minoxidil)
- Medicines for erectile dysfunction like Viagra (sildenafil), Levitra (vardenafil), or Cialis (tadalafil)
- Rosuvastatin (used to reduce fats in the blood)

**How to take Kuvan:**

Take Kuvan exactly as your doctor or healthcare professional has told you.

Take Kuvan once a day with a meal. Take the dose at the same time each day.

**Preparing the dose of Kuvan:**

Adults and children who weigh more than 10 kg:

- You can swallow Kuvan tablets whole, dissolve them in water or apple juice or crush them into soft food.
- If you choose to dissolve the tablets:
  - Add tablets to 1/2 to 1 cup of water or apple juice and drink within 15 minutes of mixing.
  - It may take a few minutes for the tablets to dissolve. To make the tablets dissolve faster, you can stir or crush them.
  - The tablets may not dissolve completely. You may see pieces floating on top of the water or apple juice. This is normal and safe for you to swallow.
  - If you still see pieces of the tablet in the cup after you drink the mixture, you should add more water or apple juice to make sure that you take all of your medicine.
- If you choose to crush the tablets:
  - Crush tablet using a pill crusher and then mix into a small amount of soft food like apple sauce or pudding. Eat the mixture within 15 minutes.

For children who weigh between 10 kg to 20 kg, there is an alternate way to give the dose of Kuvan. This option is described in the next section.

Children one month of age and older who weigh 20 kg or less:

- Crush the Kuvan tablet(s) and dissolve into water or apple juice.

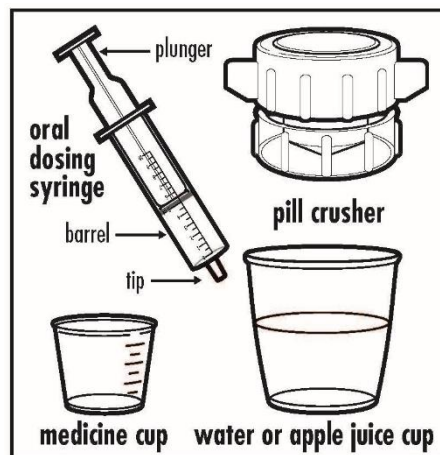
- You will need to give some or all of the mixture (crushed tablets and water or apple juice) to your child by mouth using an oral dosing syringe.
- Your doctor will tell you:
  - the number of Kuvan tablets needed for one dose,
  - the amount of water or apple juice needed to mix one dose of Kuvan, and
  - the amount of the mixture to give your child
- Give your child the exact amount of mixture that your doctor has indicated.
- To prepare your child's dose, you will need the following supplies:
  - the number of Kuvan tablets needed for one dose
  - a small cup of water or apple juice
  - a medicine cup with markings at 20, 40, 60 and 80 mL
  - a small spoon or clean utensil for mixing
  - an oral dosing syringe with markings for each mL
    - You will need a 10 mL syringe to give volumes of 10 mL or less.
    - You will need a 20 mL syringe to give volumes larger than 10 mL.
  - a pill crusher

Ask your pharmacist where to get these supplies if you do not have them.

How to prepare and give the dose of Kuvan to a child who is at least one month of age and weighs 20 kg or less:

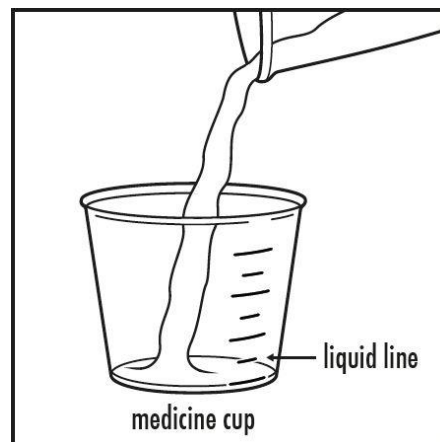
**Step 1:** Find a clean, flat work surface.

**Step 2:** Place a small cup of water or apple juice, the oral dosing syringe, an empty medicine cup, and the pill crusher on your clean, flat work surface (see Figure A).



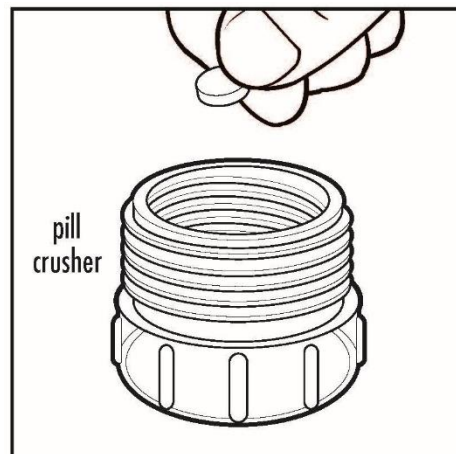
**Figure A**

**Step 3:** Pour the appropriate amount (20 mL, 40 mL, 60 mL or 80 mL) of water or apple juice from the small cup into the medicine cup, as instructed by your doctor. Check to make sure that the amount of liquid lines up with the amount that your doctor tells you (see Figure B).



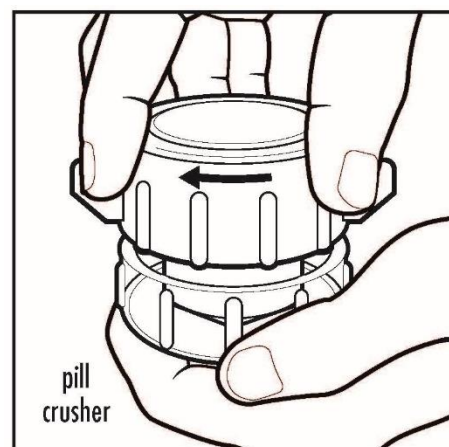
**Figure B**

**Step 4:** Use a pill crusher to crush the Kuvan tablet(s). This will make it easier to dissolve the tablet(s). (See Figure C and D).



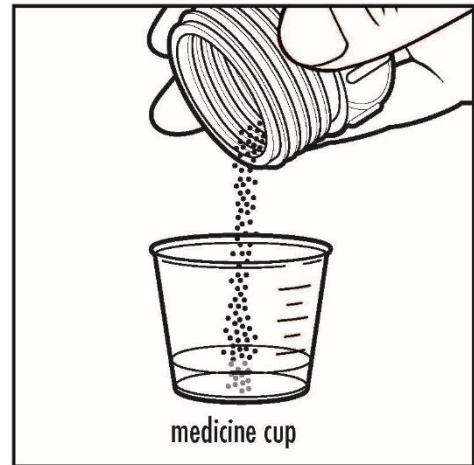
**Figure C**

and



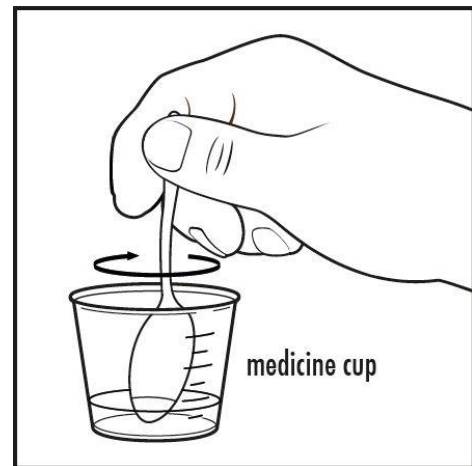
**Figure D**

**Step 5:** Place the crushed Kuvan tablet(s) in the medicine cup (see Figure E).



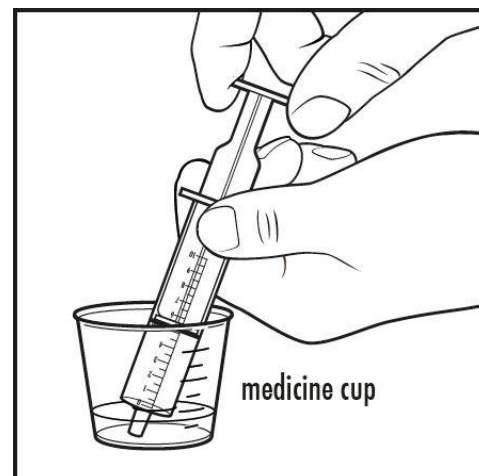
**Figure E**

**Step 6:** Stir with the small spoon or other clean utensil until the tablet(s) dissolve (see Figure F). It is normal to see very small pieces of the tablet at the top of the mixture.



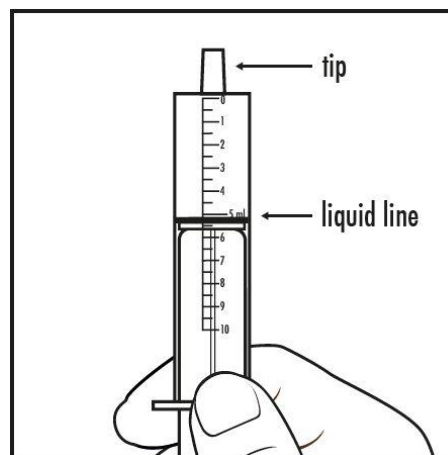
**Figure F**

**Step 7:** Place the tip of the oral dosing syringe into the liquid inside the medicine cup. Pull back on the plunger and draw up the exact amount of the mixture that your doctor has indicated (see Figure G).



**Figure G**

**Step 8:** Take the oral dosing syringe out of the medicine cup. Carefully turn the oral dosing syringe so that the tip is pointing up. Check to make sure that the amount of medicine in the oral dosing syringe lines up with the amount of mixture prescribed by your doctor (see Figure H).



**Figure H**

**Step 9:** Place the tip of the oral dosing syringe into your child's mouth. Point the tip of the oral dosing syringe towards either cheek (see Figure I).

Push on the plunger slowly, a small amount at a time, until all of the mixture in the oral dosing syringe is given.

Give your child the dose within 15 minutes of mixing. If you are not able to give your child's dose within 15 minutes after mixing, pour the unused medicine into the trash. You will need to mix a new dose.



**Figure I**

**Step 10:** Throw away any remaining mixture. Remove the plunger from the barrel of the oral dosing syringe. Wash the oral dosing syringe and medicine cup with warm water and air dry. When the oral dosing syringe is dry, put the plunger back into the barrel. Store the oral dosing syringe and medicine cup for the next use.

When taking Kuvan, any changes in diet may affect your blood Phe levels. Follow your doctor's instructions carefully. Avoid changes to your diet and Phe intake without talking to your doctor first. Your doctor will continue to monitor your blood Phe levels during your treatment with Kuvan to make sure that your blood Phe levels are not too high or too low.



Blood Phe levels may go up during a fever or sickness. Tell your doctor as soon as possible so they can change the dose of Kuvan to help keep blood Phe levels in the desired range.

**Usual Dose:**

The dose of Kuvan is based on body weight.

- Kuvan starting dose: 10 mg/kg body weight taken once a day with a meal.
- Your doctor can change your dose of Kuvan depending on how you respond to treatment.
- For children, in particular, the dose of Kuvan will change as the child grows.

**Overdose:**

Patients who have accidentally taken too much Kuvan reported mild headache, mild dizziness, stomach or belly pain and/or too much or constant activity (hyperactivity).

If you think you have taken too much Kuvan, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take your dose of Kuvan, take it as soon as you remember that day. But if you miss the dose for that day, skip the missed dose, and continue with your scheduled dose the following day. Do not take two doses of Kuvan on the same day.

**What are possible side effects from using Kuvan?**

These are not all the possible side effects that you may feel when taking Kuvan. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Runny nose and stuffy nose
- Upper respiratory tract infection (like a cold)
- Cough
- Throat pain
- Mouth sores
- Stomach or belly pain
- Back pain
- Vomiting
- Nausea
- Diarrhea
- Headache
- Blurred vision
- Anger
- Bedwetting
- Trouble speaking
- Changes in hair colour

Your healthcare professional will decide when to perform blood tests and will interpret the

results.

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
<b>UNCOMMON</b>	<b>Edema (swelling):</b> fluid accumulation beneath skin of lower limbs	√		
	<b>Hives:</b> itchy bumpy rash	√		
	<b>Severe allergic reactions:</b> heavy breathing with whistling sound, trouble breathing, coughing, feeling dizzy or faint, turning red, nausea, and rash.			√
	<b>Esophageal (food pipe) disorders:</b> food pipe pain	√		
	<b>Pale skin</b>	√		
	<b>Retching (gagging)</b>	√		
	<b>Shortness of Breath</b>	√		
	<b>Swelling of Eyelid</b>	√		
	<b>Throat tightness</b>			√
<b>RARE</b>	<b>Gastritis (inflammation of the lining of the stomach):</b> burning sensation or pain in your upper abdomen/stomach		√	
<b>FREQUENCY NOT KNOWN</b>	<b>Esophagitis (inflammation of the lining of the food pipe):</b> burning sensation or pain in your food pipe		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Online at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to: 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html).

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

- Store in a cool, dry place between 20°C - 25°C; excursions allowed between 15°C - 30°C.
- Do not leave Kuvan in hot or humid places, such as your car or bathroom cabinet.
- Keep Kuvan in its original bottle with the cap closed tightly.
- Protect from moisture. Do not remove the desiccant (the small packet included with your tablets). The desiccant absorbs moisture.
- The colour of the tablets may change over time, to yellow. This is normal and you can take these tablets.
- Do not keep Kuvan that is out of date, or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

Keep out of reach and sight of children.

### **If you want more information about Kuvan:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](https://www.canada.ca/en/health-canada.html) (<https://www.canada.ca/en/health-canada.html>); or by calling 1-877-597-6744.
- For questions, or to report problems, please contact 1-877-597-6744.

This leaflet was prepared by BioMarin International Limited

Last Revised: November 18, 2021

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

**KUVAN®**  
**sapropterin dihydrochloride for oral solution**

Read this carefully before you start taking Kuvan and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Kuvan.

**What is Kuvan used for?**

Kuvan is used in combination with a diet low in phenylalanine (Phe). It works to lower blood Phe levels in patients who have high blood Phe levels from a type of Phenylketonuria (PKU).

In PKU, an enzyme called phenylalanine hydroxylase (PAH) does not work or is not present in your body. Normally, PAH helps to break down Phe from your food. When PAH does not work properly or is missing, it can cause high Phe levels in the blood of most patients. High blood Phe levels are toxic to the brain.

**How does Kuvan work?**

Kuvan activates the enzyme PAH to help lower the blood Phe levels in some patients with PKU.

It is not possible to know whether or not Kuvan will work for you until you start taking it.

**What are the ingredients in Kuvan?**

Medicinal ingredients: sapropterin dihydrochloride

Non-medicinal ingredients: Ascorbic acid, D-mannitol, potassium citrate, and sucralose.

**Kuvan comes in the following dosage forms:**

Powder for Oral Solution: 100 mg and 500 mg

**Do not use Kuvan if:**

You or your child has ever had an allergic reaction (for example a rash or itchiness) to sapropterin dihydrochloride or any ingredient in this medicine.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Kuvan. Talk about any health conditions or problems you may have, including if you:**

- Have a fever
- Are pregnant or planning to become pregnant
- Are breast feeding or planning to breast feed
- Have liver or kidney problems
- Have burning sensation or pain in your upper abdomen/stomach
- Have too much or constant activity (hyperactivity, such as fidgeting, moving around too much, or talking too much)
- Have seizures or fits
- Have poor nutrition or have a loss of appetite
- Are taking levodopa, a drug used to treat Parkinson's Disease
- Are taking drugs that affect how your body uses the B vitamin folate (e.g., methotrexate, used for cancer treatment and to treat some immune system disorders) because these drugs could affect how Kuvan works in your body
- Are taking medicines for erectile dysfunction like Viagra (sildenafil), Levitra (vardenafil), or Cialis (tadalafil)
- Are taking any medicines that may lower your blood pressure (e.g., glyceryl trinitrate (GTN), isosorbide dinitrate (ISDN), sodium nitroprusside (SNP), molsidomin, minoxidil)

**Other warnings you should know about:**

Kuvan should be prescribed by a doctor experienced in treating PKU. Your doctor and/or healthcare professional will regularly measure your blood Phe and provide counseling on your diet. This is to ensure your blood Phe levels stay in the desirable range. Patients with PKU who are taking Kuvan should also use a diet low in Phe. Your overall protein intake will also be monitored. This is because high blood Phe levels with PKU can cause severe brain damage.

Some infants under 1 year of age and children under the age of 7 may experience low blood Phe levels.

Not all patients with PKU respond to treatment with Kuvan. Your doctor will continue to monitor your blood Phe levels during your treatment with Kuvan. This is to make sure that your blood Phe levels are not too high or too low.

Kuvan has not been studied in patients less than 1 month of age or 65 years and older. It is not known how they will respond to treatment with Kuvan.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Kuvan:**

- Levodopa (used to treat Parkinson's disease)
- Medicines for the treatment of cancer (e.g. methotrexate)

- Medicines for treatment of bacterial infections (e.g. trimethoprim)
- Medicines that may lower your blood pressure (e.g. glyceryl trinitrate (GTN), isosorbide dinitrate (ISDN), sodium nitroprusside (SNP), molsidomin, minoxidil)
- Medicines for erectile dysfunction like Viagra (sildenafil), Levitra (vardenafil), or Cialis (tadalafil)
- Rosuvastatin (used to reduce fats in the blood)

### **How to take Kuvan:**

Take Kuvan exactly as your doctor or healthcare professional has told you.

Take Kuvan once a day with a meal. Take the dose at the same time each day.

Be sure that you know the dose of Kuvan that was prescribed and whether you need to use Kuvan 100 mg sachets, 500 mg sachets or both types of sachets to make the dose.

Kuvan 100 mg is for use in children who weigh 20 kg or less.

Patients (adults and children) who weigh more than 10 kg may use Kuvan 100 mg and / or 500 mg sachets.

### **Preparing the dose of Kuvan:**

Adults and children who weigh more than 10 kg (Kuvan 100 mg and / or 500 mg sachets):

- Empty the contents of the Kuvan sachet(s) (powder) into 1/2 cup of water or apple juice. Stir until the powder is completely dissolved. If the powder does not dissolve completely into 1/2 cup of water or apple juice, add up to 1/2 cup more water or apple juice. Stir until dissolved.
- You may also mix the powder into a small amount of soft food such as apple sauce or pudding. Stir the mixture until the powder is completely dissolved.
- Drink or eat mixture within 15 minutes of mixing.

For children who weigh between 10 kg to 20 kg, there is an alternate way to give the dose of Kuvan. This option is described in the next section.

Children one month of age and older who weigh 20 kg or less (Kuvan 100 mg sachets only):

- Give the dose to your child by first dissolving the powder into water or apple juice.
- You will need to give some or all of the mixture (powder and water or apple juice) to your child by mouth using an oral dosing syringe.
- Your doctor will tell you:
  - the number of Kuvan sachets needed for one dose,
  - the amount of water or apple juice needed to mix one dose of Kuvan, and
  - the amount of the mixture to give your child
- Give your child the exact amount of mixture that your doctor has indicated. To prepare your child's dose, you will need the following supplies:
  - the number of Kuvan sachets needed for one dose
  - a small cup of water or apple juice
  - a medicine cup with markings at 20, 40, 60 and 80 mL

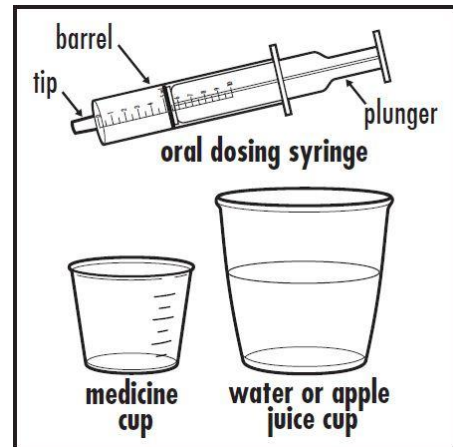
- a small spoon or clean utensil for mixing
- an oral dosing syringe with markings for each mL
  - You will need a 10 mL syringe to give volumes of 10 mL or less.
  - You will need a 20 mL syringe to give volumes larger than 10 mL.

Ask your pharmacist where to get these supplies if you do not have them.

How to prepare and give the dose of Kuvan to a child who is at least one month of age and weighs 20 kg or less (Kuvan 100 mg sachets only):

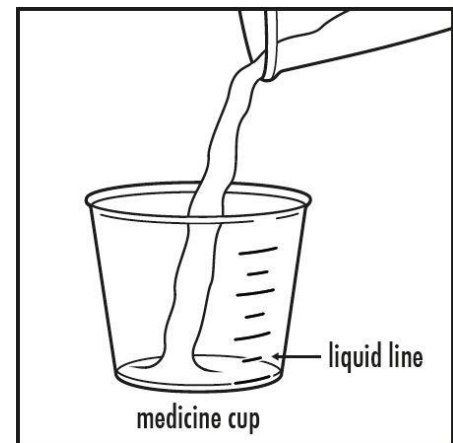
**Step 1:** Find a clean, flat work surface.

**Step 2:** Place a small cup of water or apple juice, the oral dosing syringe, and an empty medicine cup on your clean, flat work surface (see Figure A).



**Figure A**

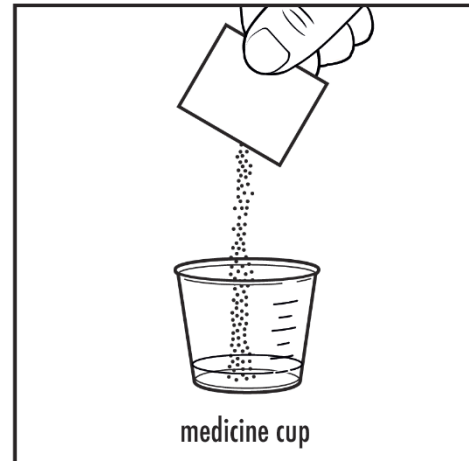
**Step 3:** Pour the appropriate amount (20 mL, 40 mL, 60 mL or 80 mL) of water or apple juice from the small cup into the medicine cup, as instructed by your doctor. Check to make sure that the amount of liquid lines up with the amount that your doctor tells you (see Figure B).



**Figure B**

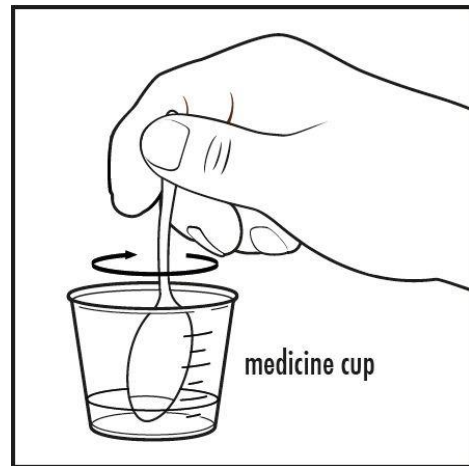


**Step 4:** Check the label on the Kuvan sachet(s). If the sachet is marked Kuvan 100 mg, empty the entire contents of the Kuvan sachet into the medicine cup (See Figure C).



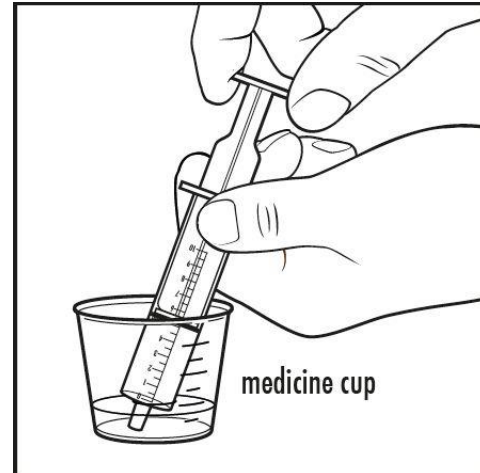
**Figure C**

**Step 5:** Stir with the small spoon or other clean utensil until all of the powder completely dissolves (see Figure D).



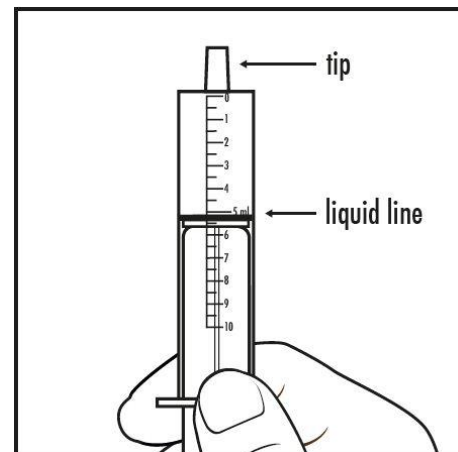
**Figure D**

**Step 6:** Place the tip of the oral dosing syringe into the liquid inside the medicine cup. Pull back on the plunger and draw up the exact amount of the mixture that your doctor has indicated (see Figure E).



**Figure E**

**Step 7:** Take the oral dosing syringe out of the medicine cup. Carefully turn the oral dosing syringe so that the tip is pointing up. Check to make sure that the amount of medicine in the oral dosing syringe lines up with the amount of mixture prescribed by your doctor (see Figure F).

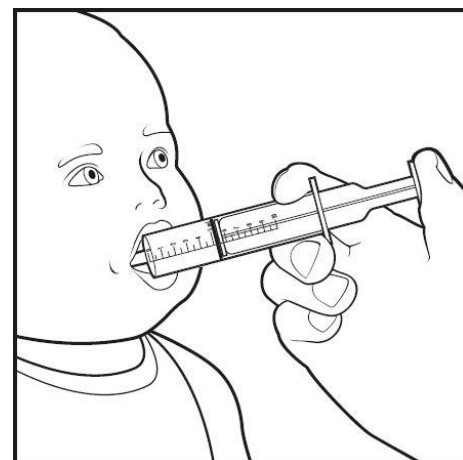


**Figure F**

**Step 8:** Place the tip of the oral dosing syringe into your child's mouth. Point the tip of the oral dosing syringe towards either cheek (see Figure G).

Push on the plunger slowly, a small amount at a time, until all of the mixture in the oral dosing syringe is given.

Give your child the dose within 15 minutes of mixing. If you are not able to give your child's dose within 15 minutes after mixing, pour the unused medicine into the trash. You will need to mix a new dose.



**Figure G**

**Step 9:** Throw away any remaining mixture. Remove the plunger from the barrel of the oral dosing syringe. Wash the oral dosing syringe and medicine cup with warm water and air dry. When the oral dosing syringe is dry, put the plunger back into the barrel. Store the oral dosing syringe and medicine cup for the next use.

When taking Kuvan, any changes in diet may affect blood Phe levels. Follow your doctor's instructions carefully. Avoid changes to your diet and Phe intake without talking to your doctor first. Your doctor will continue to monitor your blood Phe levels during your treatment with Kuvan to make sure that your blood Phe levels are not too high or too low.

Blood Phe levels may go up during a fever or sickness. Tell your doctor as soon as possible so they can change the dose of Kuvan to help keep blood Phe levels in the desired range.

#### **Usual Dose:**

The dose of Kuvan is based on body weight.

- Kuvan starting dose: 10 mg/kg body weight taken once a day with a meal.
- Your doctor can change your dose of Kuvan depending on how you respond to treatment.
- For children, in particular, the dose of Kuvan will change as the child grows.

#### **Overdose:**

Patients who have accidentally taken too much Kuvan reported mild headache, mild dizziness, stomach or belly pain and/or too much or constant activity (hyperactivity).

If you think you have taken too much Kuvan, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **Missed Dose:**

If you forget to take your dose of Kuvan, take it as soon as you remember that day. But if you miss the dose for that day, skip the missed dose, and continue with your scheduled dose the following day. Do not take two doses of Kuvan on the same day.

#### **What are possible side effects from using Kuvan?**

These are not all the possible side effects that you may feel when taking Kuvan. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Runny nose and stuffy nose
- Upper respiratory tract infection (like a cold)
- Cough
- Throat pain

- Mouth sores
- Stomach or belly pain
- Vomiting
- Nausea
- Diarrhea
- Headache
- Blurred vision
- Anger
- Bedwetting
- Trouble speaking
- Changes in hair colour

Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
<b>UNCOMMON</b>	<b>Edema (swelling):</b> fluid accumulation beneath skin of lower limbs	√		
	<b>Hives:</b> itchy bumpy rash	√		
	<b>Severe allergic reactions:</b> heavy breathing with whistling sound, trouble breathing, coughing, feeling dizzy or faint, turning red, nausea, and rash.			√
	<b>Esophageal (food pipe) disorders:</b> food pipe pain	√		
	<b>Pale skin</b>	√		
	<b>Retching (gagging)</b>	√		
	<b>Shortness of Breath</b>	√		
	<b>Swelling of Eyelid</b>	√		
	<b>Throat tightness</b>			√
<b>RARE</b>	<b>Gastritis (inflammation of the lining of the stomach):</b> burning sensation or pain in your upper abdomen/stomach		√	
<b>FREQUENCY NOT KNOWN</b>	<b>Esophagitis (inflammation of the lining of the food pipe):</b> burning sensation or pain in your food pipe		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Online at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to: 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

- Store at 15°C - 30°C. Protect from moisture.
- Do not leave Kuvan in hot or humid places, such as your car or bathroom cabinet.
- Do not keep Kuvan that is out of date, or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

Keep out of reach and sight of children.

### **If you want more information about Kuvan:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](https://www.canada.ca/en/health-canada.html) (<https://www.canada.ca/en/health-canada.html>); or by calling 1-877-597-6744.
- For questions, or to report problems, please contact 1-877-597-6744.

This leaflet was prepared by BioMarin International Limited

Last Revised: November 18, 2021