NUELIN® Syrup

Active ingredient: Theophylline (thee-off-o-lin)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nuelin Syrup. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nuelin Syrup.

Where to find information in this leaflet:

- 1. Why take Nuelin Syrup?
- 2. Before taking Nuelin Syrup?
- 3. Taking other medicines?
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- 5. While taking Nuelin Syrup?
- 6. Are there any side effects?
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1. Why take Nuelin Syrup?

Nuelin Syrup contains the active ingredient theophylline, which causes the muscle lining of the airways to relax.

Nuelin Syrup is used to treat asthma and other conditions where breathing is difficult. It also helps to prevent asthma attacks.

2. Before taking Nuelin Syrup?

Warnings

Do not take Nuelin Syrup:

- If you or your child are allergic to any medicines containing theophylline, aminophylline, caffeine or to any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin
- Always check the ingredients to make sure that you or your child can take Nuelin Syrup.
- Do not take Nuelin Syrup if the packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist if you or your child:

- Have allergies to any medicines, foods, preservatives or dyes
- Have a stomach ulcer or reflux

- Have an irregular or rapid heartbeat or any other heart disease
- Have very high blood pressure
- Have a viral infection or a fever
- Have liver, thyroid or lung disease
- Take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Before taking Nuelin Syrup check with your doctor if you are pregnant or intend to become pregnant. Nuelin Syrup may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. The active ingredient in Nuelin Syrup passes into breast milk. Irritability has been reported in infants of nursing mothers taking theophylline.

Use in Children

Do not give Nuelin Syrup to children under 2 years of age unless recommended by a doctor.

3. Taking other medicines?

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Nuelin Syrup and affect how it works.

Drugs that may <u>increase</u> the effect of Nuelin Syrup include:

- Cimetidine used to treat heartburn indigestion, stomach ulcers or reflux
- Allopurinol used to treat gout
- Propranolol used to reduce anxiety, relieve tremors and prevent migraine, angina, and high blood pressure
- Antibiotics, such as erythromycin, clarithromycin, ciprofloxacin or enoxacin
- Alcohol
- Oral contraceptives
- Mexilitene or verapamil used to treat high blood pressure, angina or other heart conditions
- Tacrine used to treat Alzheimer's disease
- Thiabendazole used to treat infections caused by worms
- Disulfiram used to treat alcoholism
- Interferon alpha used to treat different types of cancer

Drugs that may <u>reduce</u> the effect of Nuelin Syrup include:

- Tobacco or marijuana
- Phenobarbitone, phenytoin or carbamazepine used to treat epilepsy
- Lithium
- Rifampicin used to treat tuberculosis or leprosy
- Hypericum perforatum (St John's wort)

Your doctor may sometimes need to take samples of your blood to check the level of theophylline and possibly adjust your dose of Nuelin Syrup.

Tell your doctor or pharmacist if you or your child are taking medication containing any of the following:

- Halothane
- Ketamine
- Ranitidine
- Diltiazem
- Nifedipine
- Isoniazid
- Frusemide
- Influenza vaccine (flu vaccine)
- Corticosteroids
- Cold and flu medicines.

Taking these medicines and Nuelin Syrup at the same time may affect how each medication works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these will affect Nuelin Syrup.

4. How to take Nuelin Syrup

How much Nuelin Syrup to take:

• Dosage instructions are provided in the table below. For children 2 to 12 years of age, the dose depends on the body weight of the child.

Age	Dosage	How Often
Adults & children over 12 years	25 mL	Every 6 hours
Children 6-12 years	20 – 25 mL	
(average body weight 20-41 kg)		
Children 4-6 years	15 – 20 mL	
(average body weight 16-20 kg)		

Age	Dosage	How Often
Children 2-4 years	10 – 15 mL	
(average body weight 12-16 kg)		

- Follow any instructions given to you by your doctor or pharmacist on how to take Nuelin Syrup.
- Do not exceed the recommended dosage.

When to take Nuelin Syrup:

 Take Nuelin Syrup one hour before food with a glass of water. However, it can be taken with or immediately after food so that it does not upset your stomach

If you forget to take Nuelin Syrup

If you miss your dose at the usual time, take it as soon as you remember.

However, if it is more than 4 hours late, skip the dose that you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

If you take too much Nuelin Syrup

Taking too much Nuelin Syrup may make you feel irritable, agitated, or anxious; feel sick and vomit or are unable to sleep. More severe effects include a rapid or irregular heartbeat, feeling very thirsty or experiencing fever, confusion or fits.

If you think that you or your child have taken too much Nuelin Syrup, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. While taking Nuelin Syrup?

Things you should do

If you have an asthma attack, use your relieving inhaler to help with your asthma. Nuelin Syrup will not give you relief during an asthma attack as it does not work quickly enough.

If you are about to start on any new medicines, remind your doctor, dentist and pharmacist that you are taking Nuelin Syrup. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Nuelin Syrup. It may affect other medicines used during surgery.

If you are about to have any blood tests tell your doctor that you are taking Nuelin Syrup. It may interfere with the results of some tests.

Keep all doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- Think your or your child's asthma is getting worse or suffer asthma attacks
- Become pregnant while taking Nuelin Syrup.

Things you should not do:

- Do not use Nuelin Syrup to treat any other complaints unless your doctor or pharmacist tells you to
- Give Nuelin Syrup to anyone else, even if they have the same condition as you
- Stop taking Nuelin Syrup or change the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Nuelin Syrup affects you.

Children should be careful riding bicycles or climbing on playground equipment until you know how Nuelin Syrup affects them.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol may increase the effects of Nuelin Syrup.

Looking after your medicine

 Store below 30°C. Do not refrigerate. Storage under 15°C may cause the syrup to crystallise.

• Store Nuelin Syrup in the bottle until it is time to take it. Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you or your child no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
 Common side effects Nausea Vomiting Stomach pain Reactivation of stomach ulcers Loss of appetite Headache Difficulty sleeping Feeling restless, nervous or irritable Tremors Heart palpitations or fast heartbeat Blood in vomit or urine Less common side 	Speak to your doctor if you have any of these less serious side effects and they worry you.
effects	
 Diarrhoea Flushing or skin rashes Low blood pressure Rapid breathing 	

Less serious side effects	What to do
 Fast or irregular urine flow 	
High blood sugarHair loss	

Serious side effects

Serious side effects	What to do
 Changes in your heart rhythm Fits 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Nuelin Syrup contains

Active ingredient (main ingredient)	Theophylline
Other ingredients (inactive ingredients)	Berry citrus flavour Methyl hydroxybenzoate
	Propyl hydroxybenzoate Purified water
	Sucrose Sorbitol
Potential allergens	Methyl hydroxybenzoate Propyl hydroxybenzoate Sorbitol

Do not take this medicine if you are allergic to any of these ingredients.

What Nuelin Syrup looks like

Nuelin Syrup is a clear, almost colourless liquid with a berry flavour and comes in a 500 mL bottle (Registration number: AUST R 10576).

Who distributes Nuelin Syrup

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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