

Nuelin(TM) Syrup

(new-lin)

Theophylline syrup 133.3 mg/25 mL (thee-off-o-lin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nuelin Syrup. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

Throughout this leaflet we are talking about the 'patient'. By that we mean either you or your child, whoever is taking Nuelin Syrup.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks and benefits of the patient taking Nuelin against the benefits they expect it will have for the patient.

If the have any concerns about taking this medicine or giving it to your child, ask your doctor or pharmacist.

Please read this leaflet carefully before taking this medicine or giving it to your child.

If the information in this leaflet is not clear, or if you have any questions that are not covered by this leaflet, please ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

Nuelin Syrup can be bought from a pharmacy without a doctor's prescription on the advice of a pharmacist.

What NUELIN Syrup is used for

The name of the medicine is Nuelin Syrup. It is used to treat asthma and other conditions where breathing is difficult. It also helps to prevent asthma attacks. The active ingredient in Nuelin Syrup is theophylline, which causes the muscle lining of the airways to relax.

Your doctor or pharmacist may recommend Nuelin Syrup for another purpose.

If you are not sure why the patient is taking this medicine, please ask your doctor or pharmacist.

Before taking NUELIN Syrup

When the patient must not take NUELIN Syrup

Nuelin Syrup should not be taken if the patient is allergic to:

- * theophylline
- * aminophylline
- * caffeine,
- * 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

Do not give this medicine to a child under the age of 2 years unless a doctor has recommended the medicine.

Do not take this medicine or give it to a child after the expiry date printed on the pack or if the packaging shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether the patient should start taking this medicine, talk to your doctor or pharmacist.

Nuelin Syrup has been recommended for the patient only.

Do not give it to anyone else even if they suffer from the same condition.

Before starting to take it

Tell your doctor if the patient has allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if the patient has or has had any of the following medical conditions:

- * a stomach ulcer or reflux
- * an irregular or rapid heartbeat
- * any other heart disease
- * high blood pressure
- * any viral infections or lung infections
- * any liver disease
- * thyroid disease
- * lung disease

Or else if the patient:

- * has a fever
- * is pregnant or breastfeeding
- * is taking any other medicines for asthma

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

If you have not told your pharmacist or doctor about any of the above, tell him/her before the patient starts taking the medicine.**Taking other medicines****Tell your doctor or pharmacist if the patient is taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Nuelin Syrup may interfere with each other. These include:

- * antibiotics such as erythromycin (Eryc and others), clarithromycin (Klacid), ciprofloxacin (Ciproxin)
- * enoxacin (Enoxin), rifampicin (Rifadin and others) or isoniazid.
- * medicines used to treat ulcers such as cimetidine (Tagamet and others), ranitidine (Zantac and others).
- * allopurinol (Zyloprim and others).
- * propranolol (Inderal and others)
- * frusemide (Lasix and others)
- * medicines used to help lower high blood pressure such as verapamil (Isoptin and others), diltiazem (Cardizem and others), nifedipine (Adalat and others)
- * mexiletine (Mexitol)
- * medicines used to treat epilepsy or fits such as phenytoin (Dilantin), phenobarbitone or carbamazepine (Tegretol and others)
- * tacrine (Cognex)

- * lithium
- * thiabendazole (Mintezol)
- * disulfiram (Antabuse)
- * oral contraceptives (the Pill)
- * corticosteroids
- * flu vaccine
- * interferon
- * any remedies that you buy without a prescription, especially cold and flu medicines and products containing St John's Wort (*Hypericum perforatum*)

These medicines may be affected by Nuelin Syrup or may affect how well it works. The patient may need different amounts of these medicines, or may need to take different medicines.

Also tell your doctor or pharmacist if the patient drinks any alcohol or smokes cigarettes or marijuana.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking this medicine.

How to take NUELIN Syrup

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

Nuelin Syrup helps to prevent and relieve asthma attacks.

Take this medicine only as directed by your doctor or pharmacist.**How much to take**

The dose for adults is usually 25mL every six hours. However, this dose may be increased or decreased by your doctor.

For children over 2 years old, the dose of Nuelin Syrup depends on the weight of the child (1mL/kg of

bodyweight up to a maximum of 25mL every six hours).

- * Children 2-4 years, 12-16 kg: 10-15mL every 6 hours
- * Children 4-6 years, 16-20 kg: 15-20mL every 6 hours
- * Children 6-12 years, 20-41 kg: 20-25mL every 6 hours
- * Adults and children over 12 years: 25mL every 6 hours

Nuelin Syrup is not suitable for children younger than 2 years of age except on the advice of a doctor.

How to take it

It is best to take Nuelin Syrup one hour before food with a glass of water. However if it upsets the patient's stomach it should be taken with or immediately after food.

While the patient is taking NUELIN Syrup

Nuelin Syrup works best when there is a certain amount of theophylline, the active ingredient, in the blood. Your doctor may sometimes need to take samples of blood to check the level of theophylline.

If the patient forgets to take NUELIN Syrup

If the patient forgets to take Nuelin Syrup, take it as soon as you remember. However, if it is more than 4 hours late, skip the dose that the patient missed. Take the next dose at the normal time.

Never take a double dose to make up for a missed dose.

If the patient has trouble remembering when to take the medicine, ask your pharmacist for some hints.

If you or your child take too much NUELIN Syrup

If you think that you or anyone else may have taken too much Nuelin Syrup telephone your doctor or pharmacist or the Poisons Information Centre (in

Australia call 131126; in New Zealand phone toll free 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital IMMEDIATELY. Do this even if there are no signs of discomfort or poisoning.

If you or your child has taken too much Nuelin Syrup you may feel sick and vomit. You may feel irritable, agitated or anxious. You may be unable to sleep. In severe cases, your heart may beat faster and irregularly and you may have a high body temperature, be very thirsty, be very confused and have fits.

While you are using Nuelin Syrup

Things you must do

If the patient is about to be started on any new medicine remind your doctor and pharmacist that the patient is taking Nuelin Syrup.

Tell any other doctors, dentists and pharmacists who treat the patient that they are taking this medicine

If the patient is going to have surgery, tell the surgeon or anaesthetist that the patient is taking this medicine.

It may affect other medicines used during surgery.

If the patient becomes pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

The patient must not take Nuelin Syrup to treat any other complaints unless the doctor or pharmacist tells them to.

Do not give this medicine to anyone else, even if they have the same condition as the patient.

The patient should not stop taking the medicine or lower the dosage without checking with the pharmacist or doctor.

Things to be careful of

Be careful when drinking alcohol or smoking cigarettes or marijuana, these can interfere with how well Nuelin Syrup works.

Side Effects

Tell your doctor or pharmacist as soon as possible if the patient does not feel well while taking Nuelin Syrup.

This medicine helps most people with asthma and other conditions where breathing is difficult or to prevent asthma attacks, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * nausea, vomiting, stomach pain, loss of appetite
- * heartburn
- * headache
- * difficulty sleeping
- * feeling restless, nervous or irritable

Tell your doctor or pharmacist as soon as possible if you notice any of the following:

- * diarrhoea
- * abnormal heartbeat
- * low blood pressure
- * flushing, skin rash
- * rapid breathing
- * increased or decreased urine flow
- * blood in the urine
- * high blood glucose

- * hair loss
- * worsening of a stomach ulcer
- * fast or irregular heartbeat
- * tremor

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happens, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- * very irregular or faster heartbeat
- * fits
- * blood in the vomit

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making the patient feel unwell.

Other side effects not listed above may also occur in some people.

If the patient has any side effect, whether it is listed above or not, please tell your doctor or pharmacist.

After Using Nuelin Syrup

Storage

Keep your syrup in the bottle until it is time to take it.

If you take the syrup out of the bottle it may not keep well.

Keep Nuelin Syrup in a cool dry place where the temperature stays below 30 degrees C.

Do not refrigerate it.

Do not store Nuelin Syrup or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Nuelin Syrup where children cannot reach it.

A locked cupboard one-and-a-half metres above the ground is a good place to store medicine.

Disposal

If your doctor or pharmacist tells the patient to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What NUELIN Syrup looks like

Nuelin Syrup is a clear, almost colourless liquid with a berry like flavour contained in a 500mL bottle.

Ingredients

Each 25mL of Nuelin Syrup contains 133.3mg of the active ingredient theophylline.

Nuelin Syrup also contains:

- * sucrose
- * sorbitol
- * berry citrus flavouring
- * purified water.

Methyl hydroxybenzoate and propyl hydroxybenzoate are used as preservatives.

Nuelin Syrup does not contain gluten.

Manufacturer

Nuelin Syrup is made and supplied by:

iNova Pharmaceuticals (Aust) Pty Ltd

(ABN 88 000 222 408)

9-15 Chilvers Road

Thornleigh NSW 2120 AUSTRALIA

Distributor

Nuelin Syrup is distributed in New Zealand by:

Douglas Pharmaceuticals Ltd

Central Park Drive, Lincoln

Auckland 0610

NEW ZEALAND

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(TM) = Trademark

This leaflet was prepared in August 2008.