NUELIN-SR™ TABLETS

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Theophylline (thee-off-o-lin) Tablets

Consumer Medicine Information

What is in this leaflet

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

If you need any more information about Nuclin-SR tablets, please ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Nuelin-SR tablets against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

What NUELIN-SR Tablets are used for

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

Nuelin-SR tablets are a slow release medicine which means each tablet works for about 12 hours.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may prescribe Nuelin-SR tablets for another purpose.

Nuclin-SR tablets are available only with a doctor's prescription.

If you are not sure why you are taking this medicine, ask your doctor.

Before you take NUELIN-SR Tablets

When you must not take it Do not take Nuelin-SR tablets if you have

an allergy to:

- Any medicine containing theophylline, aminophylline or caffeine
- Any of the ingredients listed at the end of this leaflet
- Any other similar medicines used to treat asthma and other conditions where breathing is difficult

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 take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

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

Do not give it to anyone else even if their condition is the same as yours.

Do not use Nuclin-SR tablets to treat an asthma attack.

Use a reliever inhaler such as Airomir instead.

Before you start to take it

Tell your doctor if you have allergies to any medicines, foods, preservatives or dyes.

Tell your doctor if you have:

- · A stomach ulcer or reflux
- An irregular or rapid heartbeat or any other heart disease
- · Very high blood pressure
- · Any viral infections or lung infections
- Any liver disease; thyroid disease or lung disease

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding.

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

If you have not told your doctor about any of the above, tell them before you start taking Nuelin-SR tablets.

Taking other medicines

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

Some medicines may affect the way Nuelin-SR tablets work.

Tell your doctor or pharmacist if you are taking any other medication, in particular:

- Antibiotics such as erythromycin, clarithromycin, ciprofloxacin, enoxacin or rifampicin
- Cimetidine
- Allopurinol
- Propranolol
- Verapamil
- Mexiletine
- Phenytoin, phenobarbitone or carbamazepine
- Tacrine
- Lithium
- Thiabendazole
- · Oral contraceptives
- Flu vaccine
- Interferon
- Any remedies that you buy without a prescription, especially cold and flu medicines and products containing St John's wort.
- Also tell your doctor if you drink any alcohol or if you smoke cigarettes or marijuana.

These medicines may be affected by Nuelin-SR tablets or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

How to take NUELIN-SR Tablets

Carefully follow all directions given to you by your doctor or pharmacist.

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.

How much to take

The dose for adults is usually one tablet twice a day. However, this dose may be increased or decreased by your doctor.

For children over 2 years old, the dose of Nuelin-SR tablets depends on the weight of the child. Follow all instructions from your doctor when giving Nuelin-SR tablets to children over 2 years old.

Nuclin-SR tablets are not suitable for children younger than 2 years of age.

Nuclin-SR tablets should be taken every 12 hours.

How to take it

Take Nuelin-SR tablets with a full glass of water and DO NOT chew or crush the tablets.

When to take it

You can take Nuelin-SR tablets with or immediately after food so that it does not upset your stomach.

Nuclin-SR tablets help to prevent asthma attacks.

Always take Nuelin-SR tablets regularly, as your doctor has told you to, even if you are not suffering any asthma symptoms.

If you think your asthma is getting worse or if you suffer asthma attacks, please consult your doctor immediately.

Nuclin-SR tablets will not give you relief during an asthma attack.

If you have an asthma attack, please use your relieving inhaler (such as Airomir, Ventolin, Asmol or Bricanyl).

Nuelin-SR tablets work best when there is a certain amount of theophylline, the active ingredient, in your blood. Your doctor may sometimes need to take samples of your blood to check the level of theophylline.

How long to take it

Continue taking this medicine for as long as your doctor tells you.

If you forget to take it

If you forget to take Nuclin-SR tablets, take it as soon as you remember.

However, if it is more than 4 hours late, skip the dose that you missed. Take your next dose at the normal time.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too many Nuelin-SR tablets. Do this

even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many Nuelin-SR tablets you may:

- · Feel sick and vomit
- Feel irritable, agitated or anxious
- · Are unable to sleep

More severe effects include:

- · Rapid or irregular heart beat
- Fever
- · Feel very thirsty
- Confusion
- Fits

While you are using Nuelin-SR Tablets

Things you must do

If you are about to be started on any new medicine remind your doctor and pharmacist that you are taking Nuelin-SR tablets.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests tell your doctor that you are taking this medicine.

It may interfere with the results of some tests

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

Things you must not do

Do not take Nuelin-SR tablets to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Nuelin-SR tablets affect you.

Side effects

All medicines can have side effects and this may occur with the normal use of Nuelin-SR tablets

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nuelin-SR tablets.

The more common side effects include:

- Nausea, vomiting, stomach pain, loss of appetite
- · Fast or irregular heartbeat
- Headache
- Difficulty sleeping
- Feeling restless, nervous or irritable
- Tremor

Less common side effects include:

- Diarrhoea
- · Worsening of a stomach ulcer
- · Blood in the vomit
- · Low blood pressure
- · Flushing, skin rash
- · Rapid breathing
- · Increased or decreased urine flow
- · Blood in the urine
- · High blood glucose
- Hair loss

Very rare side effects include:

Fits

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

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

After using NUELIN-SR Tablets

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep Nuelin-SR tablets in a cool dry place where the temperature stays below 30°C.

Do not store Nuelin-SR tablets 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-SR tablets where children cannot reach it.

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

Disposal

If your doctor tells you 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 it looks like

Nuelin-SR 200 mg tablets are small white tablets marked N/L on one side and 200 on the other and come in a bottle of 100 tablets.

Nuelin-SR 250 mg tablets are small white tablets marked N/L on one side and 250 on the other and come in a bottle of 100 tablets.

Nuelin-SR 300 mg tablets are small white tablets marked N/L on one side and 300 on the other and come in a bottle of 100 tablets.

Ingredients

Nuelin-SR tablets contain 200mg, 250mg or 300mg of the active ingredient, theophylline. Nuelin-SR tablets also contains the following inactive ingredients:

- guar gum
- · magnesium stearate

Nuelin-SR tablets do not contain gluten.

Sponsor

Nuclin-SR tablets are distributed in Australia by:

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539 Level 10, 12 Help Street Chatswood NSW 2067 Tel: 1800 630 056 AUSTRALIA

Australian Registration Numbers

Nuelin-SR 200 mg tablets: AUST R 59526 Nuelin-SR 250 mg tablets: AUST R 46069 Nuelin-SR 300 mg tablets: AUST R 59527

TM = Trademark

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