

- you have a headache
- you feel restless and have difficulty sleeping (insomnia).

Nuelin SA are prolonged release tablets. This means they release the medicine slowly over a long period of time. This reduces the chance of you getting any side effects and makes any side effects milder.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### Reporting of side effects

If you get 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](http://www.mhra.gov.uk/yellowcard)

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

### 5. How to store Nuelin SA

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Nuelin SA contains

- The active substance in Nuelin SA is theophylline. Each 175 mg tablet contains 175 mg theophylline. Each 250 mg tablet contains 250 mg theophylline.
- The other ingredients are lactose, cellulose acetate phthalate and magnesium stearate.

#### What Nuelin SA looks like and contents of the pack

Nuelin SA prolonged release tablets come in two strengths: 175 mg and 250 mg. The tablets are white, round, biconvex, uncoated tablets with "T" on one face and "175" or "250" on the other with a score line (only for the 250 mg tablet).

They come in a bottle or blister pack of 60 tablets.

**Marketing Authorisation Holder:** Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop's Stortford, CM22 6PU, United Kingdom.

**Manufacturer:** 3M Health Care Ltd, Loughborough, Leicestershire, LE11 1EP, United Kingdom.

This leaflet was last updated in 09/2016

**If this leaflet is difficult to see or read and you would like it in a different format, please contact Meda Pharmaceuticals, Skyway House, Parsonage Road, Takeley, Bishop's Stortford, CM22 6PU, United Kingdom.**

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# Patient Information Leaflet Nuelin SA 175 mg & 250 mg Prolonged Release Tablets

Theophylline

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

#### What is in this leaflet:

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

### 1. What Nuelin SA is and what it is used for

Nuelin SA belongs to a family of medicines called bronchodilators. Bronchodilators are used to treat, and relieve the symptoms of diseases where the passages in your lungs are blocked.

Nuelin SA works by widening the air passages in your lungs which allows you to breathe more easily and feel less tight chested. You may take Nuelin SA if you have asthma or a chest disease such as chronic obstructive pulmonary disease (COPD) that makes you wheeze, cough or become short of breath.

You must talk to a doctor if you do not feel better or if you feel worse.

### 2. What you need to know before you take Nuelin SA

#### Do not take Nuelin SA:

- if you are allergic to theophylline or other bronchodilators (such as xanthines), or any of the other ingredients of this medicine (listed in section 6).
- if you are under 6 years of age
- if you are a child and are taking medicines containing ephedrine (e.g. children's cold and cough medicines)
- if you have a disease called porphyria which may cause skin problems, chest and stomach pains, sickness and diarrhoea. If any of the above applies to you talk to your doctor or pharmacist.

#### Warnings and precautions

#### Check with your doctor or pharmacist before taking Nuelin SA:

- if you have an irregular, or abnormally fast or slow heart beat
- if you have a stomach or intestinal ulcer
- if you suffer from epileptic seizures
- if you have lung disease
- if you have liver disease
- if you have very high blood pressure





- if you have been told you have an overactive thyroid gland
- if you have a disease called acute porphyria which may cause stomach pain, sickness, diarrhoea, seizures or mental disorders
- if you are an alcoholic
- if you have a high fever, headache and chills that came on suddenly (acute febrile illness)
- if you smoke.

If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor or pharmacist before taking this medicine.

#### Other medicines and Nuelin SA

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines. It is very important that you do this, as your doctor or pharmacist may have to alter the dose of Nuelin SA that you take:**

- isoprenaline and another xanthine called aminophylline which are used to treat asthma or lung disease
- drugs to treat stomach or intestinal ulcers such as cimetidine or nizatidine
- drugs to treat high blood pressure such as beta-blockers, furosemide, diltiazem or verapamil
- drugs to treat an overactive thyroid gland such as carbimazole
- drugs to treat infections such as erythromycin or other macrolide antibiotics, ciprofloxacin or norfloxacin
- drugs to treat fungal infections such as fluconazole
- drugs to treat a joint disease called gout such as allopurinol or sulfinpyrazone
- drugs to treat skin diseases (corticosteroids)
- oral contraceptives (i.e. 'the pill')
- drugs to treat irregular heart beat such as mexiletine or propafenone
- drugs to treat depression such as fluvoxamine
- a vaccine for preventing flu
- drugs used to treat alcoholism such as disulfiram
- interferon alfa, a drug used to treat several cancers
- drugs to treat tuberculosis such as isoniazid or rifampicin
- drugs to treat diseases of the small blood vessels such as pentoxifylline
- drugs to prevent and treat epileptic seizures such as phenytoin, carbamazepine, barbiturates or primidone
- aminoglutethimide, a drug used to treat a disease called Cushings Syndrome
- St John's Wort (*Hypericum perforatum*), a herbal remedy used to treat depression
- ketamine, a drug used as an anaesthetic
- doxapram, a drug used to stimulate breathing in patients who struggle to breathe for themselves.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

#### Nuelin with food and drink

Nuelin SA should always be taken after you have eaten.

#### Pregnancy, breast-feeding and fertility

##### Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

##### Breast-feeding

You must not breast-feed while taking this medicine.

#### Driving and using machines

Nuelin SA does not affect your ability to drive or use machines.

#### Nuelin SA contains lactose

### 3. How to take Nuelin SA

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is:

##### Adults:

Nuelin SA 175 mg tablets: The usual dose is one tablet taken twice a day.

If necessary, this may be increased to two tablets twice a day.

Nuelin SA 250 mg tablets: The usual dose is one tablet taken twice a day.

If necessary, this may be increased to two tablets twice a day.

##### Elderly:

Your doctor or pharmacist will tell you exactly how much to take. The dose you take may be lower than the usual adult dose.

While you are taking this medicine, your doctor may ask you to have check-ups.

These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

#### Use in children and adolescents

##### Children (aged 6-12 years):

Nuelin SA 175 mg tablets: The usual dose is one tablet taken twice a day.

Nuelin SA 250 mg tablets: The usual dose is half to one tablet taken twice a day.

**Remember:** Nuelin SA should always be taken after you have eaten. Nuelin SA tablets should be swallowed whole. Do not crush or chew the tablets. To get the correct dose, the 250 mg tablets may have to be broken in half along the line down the middle. Your doctor or pharmacist will tell you how to do this.

#### If you take more Nuelin SA than you should

Do not take more Nuelin SA than you should. If you accidentally take too much, immediately contact your doctor or nearest hospital casualty department.

Taking too much Nuelin SA can have very serious effects. You may feel or be sick, have stomach pains, and vomit blood. Your heart may beat faster or you may shake uncontrollably. Severe cases of overdose may cause you to have a fit, go into a coma, or die.

#### If you forget to take Nuelin SA

Do not take a double dose to make up for a forgotten dose. Take your next dose as planned.

#### If you stop taking Nuelin SA

Do not stop taking Nuelin SA without first talking to your doctor or pharmacist. If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse.

### 4. Possible side effects

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

#### Tell your doctor or pharmacist if:

- you notice your heart beating irregularly, or abnormally fast or slow
- you have a fit (convulsions)
- you feel sick
- you have cramps, or a burning sensation in your stomach