

N-ACETYLCYSTEINE

This leaflet contains information about N-acetylcysteine to treat idiopathic pulmonary fibrosis.

It tells you:

- how the medicine works
- how you should take it
- about potential side effects.

Why have I been given this leaflet?

For most medicines, more information is found in the medicine package. However, this medicine does not have a licence for use in the UK. This means that the manufacturer has not provided any information. So we have written this leaflet for you instead.

So this medicine does not have a licence. What does this mean?

Medicines usually have a manufacturer's licence for use in the UK. N-acetylcysteine does not have a licence for use in the UK, though it is licensed for use in Europe. This means that your doctor should have explained to you the risks and benefits of treatment and the known (and potential for unknown) side effects.

Why does N-acetylcysteine not have a licence?

N-acetylcysteine does not have a licence for use in idiopathic pulmonary fibrosis because it is not made for use in the United Kingdom. It is imported from Germany where it is licensed for reducing sputum viscosity in the treatment of lung diseases.

Remember that your doctor will have thought carefully about which medicine is best for your condition. N-acetylcysteine is recommended in national guidelines for the treatment of idiopathic pulmonary fibrosis, so its place in therapy and its safety is well established.

What is N-acetylcysteine and how does it work?

N-acetylcysteine increases the amount of a substance called glutathione in the body. This has been shown to help protect the lung from the harmful effects of inflammation and prevent further deterioration in lung function.

How should I take or use N-acetylcysteine?

One tablet of N-acetylcysteine should be taken three times a day, until your doctor tells you to stop. The tablets will dissolve in water if you find them difficult to swallow.

The tablets should be stored in the original packaging and at room temperature. Avoid storing in a moist environment, eg bathroom.

When shouldn't I use N-acetylcysteine?

- do not take or use this medicine if you have previously had a reaction to N-Acetylcysteine (Parvolex®)
- take extra care if you have recently had a stomach/duodenal ulcer or have liver disease.
- Please tell your doctor if you have either of these conditions.

Are there any side effects?

It is well known that some medicines can cause side effects. N-acetylcysteine can sometimes cause diarrhoea, nausea and vomiting and possibly dizziness. Only contact your GP if these side effects carry on for more than a few days or make you feel worse.

More rarely, patients may suffer an allergic reaction to N-acetylcysteine. This may cause a rash or possibly cause swelling in the mouth and throat making it difficult to breathe. If you have any of these effects, stop taking N-acetylcysteine and contact your GP as soon as possible.

Will N-acetylcysteine affect any other medicines?

N-acetylcysteine is not known to affect any other medications. Tell your GP, dentist or pharmacist about all the other medicines you take. This includes any medicines you have had prescribed by another doctor as well as medicines bought from a pharmacy or supermarket and any herbal remedies.

Can I drink alcohol while I am taking N-acetylcysteine?

Yes, it safe to drink alcohol while you are taking N-acetylcysteine. However, you should remain within recommended limits of 14 units a week for women and 21 units per week for men.

Where do I get my next supply?

Further prescriptions are available from the hospital. Phone your consultant's secretary at least two weeks before you are due to run out and ask for a prescription to be written. Once you have collected it, take the prescription to your local pharmacy in good time. The pharmacy may not have the medicine in stock. To help arrange a supply, you should give the information attached to your local pharmacist for their information.

If you have any further questions, please contact your doctor or pharmacist, showing them the information on the following page.

PHARMACY

The following information is for your pharmacist:

To the Community Pharmacist

Of

under the care of (Consultant)

See at Outpatients / discharged on or about

This patient has been prescribed N-acetylcysteine 600mg three times daily for the treatment of idiopathic pulmonary fibrosis.

Availability of further supplies

N-acetylcysteine tablets are unlicensed in the UK. In Doncaster and Bassetlaw Hospitals NHS Foundation Trust, we obtain supplies from IDIS World medicines. However, other importers may be able to source this product.

Supplier information

IDIS Telephone Number: 01932 824 000

PRODUCT DETAILS

Brand Name:	ACC-600
Manufacturer:	Hexal AG Germany
Strength:	600 mg
Form:	Tablet
Pack Size:	1 x 100
Storage Instructions:	No special storage
Generic Name:	Acetylcysteine
Cytotoxic:	NO
Controlled Drug:	NO

IDIS tend to source products with a European license first, but sometimes there is a requirement to look more widely, and so the next step would be to look at ICH countries (ICH = International Conference on Harmonisation, and members include countries from the EU, USA, Canada and Australia) who have well established quality expectations.

PHARMACY

IDIS give the following assurances about this product:

- ACC-600 (N-acetylcysteine) is available for next day delivery (if ordered before 4.00 pm)
- IDIS can provide an English SPC free-of-charge to all pharmacists that request it
- this product is fully TSE (Transmissible Spongiform Encephalopathies) compliant, and comes with additional certification
- IDIS evaluates every supplier assuring their GMP compliance - this is either through auditing (they have trained and experienced Pharmaceutical Lead Assessors) or via evidential audit by mail. Suppliers are not adopted unless they are signed off by QA.
- when products arrive at IDIS for the first time, they receive an enhanced check, over and above the statutory checks, to ensure that the product truly reflects what is required
- IDIS uses barcode reading to systemise goods-in checks to take out the human error aspect of booking any product on to the system
- IDIS tends to source products from European licensed suppliers first, but sometimes there is a requirement to look wider. So the next step would be to look at MR countries and then to countries like USA, which have well-established quality expectations
- IDIS looks to form partnerships with manufacturers to facilitate ensuring that the legitimate/authentic product is procured
- IDIS holds all of the requisite licenses and is audited by the MHRA every two years. It is audited to full GMP not just GDP
- IDIS' quality management system is based on the 'Orange Guide'
- IDIS has designated individuals responsible solely for quality assurance
- any retail chemist, whether a large chain or an independent, can open an account with IDIS.

Please note: This information is intended to give availability/supply information only. It is not a prescription. If you have any difficulty sourcing a supply, please ring 01302 366666 extension 3134 (purchasing department) for advice.