ADULT SHARED CARE GUIDELINES

It is vital for safe and appropriate patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Consultants and General Practitioners (GPs).

This guideline reinforces the basic premise that:

When clinical and / or prescribing responsibility for a patient is transferred from hospital to GP, the GP should have full confidence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a GP would not normally be familiar with, should not take place without the “sharing of information with the individual GP and their mutual agreement to the transfer of care.”

These are not rigid guidelines. In all cases, Consultants and GPs should discuss the appropriate management of individual patients personally. On occasions, Consultants and GPs may agree to work outside of this guidance. As always, the doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Drug Name:

ACETYLCYSTEINE TABLETS - Idiopathic Pulmonary Fibrosis

Licensed indication:

Acetylcysteine tablets are unlicensed in the UK. Treatment is recommended by British Thoracic Society Interstitial Lung Disease Guideline for the treatment of interstitial pulmonary fibrosis (IPF) in combination with prednisolone and azathioprine therapy (2008). Acetylcysteine is an anti-oxidant acting as a precursor for glutathione synthesis.

Dosage and administration:

600mg three times a day orally. Duration is life-long for responding patients.

Cautions and contraindications:

- Hypersensitivity to acetylcysteine or to any of the excipients.
- Acetylcysteine tablets should not be used in patients with hepatic or renal failure in order to avoid further supply of nitrogenous substances
- The occurrence of severe skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome has very rarely been reported in temporal connection with the use of acetylcysteine.
- If cutaneous and mucosal alterations newly occur – the use of acetylcysteine should be terminated and the patient should be referred back to the Respiratory Physician.
- Use should be avoided in patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption.

For full information see the current edition of the British National Formulary (BNF)

Adverse effects:

- **Uncommon**: Stomatitis, headaches and tinnitus.
- **Rare**: Heartburn, nausea, vomiting and diarrhoea. Allergic reactions such as pruritus, urticaria, exanthema, rash, bronchospasm, tachycardia, and decrease in blood pressure. Very rare reports of bronchospasm predominantly in patients with hyper-reactive bronchial systems in connection with asthma. Haemorrhages, partly in the course of hypersensitivity reactions.

For full information see the current edition of the British National Formulary (BNF).

Monitoring requirements:

Baseline Tests:
- Blood tests
- Urine dipstick
- Lung function tests
- Chest radiography
- CT scans

Disease monitoring:

The efficacy of therapy will be monitored with serial lung function tests and chest imaging, where indicated, on the basis of clinical signs and symptoms.

Action to be taken if abnormal results/adverse effects:

Stop therapy if treatment ineffective/ adverse events occur and the patient should be referred back to the Respiratory Physician.

Drug interactions:
Combined use of antitussives (cough-relieving agents) with acetylcysteine may cause a dangerous secretory congestion due to the reduced cough reflex.

Oral antibiotics should be administered separately and at an interval of at least 2 hours. (*In vitro* experiments report an inactivation of antibiotics (tetracycline, aminoglycosides, penicillins) due to acetylcysteine when relevant substances were directly mixed.) For full information see the current edition of the British National Formulary (BNF).

**Specialist responsibilities:**
- Diagnosis of idiopathic pulmonary fibrosis based on a timely and comprehensive assessment.
- Initiation of prescription of acetylcysteine effervescent 600mg tablets, in conjunction with prednisolone and azathioprine
- Supplying the initial 56 days treatment.
- Monitoring for response and adverse drug reactions (ADRs) during the initiation period.
- Liaison with the general practitioner (GP) to share the patient’s care when proven benefit has been established.
- Outlining to GP when therapy may be stopped assuming no improvement is recognised in the patient’s condition. Regular review of patients in secondary care, whilst on triple therapy (prednisolone, azathioprine and acetylcysteine), with consideration at each review as to whether treatment needs to continue.
- Evaluating ADRs raised by the GP and evaluating any concerns arising from physical checks and reviews undertaken by GP.
- Advising GP on related issues such as drug interactions etc.
- Liaise with the patient's community pharmacist regarding the purchasing of acetylcysteine tablets.

**GP responsibilities:**
- Monitoring the patient’s overall health and well being.
- Observing patient for evidence of ADRs or any abnormalities and discussing with secondary care clinician if necessary.
- Prescription of acetylcysteine after achievement of a stable dose regime by secondary care.
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient’s physical health status.
- Reducing and stopping treatment in line with secondary care clinician’s original request.

**Patient responsibilities:**
- Report any adverse effects to their GP and/or specialist whilst treated with acetylcysteine.
- Ensure they have a clear understanding of their treatment.

**Secondary care review:**
Suggested review of patient’s condition and efficacy of treatment 6 months after discharge from secondary care, and then annually thereafter, with consideration at each review as to whether treatment needs to continue.

**Availability/Other special considerations:**

**Proprietary name:** Fluimucil®. **Manufacturer:** Zambon. **Supplied via IDIS Ltd.**

**Special Considerations:**
One 600mg effervescent tablet contains 6.82mmol of sodium. This needs to be taken into account with patients on a low-sodium diet.
One 600mg effervescent tablet contains 11mg phenylalanine. This may be harmful to patients with phenylketonuria.

**Cost:**
Per patient per 28 days: £23.69 including VAT

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In consultation with Medicines Management Team, Wirral PCT