

Shared Care Guideline: **Nebulised Dornase alfa**

Name of patient treated under this guideline:

This shared care guideline has been produced to support the seamless transfer of prescribing and patient monitoring from secondary to primary care, and provides an information resource to support clinicians providing care to the patient. It does not replace discussion about sharing care on an individual patient basis.

This guideline was prepared using information available at the time of preparation, but users should always refer to the manufacturer's current edition of the Summary of Product Characteristics (SPC or "data sheet") for more details.

1.0 Status of nebulised Dornase alfa

Dornase alfa is an "amber" drug using our local traffic light system. This means that treatment will usually be initiated in secondary care and may be transferred to primary care if the initial response is good. The key principle is that the GP is provided with information and given the opportunity to accept (or decline) prescribing responsibility before the transfer occurs.

2.0 Licensed Indications and Dose

Dornase alfa is licensed for patients with cystic fibrosis who have a forced vital capacity of greater than 40% predicted and over 5years in order to improve lung function. In children (from 5years) and adults the dose is 2.5mg nebulised once daily. Dornase alfa should not be mixed with any other drugs.

3.0 Referral Criteria

Consultants will consider dornase alfa nebuliser solution for any patient with cystic fibrosis who is older than 5years and has deteriorating lung function.

4.0 Patient Selection

Patients will be selected on the basis of their pulmonary function and ability to use a nebuliser system.

5.0 Safety Issues

5.1 Contra-indications (see BNF or SPC)

- Hypersensitivity to an active ingredient or excipient.

5.2 Cautions (see BNF or SPC)

- Pregnancy.

5.3 Common Side Effects (See BNF or SPC)

- Pharyngitis
- Voice alteration
- Chest pain

5.4 Drug Interactions (see BNF or SPC)

- No known interactions.
- Do not mix with any other nebulised drugs.

5.5 Pre-treatment Assessment

- Patient should be taught how to use the nebuliser and compressor system.
- Patient should be given relevant information and advice.

5.6 Assessment of therapeutic trial

- Each patient will receive a 3 month trial of therapy
- At the end of each month the patient will undergo pulmonary function testing
- Approximately 10% of patients will show a reduction in lung function, any patient with decreased FEV₁ will not continue with therapy.
- Patients with stabilisation or improving lung function and good tolerance will continue therapy.

6.0 Role of Consultant

The decision to use dornase alfa nebuliser solution will be made by a consultant specialising in CF.

1. To assess the suitability of the patient for dornase alfa nebuliser solution.
2. To discuss relevant safety issues with patients, and to make them aware of cautions or side effects.
3. Supervision of first dose with evaluation for the development of bronchospasm.
4. To ask the GP in writing whether they are willing to participate in shared care, this should include a copy of the shared care guideline. This correspondence should occur prior to initiating treatment.
5. To initiate therapy and prescribe the therapeutic trial.
6. Prompt communication in writing with the GP of any changes in treatment and assessment of response and occurrence of adverse effects.
7. To assess response to treatment by lung function testing and quality of life scoring.
8. Advice on when to stop treatment.

7.0 Role of GP

1. To reply to the consultant accepting shared care if appropriate following a 3 month therapeutic trial.
2. To ensure all other practice staff are aware of the shared care guideline.
3. Prescribing of dornase alfa nebuliser solution once informed by the specialist that the patient has responded and is tolerating treatment.
4. To write the prescription in accordance with this shared care guideline.
5. Report adverse events to CF specialist and Medicines and Healthcare products Regulatory Agency.
6. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.

8.0 Role of Patient or Parent

1. Report any adverse effects to the GP whilst taking dornase alfa.
2. Ensure they have a clear understanding of their treatment.

3. Ensure correct storage and administration of the nebuliser solution.

9.0 Role of the Specialist Physiotherapist

1. To make sure all patients have an appropriate nebuliser system.
2. To administer the test dose of dornase alfa nebuliser solution.
3. To monitor lung function pre and post dose.

10.0 Further Information

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