

**Cardiff & Vale (C&V) UHB Corporate Medicines Management Group (c MMG)
SHARED CARE**

Drug: DORNASE ALFA

Protocol number: CV 38

Indication: Cystic fibrosis

General guidance

This protocol sets out details for the shared care of patients taking **Dornase alfa** and should be read in conjunction with the General Guidelines for Shared Care . Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribed the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

Dornase alfa is indicated in the management of cystic fibrosis patients with poor lung function and over 5 years of age to improve pulmonary function and/or aid sputum expectoration. It has been shown in placebo controlled trials in the United Kingdom to improve lung function over a 12 month period by > 7% and improvements of up to 25% in FEV₁ may be obtained ¹. In the responders there is a reduction in antibiotic usage of the intravenous and oral type, reduction in hospitalisation and improvement of well-being and body weight ².

Patients will be assessed for suitability of treatment using an agreed assessment protocol after one month of treatment. GPs will be asked to prescribe after the first month of treatment. Patients will be assessed at the hospital and treatment stopped if no response is observed.

Responsibilities

A. Consultant responsibilities

1. When treatment is **initiated** send Shared Care request form with Shared Care Protocol to GP.
2. Determine when initiation of treatment with dornase alfa is appropriate.
3. When a GP positive response to SC has been received and patient has been stabilised send a letter to GP "handing over" the Shared Care of the patient to the GP.
4. Discuss with patient the potential benefits and side effects, possible drug interactions, and the correct storage and administration of dornase alfa.
5. Co-ordinate the supply of a nebuliser and compressor to the patient.
6. Initiate treatment by providing four weeks supply of dornase alfa.
7. Complete baseline monitoring of FVC and forced expiratory volume in 1 second (FEV₁).
8. Monitor FVC and FEV₁ after four weeks. Stop treatment if no benefit seen.
9. Regular assessment of lung function & clinical effects of treatment at three monthly

¹ References - Shah P.L et al. Respiratory Medicine 1995, 89 : 499-502

² - Fuchs H J et al. New England Journal Medicine 1994, 331 : 637-642

intervals.

10. Respond to any request from GP to review the patient due to adverse effects of therapy.
11. Advise the GP on continuing or stopping dornase alfa therapy, following any medical review of the patient and associated drug therapy.
12. Ensure clear arrangements in place for prompt back up advice and support.
13. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

B. General practitioner responsibilities

1. Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Prescribe dornase alfa as part of the shared care agreement.
3. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
4. Inform the specialist centre of significant illness, life events or potential non-compliance.
5. Monitor the general health of the patient.
6. Stop treatment on advice of specialist.
7. To act on advice provided by Consultant if patient does not attend for appropriate monitoring.

C. Patient responsibilities

1. Consent to treatment with dornase alfa.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst taking dornase alfa.

Dosage Regimen

The recommended dose of dornase alfa is 2.5mg (one ampoule) nebulised undiluted once daily. Some patients may be prescribed 2.5mg on alternate days.

Some patients over the age of 21 may benefit from twice daily dosage. If appropriate this will be decided by the consultant and communicated to the GP.

Monitoring

FVC, FEV₁ and oximetry prior to treatment.

FVC, FEV₁ and clinical assessment at 4 weeks and then every three months.

Adverse effects

Adverse effects attributed to dornase alfa are rare. The following have been reported:

Respiratory system: voice alteration (hoarseness), pharyngitis, dyspnoea, laryngitis and rhinitis. Upon initiation of therapy, there may be a transient decline in pulmonary function and expectoration of sputum may increase.

Other adverse effects: chest pain (pleuritic/non-cardiac), fever, conjunctivitis, dyspepsia, rash and urticaria (usually mild and transient).

For a full list of potential adverse effects please consult the SPC for dornase alfa (Pulmozyme) and see attached.

Interactions

There are no known interactions. Dornase alfa should not be mixed with other drugs or solutions in the nebuliser.

Special recommendations

The safety of dornase alfa has not been established in pregnant women. Animal studies have shown no evidence of impaired fertility, teratogenicity or developmental effects. Advising patients in pregnancy is the responsibility of the consultant.

It is not known whether dornase alfa is excreted in human milk. Advising patients who are breast feeding is the responsibility of the consultant.

Date of review April 2020