

Prescribing and Medicines Optimisation Guidance

Issue: 44

Date: 21st April 2021

1. MHRA COVID-19 Therapeutic Alert - Inhaled Budesonide for Adults (50 Years and over) with COVID-19. [\(Link\)](#)

The recent announcement of the interim results from the National Institute for Health Research (NIHR) supported PRINCIPLE trial shows that inhaled budesonide (typically used and licensed in the management of asthma) can reduce the recovery time for COVID-19 positive patients being managed within primary care. This is the first COVID-19 treatment for use in the UK within a community setting.

Inhaled budesonide can be considered (off-label) on a case-by-case basis for symptomatic COVID-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities, in line with the published Interim Position Statement.

The interim results from PRINCIPLE build on the findings of the STOIC trial Phase II study on inhaled budesonide. This study suggests that early administration of inhaled budesonide reduces the likelihood of needing urgent medical care and reduces time to recovery following early COVID-19 infection.

The PRINCIPLE trial used inhaled budesonide (Pulmicort Turbohaler® 400 micrograms), 800 micrograms twice daily for up to 14 days or until all doses of the inhaler are used (whichever comes first). Supplementary information for patients on the use of a budesonide inhaler is available here. [\(Link\)](#)

Key messages from PRINCIPLE trial are:

- The trial included people in the community with COVID-19 at higher risk of complications from COVID-19 who are either 65 years or over or 50-64 years with comorbidities.
- Time to first self-reported recovery was shorter in the budesonide group (n=751) compared to usual care (n=1028) with an estimated median benefit of 3 days in patients with a positive SARS-CoV-2 test.
- There was no statistically significant improvement in COVID-19-related hospitalisation or deaths within 28 days of follow-up.
- There was benefit in self-reported early sustained recovery at 28 days.
- 79.7% of participants randomised to budesonide reported taking budesonide for at least 7 days.
- Results from the STOIC trial have been published, reporting a benefit from using inhaled budesonide in the community for people with COVID-19 within a smaller phase 2 trial

This alert is an Interim Position Statement based on pre-publication evidence. Further data from the PRINCIPLE trial is expected when the full cohort of patients completes their 28-day follow-up period.

As further evidence is released guidance will be published for the use of budesonide in COVID-19 positive patients being managed within primary care.

2. Enoxaparin biosimilar (Inhixa) – Always prescribe and dispense by brand

Enoxaparin is a biological medicine and therefore must always be prescribed and dispensed by brand. (See NICE: Biosimilar medicines ([link](#)))

Inhixa is the preferred brand of enoxaparin prescribed in Basingstoke, Southampton, Winchester and Portsmouth hospitals. A local factsheet is available with prescribing and administration advice. ([link](#))

Care should be taken to avoid automatic substitution at point of prescribing, dispensing or administering. Any pharmacy receiving a generic prescription for enoxaparin should take necessary steps to try and confirm the brand required before dispensing. Administration techniques also differ across the available brands.

3. Dementia and Older People’s Mental Health: Guidance for Primary Care Networks and Care Homes. March 2021 ([Link](#))

This document has been produced by NHS South East and aims to equip staff working in care homes and primary care, with understanding of dementia and mental health conditions. It includes structured medication review information as approved by NICE to optimise medication use.

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Previous bulletins can be found at:

<https://gp-portal.westhampshireccg.nhs.uk/medicines/covid-19-medicines-information/covid-19-medicines-optimisation-bulletins/>

For COVID-19 vaccine related updates, please refer to the regular NHSE&I Primary Care Bulletins.
Please click on this link to subscribe ([Link](#))

