

From the Chief Medical Officer  
Dr Michael McBride



Department of  
**Health**

An Roinn Sláinte

Mánnystrie O Poustie

[www.health-ni.gov.uk](http://www.health-ni.gov.uk)

**HSS(MD) 29/2021**

**FOR ACTION**

Chief Executives HSC Trusts (*for onward cascade to all staff involved in the management of COVID-19 patients*)

Chief Executive, Public Health Agency and Health and Social Care Board (*for onward cascade as appropriate*)

Assistant Director of Integrated Care, Head of General Medical Services, Health and Social Care Board (*for onward cascade to all General Practitioners, GP Locums and Practice Staff*)

OOHs Medical Managers

Assistant Director of Integrated Care, Head of Pharmacy and Medicines Management, Health and Social Care Board (*for onward cascade to Community Pharmacies*)

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Our Ref: HSS(MD) 29/2021

Date: 13 April 2021

**PLEASE SEE ATTACHED FULL CIRCULATION LIST**

Dear Colleague

**COVID-19 THERAPEUTIC ALERT – INHALED BUDESONIDE FOR ADULTS (50 YEARS AND OVER) WITH COVID-19**

**Recommendation**

Inhaled budesonide is not currently being recommended as standard of care but 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](#).

**ACTION REQUIRED**

Prescribers are asked to:

- Consider prescribing inhaled budesonide (off-label, on a case-by-case basis) for symptomatic COVID-19 positive patients in line with the published [Interim Position Statement](#) via a HS21 prescription or equivalent, where supply allows. Prescribers will be advised if there are any national supply restrictions.
- Note that the recommended product is the Pulmicort 400 Turbohaler (AstraZeneca UK Ltd), studied within the PRINCIPLE and STOIC trials. A single inhaler should be used for a maximum of 14 days (or until the inhaler is used up, if sooner) with two doses, twice

a day (a total daily dose of 1,600 micrograms). Please see the Supply section below for details of alternative products.

- Note that supplementary information for patients is available [here](#), including links to [video resources](#).
- Report any suspected adverse drug reactions (ADRs) for patients receiving budesonide to the MHRA via the Yellow Card reporting site at: <https://yellowcard.mhra.gov.uk/>

**Community pharmacies and dispensing practices** are asked to:

- Use business as usual routes to order supplies of inhaled budesonide from wholesalers, maintaining stock levels to meet both routine use (i.e. the management of asthma) and prevailing demand for therapeutic use in the management of COVID-19. Pharmacies will be advised if there are any national supply restrictions.
- Ensure patients (or their representatives) are aware of how the inhaler should be used and signpost them to additional support. Supplementary information for patients is available [here](#) and includes links to [video resources](#).
- Report any suspected adverse drug reactions (ADRs) for patients receiving budesonide to the MHRA via the Yellow Card reporting site at: <https://yellowcard.mhra.gov.uk/>

## **Supporting evidence**

After completing an interim analysis, the PRINCIPLE trial has [reported](#) that **inhaled budesonide (800 micrograms taken twice daily, for up to 14 days) can reduce recovery time by a median of 3 days in symptomatic COVID-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities. A benefit in self-reported early sustained recovery at 28 days was also identified.**

The analysis has not established whether budesonide can reduce hospital admissions or reduce mortality.

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.

## **Eligibility**

In summary, potentially eligible patients will:

- Have COVID-19 symptoms, with symptom onset within the last 14 days, AND
- Be COVID-19 positive, confirmed by a recent polymerase chain reaction (PCR) test, AND
- Be aged 65 or over, or aged 50 or over with one or more co-morbidities consistent with the long-term conditions referenced in the [flu vaccine](#) list

Please see the published [Interim Position Statement](#) for more details on the specific inclusion and exclusion criteria.

## **Supply**

Additional supplies of the Pulmicort 400 Turbohaler (AstraZeneca UK Ltd) are now available to be ordered through business as usual routes from wholesalers.

In the case of limited supplies, the following alternatives may be considered in the order of preference set out below (noting that additional guidance may need to be provided to help patients to achieve the correct total daily dose of 1,600mcg):

- Lower dose strength Pulmicort Turbohaler (200 micrograms) (100 doses per inhaler)
- Budelin Novolizer 200 micrograms per actuation inhalation powder (Mylan) (100 doses per inhaler)
- Easyhaler Budesonide 400micrograms / dose dry powder inhaler (Orion Pharma (UK) Ltd) (100 doses per inhaler)
- Easyhaler Budesonide 200micrograms / dose dry powder inhaler (Orion Pharma (UK) Ltd) (200 doses per inhaler)

## **Product details**

The Interim Position Statement has been informed by the PRINCIPLE trial protocol and the Summary of Product Characteristics ([SmPC](#)) for inhaled budesonide.

Inhaled budesonide has a local anti-inflammatory effect and is used in the treatment of asthma.

The use of inhaled budesonide in the management of COVID-19 under the published Interim Position Statement is off-label, which should be explained to the patient as part of shared decision making. Further guidance on the prescribing of off-label medicines can be found below:

<https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>

Further enquiries from general practice or community pharmacy should in the first instance be directed to the local Health and Social Care Board (HSCB) office.

Yours sincerely



**DR MICHAEL McBRIDE**  
Chief Medical Officer



**MRS CATHY HARRISON**  
Chief Pharmaceutical Officer

## **Circulation List**

Director of Public Health/Medical Director, Public Health Agency (for onward distribution to all relevant health protection staff)

