

T: 0131-244 2528 0131-244 2375  
E: irene.fazakerley@scotland.gsi.gov.uk  
9 March 2011

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

Dear Healthcare Professional,

**DRUG ALERT NO 5 – CLASS 4**

Please find attached revised drug safety information from the Medicines and Healthcare products Regulatory agency (MHRA) for onward transmission (see list below)

1. Please could all Directors of Pharmacy forward this alert to:-
  - Community Pharmacists
  - Hospital Pharmacists
  - Chief Pharmacists to forward on to Medicines Information Pharmacists
2. Please could Medical Directors forward this alert to:-
  - General Practitioners
  - Relevant Clinics
  - Chief Executives of NHS Boards

Thank you for your co-operation.

Yours sincerely

**IRENE FAZAKERLEY**  
Pharmacy Division

Safeguarding public health  
Defective Medicines Report Centre  
151 Buckingham Palace Road  
London  
SW1W 9SZ  
Telephone +44 (0)20 3080 6574

**MHRA**

## **DRUG ALERT**

### **CLASS 4 MEDICINES DISCONTINUATION INFORMATION**

**For prompt distribution in normal working hours**

Date: 9 March 2011

EL (11)A/05

Our Ref: MDR 04-02/11

Dear Healthcare Professional,

#### **AstraZeneca UK Ltd**

<b>Pulmicort CFC-free Inhaler 100 &amp; 200 micrograms and NebuChamber Spacer</b>	<b>PL 17901/0247 &amp; PL 17901/0246</b>
<b>Budesonide</b>	

AstraZeneca UK Ltd has discontinued production of the above products with immediate effect due to complex manufacturing issues. The NebuChamber spacer is only licensed for use with these two inhaler presentations. This issue does not apply to any other AstraZeneca inhalers or components which will remain in normal supply and use.

Patients can continue using PULMICORT CFC-free Inhaler 100 & 200 micrograms until their current supply is finished. At that time, patients should be changed to an appropriate alternative inhaled corticosteroid treatment for their specific medical condition.

Guidance on equipotent doses of alternative inhaled corticosteroids can be found in the BTS/SIGN British Guideline on the management of asthma:-

<http://www.brit-thoracic.org.uk/Portals/0/Clinical%20Information/Asthma/Guidelines/sign101%20revised%20June%2009.pdf>

Contd/.....

#### **MHRA Distribution:**

Regional Contacts for NHS Trusts and Provider Units  
Chief Pharmacists: England, Scotland, Wales, Northern Ireland  
Prison Health Policy Unit (DH)  
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar  
Special Hospitals  
Healthcare Commission for distribution to Independent Health Care Establishments  
Primary Care Trusts (England)

**Medicines and Healthcare products Regulatory Agency (MHRA)**  
151 Buckingham Palace Road London SW1W 9SZ UK  
T 020 3080 6000 [www.mhra.gov.uk](http://www.mhra.gov.uk)

An executive agency of the Department of Health

Date: 9 March 2011

EL (11)A/05

Our Ref: MDR 04-02/11

AstraZeneca have advised us that the following medicines contain Budesonide for inhalation and may provide suitable alternative treatments for these patients, in accordance with approved labelling:-

Budesonide Alternatives	Manufacturer
Pulmicort Turbohaler (100, 200 and 400mcg) A dry powder inhaler	AstraZeneca Pharmaceuticals
Easyhaler Budesonide (100, 200 and 400mcg) A breath-actuated device (dry powder)	Orion Pharmaceuticals
Novolizer Budesonide 200 mcg Inhalation Powder A cartridge device that is breath-actuated	Meda Pharmaceuticals

**Please note - none of these alternatives are licensed for use in children under 5 years**

Please note that alternative inhaled corticosteroid medicines may require different inhalation techniques for correct dose delivery compared to PULMICORT CFC-free inhaler and patients may require advice on correct usage and may need assessment on their ability to use the device. It should also be noted, that some formulations contain lactose and should not be used in at-risk patients.

Patients who are prescribed a suitable alternative medicine or device should be monitored frequently in the normal way for the emergence or worsening of symptoms, or adverse events.

For other information regarding the product, please call AstraZeneca Medical Information on 0800 783 0033 or email at: [medical.informationUK@astrazeneca.com](mailto:medical.informationUK@astrazeneca.com)

If you have any questions relating to the supply of this product, please call AstraZeneca Supply Chain Team on 0800 032 0501 or email at: [supply.chain@astrazeneca.com](mailto:supply.chain@astrazeneca.com)

Recipients of this Drug Alert are requested to bring it to the attention of relevant professionals by copy of this letter. Primary Care Trusts are asked to forward this information to General Practitioners, Community Pharmacists and relevant clinics by copy of this letter.

Yours faithfully  
Ian Holloway  
MHRA DMRC Manager