

T: 0131-244 2528 0131-244 2375
E: irene.fazakerley@scotland.gsi.gov.uk
23 November 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 29 & 30 – CLASS 2

Please see the attached drug alert for onward transmission as below.
Please could all Directors of Pharmacy forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

1. Please could Medical Directors forward this alert to:-

- Oncology Departments
- Accident & Emergency Departments
- General Practitioners
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines 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 2 DRUG RECALL TO HOSPITALS, CLINICS AND WHOLESALERS
FOR ACTION WITHIN 48 HOURS**

Date: 23 November 2011

EL (11)A/29

Our Ref: MDR 33-11/11

Dear Healthcare Professional,

JANSSEN-CILAG Ltd

**Velcade 3.5mg powder for solution for injection
(Bortezomib)**

EU/1/04/274/001

Batch Number	Expiry Date	Pack Size	First Distributed
9AZSY00	Dec 2011	1 x 3.5 mg	08.10.2009
9CZTF00	Feb 2012	1 x 3.5 mg	07.12.2009
AGZSH00	June 2013	1 x 3.5 mg	05.01.2011
AGZSH01	June 2013	1 x 3.5 mg	19.01.2011
AIZTY00	Aug 2013	1 x 3.5 mg	14.01.2011
AIZTY01	Aug 2013	1 x 3.5 mg	01.03.2011
BAZS100	Dec 2013	1 x 3.5 mg	18.04.2011
BAZS101	Dec 2013	1 x 3.5 mg	13.05.2011

Janssen-Cilag Ltd is recalling all remaining stock of the above batches due to concerns that acceptable levels of sterility assurance during manufacture cannot be guaranteed. Serious GMP concerns were raised during an inspection of the contract manufacturing site for this product.

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

An executive agency of the Department of Health

Date: 23 November 2011

EL (11)A/29

Our Ref: MDR 33-11/11

Please note that only the batches listed above are being recalled. More recent batches have been sourced from alternative manufacturing sites and there are currently no concerns for the sterility assurance of later batches.

Any remaining stock of the batches listed above should be quarantined. Janssen-Cilag Ltd will be contacting direct customers with instructions for return and replacement/credit. For stock enquiries please telephone 0800 333 001.

Recipients are requested to report any suspected side effects associated with this product to the Yellow Card scheme. Reports can be made via <http://yellowcard.mhra.gov.uk/>

For medical information enquiries, please contact the UK office of Janssen Cilag on 0800 0323013.

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 relevant clinics by copy of this letter.

Yours faithfully

Ian Holloway

MHRA DMRC Manager