

Safeguarding public health
Defective Medicines Report Centre
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MHRA

DRUG ALERT
CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 21 Mar 2012

EL (12)A/13

Our Ref: MDR 46-02/12

Dear Healthcare Professional,

Novartis Vaccines and Diagnostics GmbH

Rabipur

PL 16033/0008

(Rabies vaccine, inactivated)

Potential issue with syringes included with listed batches.

Batch Number	Expiry Date	Pack Size	First Distributed
490011C	30 Apr 2015	1 Dose	12 Oct 2011
493011A	31 May 2015	1 Dose	22 Dec 2011

Novartis Vaccines has informed us that there is a potential problem with the packaging of the syringes supplied with the above batches. The outer packaging of some of the individually packed syringes associated with a different batch of Rabipur, but which used the same syringe batch, was found to be discoloured and there was mould present in some cases. No samples from the above listed batches have been found to be affected.

The risk of any syringes provided with batches 490011C and 493011A being affected is considered by the company to be very low. As a precaution, however, healthcare professionals are requested to inspect the outer packaging of these syringes for signs of a yellow discolouration or mould. If no issues are identified by the inspection, the syringes may be used as normal. If discolouration or mould is identified, the affected syringes should be discarded and replaced with commercially available syringes with the same specification, i.e. a 2ml luer cone with 0.6x30mm needle. If this needle is not available, the product can be injected using a needle of a size to suit the patient.

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)
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An executive agency of the Department of Health

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A new batch of unaffected Rabipur is expected to be available for distribution during week commencing 09 April 2012. If you have any questions regarding this information, please contact Novartis Vaccines Customer Services on 08457 451500

The quality of the vaccine and the diluent is not affected by this issue and the risk of an adverse reaction occurring in an individual who has received Rabipur from a potentially affected syringe is considered by the company to be very low. The company also considers the probability of decreased effectiveness of the vaccine as a result of this issue to be low, therefore re-vaccination of individuals previously vaccinated with Rabipur from the batches mentioned above is not being recommended.

For medical information enquiries, please contact Novartis Vaccines on 01748 828816

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to general practitioners, community pharmacists and relevant clinics.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC