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Direct Healthcare Professional Communication

selenase® (sodium selenite pentahydrate) 100 micrograms, oral solution, and selenase® (sodium selenite pentahydrate) 100 micrograms, solution for injection: similarity of oral and parenteral preparations; risk of dispensing errors

Dear Healthcare Professional,
biosyn Arzneimittel GmbH, Germany, and Baxter Healthcare Ltd., UK, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), wish to inform you of the following:

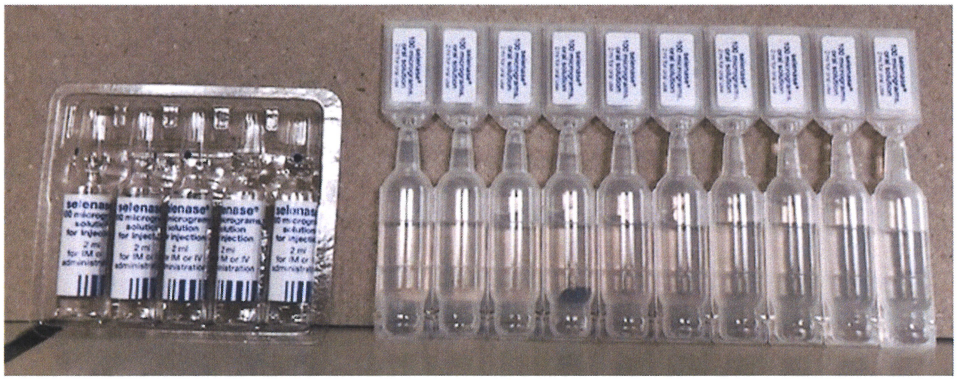
Summary

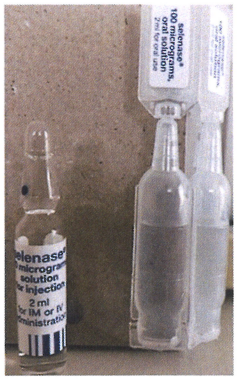
- A report has been received of a dispensing error that led to selenase® 100 micrograms, oral solution, being given intravenously to a patient.
- The oral solution is presented in a plastic ampoule with a twist-off flap containing the label. The solution for injection is presented in a glass ampoule with an open point cut (see pictures below).
- Care should be taken during the dispensing and administration of these medicines, in order to avoid inadvertent administration of the wrong dosage form to the patient.
- Changes to the product packaging will be made to allow better differentiation between the two products and be submitted in April 2019 for approval by the MHRA. However, batches of products containing the revised packaging may not be available until early 2020.

Further information on the safety concern

selenase® is indicated for the treatment of proven selenium deficiency that cannot be compensated by nutrition alone.

We have received a spontaneous report of a medication error that led to the solution for oral application being given intravenously. This has been attributed to the similarity in packaging between the oral and injectable preparations, the presentation of the oral solution in ampoules and the fact that the product information for the oral solution is on the part of the ampoule that is torn off when opened.





The first picture shows a blister with glass ampoules of the solution for injection on the left and a strip of ampoules of the oral solution on the right. The second picture shows a single glass ampoule of the solution for injection alongside plastic ampoules of the oral solution.

After opening the plastic ampoule containing the oral solution, the flap containing the label should not be discarded. Healthcare professionals should adhere to local guidelines concerning the safe administration of medicines.

Benefit-risk-evaluation

With regard to the product quality and potential patient risks, it can be stated that the manufacturing steps of selenase® 100 micrograms, oral solution (50 micrograms/ml), and selenase® 100 micrograms, solution for injection (50 micrograms/ml), both comply with the European Guidelines on Good Manufacturing Practice in the manufacture of sterile medicinal products. The products are tested for sterility according to the European Pharmacopoeia. The risk of an adverse event occurring in the patient as a result of inadvertent administration of the wrong dosage form is therefore considered negligible. The positive benefit-risk ratio remains unchanged.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789

or

- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Adverse reactions relating to selenase® 100 micrograms, oral solution, and selenase® 100 micrograms, solution for injection, including medication errors can also be reported to Baxter Healthcare Ltd. 01635 206360 or http://baxterhealthcare.co.uk/contact-and-support/pharmacovigilance.page .

Outside the UK, reports can be submitted to pharmacovigilance@biosyn.de or by contacting biosyn pharmacovigilance department +49 711 57532211.

Communication information

Further information can be obtained from Baxter medical information on 01635 206345 or email medinfo_uki@baxter.com; or contacting biosyn pharmacovigilance department directly on pharmacovigilance@biosyn.de or +49 711 57532211.

Kind regards,

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