17 September 2020

Direct Healthcare Professional Communication (DHPC)

Sandostatin® LAR® (octreotide) 30mg powder and solvent for suspension for injection: Incorrect dosage information on one side of carton

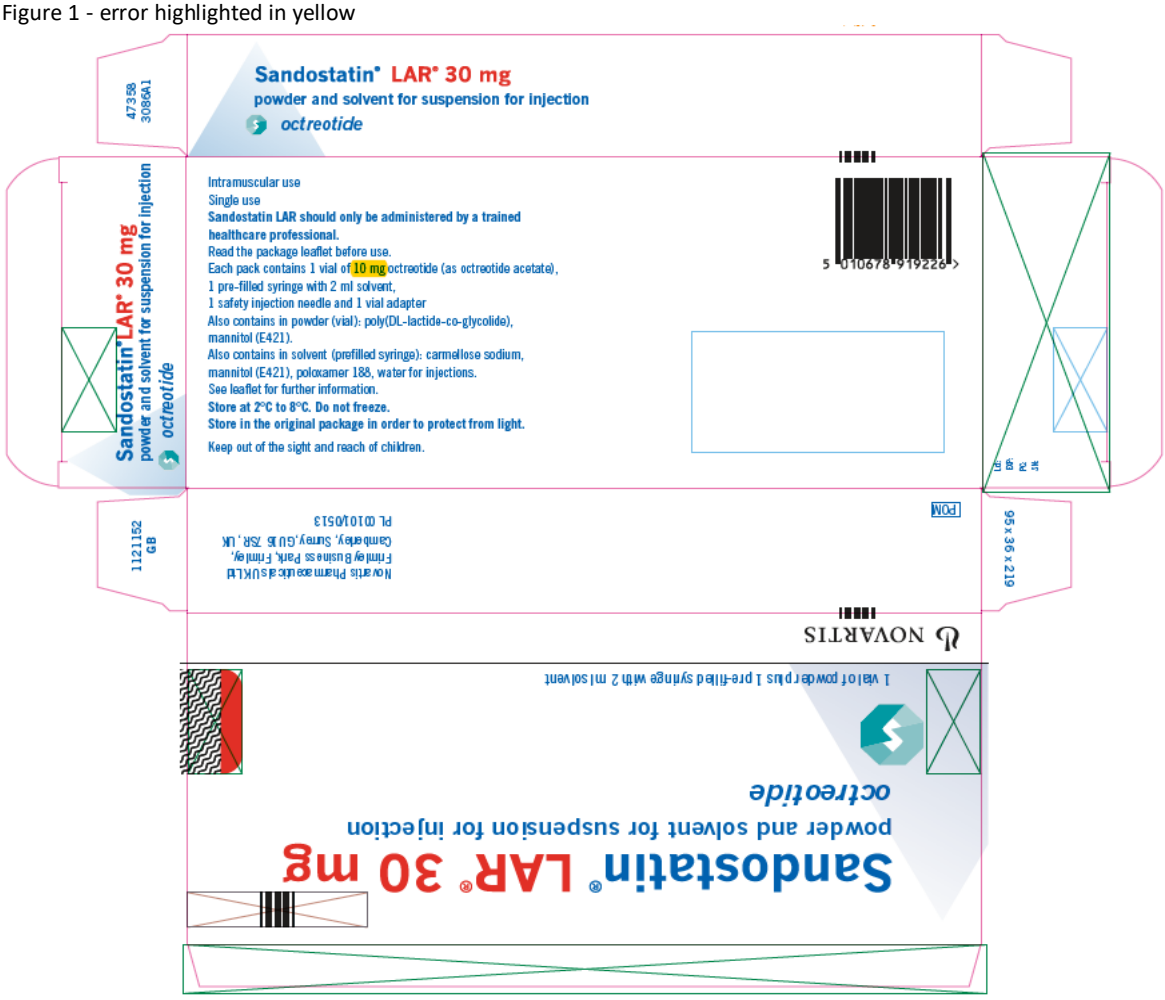
Dear Healthcare Professional,

Novartis Pharmaceuticals in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- For the listed batches of Sandostatin LAR 30mg, one side of the folding box reports an incorrect dosage form (10mg instead of 30mg) (see figure 1 below)
- The drug name and dosage form on other three of the sides of the folded box (30mg – in red) and on the vial is correct. Therefore, Novartis Pharmaceuticals is not recalling these batches and they can be used as normal.
- Please check both the packaging and the vial label for the correct dose when preparing Sandostatin LAR 30mg suspension prior to administration to the patient. The product should be administered to the patient by a trained health care professional and is not for self-medication. An evaluation of benefit-risk with a decision on administration should be made on a case-by-case basis.

Figure 1 - error highlighted in yellow



The following batches have been packaged with artwork containing the error.

Table 1 - Affected product batch numbers

Batch Number	Expiry Date
361843	Dec 2022
362202	Feb 2023
362203	Feb 2023
362311	Mar 2023
362299	Mar 2023

A corrective action has been initiated to update the carton labelling for all future batches of Sandostatin LAR 30mg. Sandostatin LAR 10mg and 20mg have not been affected by the printing error.

Please ensure that a copy of this letter is shared with all relevant departments within your institutions to ensure that staff are aware.

Therapeutic indication
Sandostatin LAR 30mg is indicated for treatment of acromegaly (where surgery is inappropriate or ineffective, or until radiotherapy becomes fully effective), symptoms associated with functional gastro-entero-pancreatic endocrine tumours, advanced neuroendocrine tumours of the midgut or of unknown primary origin where non-midgut sites of origin have been excluded, and treatment of TSH-secreting pituitary adenomas (when secretion has not normalised after surgery and/or radiotherapy; in patients in whom surgery is inappropriate; or in irradiated patients, until radiotherapy is effective).

Call for reporting
Please report suspected adverse reactions to this medicine to the MHRA through the Yellow Card scheme website www.mhra.gov.uk/yellowcard, search for MHRA Yellow Card in the Google Play or Apple App Store, or via some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

If there is no online access to report a suspected side effect to the Yellow Card Scheme, call 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

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 events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the patient safety information (PSI) tool at www.report.novartis.com.

Company contact points
If you have any questions or require further information, please contact Novartis Medical Information department on 01276 698370 or email medinfo.uk@novartis.com.

We apologise for any inconvenience this may cause you and your staff.

Sincerely,

Moses Heather

Digitally signed by Moses Heather
DN: dc=com, dc=novartis, ou=people, ou=PH, serialNumber=2460759, cn=Moses Heather
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