20th April 2017

Ammonaps (sodium phenylbutyrate) tablets and granules should only be used when there is no alternative treatment

Dear Healthcare Professional,

Swedish Orphan Biovitrum International AB (Sobi), in agreement with the European Medicines Agency and the Maltese Medicines Authority, would like to inform you of the following:

Summary

- The manufacturing site of Ammonaps (sodium phenylbutyrate) was found to have several shortcomings in relation to good manufacturing practice (GMP). There is no indication of risk to patients and corrective measures are being taken to address the shortcomings.
- While the measures are being implemented, Ammonaps tablets and granules should, as a precaution, now only be used in patients when other sodium or glycerol phenylbutyrate-containing medicines cannot be used instead.
- If the alternative phenylbutyrate medicine is not suitable for patients with nasogastric tube or gastrostomy, Ammonaps granules can continue to be used in these patients.

Further information on the recommendations

The recommendations result from a review into shortcomings of manufacturing practice at Pharmaceutics International Inc. These relate to risk of cross-contamination between medicines manufactured at the same site, and deficiencies in the systems for maintaining quality assurance.
The recommendations are precautionary; to date no evidence of a specific adverse effect resulting from the GMP issues has been identified.

The Medicines Agency considers that Ammonaps granules and tablets are critical for the patients since no alternative medicine is available. Therefore, in Malta, Ammonaps granules and tablets will be available.

Further information on the review can be accessed at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Pharmaceutics_International/human_referral_000406.jsp&mid=WC0b01ac05805c516f

Further information on Ammonaps
Ammonaps (sodium phenylbutyrate) is indicated for use as adjunctive therapy in the chronic management of urea cycle disorders, involving deficiency of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.

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It is indicated in all patients with *neonatal-onset* presentation of urea cycle disorder (complete enzyme deficiencies, presenting within the first 28 days of life). It is also indicated in patients with *late-onset* disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonaemic encephalopathy.

Ammonaps is available in Malta as tablets and granules.

Call for reporting

You are reminded of the need to report any adverse reactions with the national spontaneous reporting system:

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

Company contact point

Company contact point in your country is Dr. Gema Alvarez Nieto, telephone number +39 366 7765147. You can also send an email to medical.information.it@sobi.com. Our web site is www.sobi.com.

Annexes

There are no Annexes.
Product Information has not been revised

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