Azurity Pharmaceuticals, Inc. Introduces the Nymalize® (nimodipine) oral solution Prefilled ENFit® Syringe

Azurity® Pharmaceuticals, Inc. has embraced the ENFit® standard with its introduction of the Nymalize® (nimodipine) oral solution in a Prefilled 30 mg/5 mL ENFit® Syringe. NYMALIZE is indicated for the improvement of neurological outcomes by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e., Hunt and Hess Grades I-V).[1]

What is ENFit®?

ENFit® represents a significant advancement in enteral feeding systems and patient safety. Designed to prevent medical tubing misconnections, it features standardized connectors for feeding tubes and enteral syringes. By ensuring that only enteral devices can connect to each other, ENFit® is designed to reduce the risk of accidental connections with intravenous or Luer connectors, ultimately enhancing drug administration safety.[2-4] In 2014, the Joint Commission, Food and Drug Administration (FDA), and Global Enteral Device Supplier Association (GEDSA) recommended that all hospitals transition from legacy enteral connectors to an ENFit® system to reduce the rate of misconnections and to improve patient outcomes.[5]

A prior concern regarding the previous Nymalize® oral syringe formulation packaging was how the drug would be administered to patients with feeding tubes lacking connection compatibility, as not all feeding tubes easily accommodate an oral syringe. With the mandate for hospitals to convert to ENFit® tubing, alongside the GEDSA announcement that member manufacturers will begin phasing out the manufacturing of legacy feeding tubes, administration sets, and transition adapters over the next year, it was evident that the nimodipine oral syringe would need to be repackaged for compatibility with ENFit®. The now-available Nymalize® (nimodipine) oral solution in a Prefilled 30 mg/5 mL ENFit® Syringe addresses this concern and is now compatible within the majority of US hospitals that have adopted the safer ENFit® system.

New Nymalize Packaging Configuration

The introduction of Nymalize® (nimodipine) oral solution in a Prefilled 30 mg/5 mL ENFit® Syringe is designed to mitigate the challenges previously associated with medication delivery, enhancing both accurate and safe administration. The updated Nymalize syringes are now compatible with ENFit® connectors, designed to significantly reduce the risk of misconnections.[2-4] This compatibility feature provides a secure connection to ENFit® tubing, addressing concerns over the potential for incompatible connectors or accidental disconnections during enteral administration.[2-3]

The Institute for Safe Medication Practices (ISMP) and GEDSA recognize these improvements as significant strides towards safer medication administration practices and encourages healthcare providers to note these changes in their protocols. With ENFit® now defined as the global standard,

Azurity remains committed to providing updates and supporting a seamless transition for all institutions and patients.[6,7]

Errors with Nimodipine Gel Capsules

Before Nymalize was formulated and approved by FDA, nimodipine was only available in liquid-filled gel capsules. Dosing and administration errors occasionally occurred when the drug was withdrawn from these capsules using a parenteral syringe and needle for oral or feeding tube administration. Additionally, the drug withdrawn from the gel capsules was sometimes mistakenly administered intravenously (IV), which can cause profound hypotension and, in some cases, fatalities.[7,8] Because of these issues, ISMP has advocated for the use of nimodipine oral solution since its introduction.

2020 Nymalize® Formulation Enhancement

In 2020, Arbor Pharmaceuticals LLC, a subsidiary of Azurity Pharmaceuticals, Inc., announced several changes for Nymalize®. First, the company changed the concentration from 3 mg per mL to 6 mg per mL to provide a higher concentration per dose to enable a reduction in the total liquid volume. Furthermore, as part of the reformulation, a safety enhancement was introduced by reducing the polyethylene glycol content per dose thereby aiming to improve GI tolerability. Finally, the company had concerns with having two different concentrations as the new, higher concentration, would require half the volume to reach the equivalent Nymalize® dose; having two different dose strengths could come with increased risk for patients either being under-dosed (with half the volume of a 3 mg/mL concentration) or over-dosed (with double the volume of the 6 mg/mL formulation). As a result, the lower concentration oral solution (3 mg/mL) was removed from the market.

Conclusion

The introduction of Nymalize® (nimodipine) oral solution in a Prefilled 30 mg/5 mL ENFit® Syringe represents a significant advancement for enteral feeding system administration of nimodipine in the treatment of subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms. This new formulation is now offered as the only ready to use nimodipine formulation that enables adherence by institutions to the Joint Commission, ISMP, FDA, and GEDSA recommendation that all hospitals utilize an ENFit® system to reduce the rate of misconnections and to improve patient outcomes.[5]

For important safety information and full prescribing information, please visit www.nymalize.com.

References:

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