

Practice sting The administration of omeprazole suspension Pedippi[®] to babies

This Practice sting was written in collaboration with Lareb

At the end of 2019, the omeprazole suspension Pedippi[®] 2 and 4 mg/ml came into the market. The 2 mg/ml is particularly suitable for children up to 1 year. The suspension is difficult for babies to swallow. This can cause major health problems, as shown by reports received by the Netherlands Pharmacovigilance Centre Lareb.

Notifications

Up to mid-April 2023, the Netherlands Pharmacovigilance Centre Lareb received 22 reports of babies having problems swallowing Pedippi omeprazole suspension. Reporters described that the suspension for babies is too thick and too slimy. This causes the babies to choke on it. Some children can hardly breathe and sometimes turn blue. This causes concern for the parents. In a few reports, the babies have been seen in the emergency room. In the vast majority of notifications, the suspension was not diluted with milk.

Analysis

Omeprazole is used in babies to treat reflux symptoms. Pedippi omeprazole suspension is registered for children older than one month. The suspension is thick and slimy making it difficult for babies to swallow. To make swallowing easier, the advice of the Dutch Medicines Evaluation Board (MEB) is to dilute Pedippi with 20 to 30 milliliters of (expressed) milk before administration. This administration instruction is not (yet) included in the Pedippi package leaflet. This administration instruction is included on www.pharmacy.nl.

Recommendations

Pharmacists

 Advise parents of babies to dilute Pedippi with 20 to 30 milliliters of (expressed) milk before administration.

Pediatric nurses

• Before administration to babies, dilute Pedippi with 20 to 30 milliliters of (expressed) milk.