

Chymotrypsin (Chymoral Forte) Adverse Drug Event: Diarrhoea in Exclusively Breastfed Neonates

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ABSTRACT

A healthy full term newborn delivered by Caesarean Section was seen at two weeks of age with complaints of diarrhoea. He was on exclusive breastfeeding since birth. Mother was receiving enzymes Chymoral and Serratiopeptidase since caesarean ostensibly to 'speed up 'wound healing' and to 'reduce stitch edema'. The mother was advised to stop the enzymes, drink more water and breast feed more often to increase the breast milk output. Second case was similar. Such drugs should not be prescribed or prescribed only for three to five days, and, not for such a long time.

Keywords: Adverse drug event, ADR, Neonate, Breastfeeding, Diarrhoea, Caesarean section.

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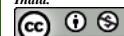
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INTRODUCTION

Exclusive breastfed neonates / infants generally do not develop diarrhoea. Occasionally loose stools may be a feature of human breast milk diet. However when loose stool develop after 10 days of normal stools in a breastfed neonate, the etiology could be side effects of the drugs that mother is receiving and excreted in breast milk. Many drugs like antibiotics, antipyretics, vitamins and minerals are prescribed to mother but they must be safe for a feeding neonate.

Occasionally an unusual drug may be prescribed for prolonged time to a lactating mother that may cause diarrhoea in the neonate. Here we present two such cases where neonates developed loose stools after mother received chymotrypsin/ trypsin or serratiopeptidase in oral formulations for more than the prescribed

3 to 5 days. This is first time a side effect in a neonate from such a drug received by the mother is reported.

CASE STUDY

Case 1:

A 16-day old male full-term neonate appropriate for date delivered by lower segment caesarean section visited the outpatient with complain of loose watery stools 4 to 5 times per day since last three days, and as the baby was exclusively breast fed, the mother was inquired for drug intake. She was receiving in addition to iron/ folic acid/ zinc/and calcium-vitamin D3, Chymoral Forte® [chymotrypsin/ trypsin] orally three times a day since delivery. It was prescribed for 'reduction of edema' 'pain' and 'better wound

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healing' as told to us by the mother. After stopping the drug diarrhoea stopped.

Case 2:

An 18-day old male full-term neonate appropriate for date delivered by lower segment caesarean section visited the outpatient, and the father informed that when he is changing the diaper of his baby after urine passage he observed that minimal amount liquid stool was oozing or coming from anus. Here also the mother was receiving Chymoral Forte® and serratiopeptidase oral twice a day since delivery in addition to supplements. It was started for similar reasons. After stopping the drug the oozing of loose stools stopped.

Adverse drug event /reaction (ADR) form was filled and the doctor was informed about such prescription and duration of drug.

DISCUSSION

Chymoral is a protein cleaver enzyme and is mainly used for exocrine pancreatic insufficiency. It is also used for wound management and oedema reduction. The product leaflet mentions that it is better to avoid in pregnancy and lactation, to be on the safe side, though no side effects have been reported in neonates.

Breast milk naturally contains alpha1 α_1 -antitrypsin and antichymotrypsin, and the resistance of milk α_1 -antitrypsin to digestion, the ability of α_1 -antitrypsin to protect lactoferrin from proteolysis, and the detection of transcripts of the protease inhibitors through PCR of mammary gland cDNA is depicted by Winyoo,¹ so how these drugs interact in the neonate gut need to be assessed.

Diarrhoea has been reported in adults using this medication and similar side effects may happen in neonate when prescribed for prolonged periods.^{2,3}

While other websites mention that: enough is not known and although no side effects during lactation is reported, avoid use during pregnancy and Lactation to be on the safe side.²⁻⁷

CONCLUSION

This is the first report of Chymoral Forte® (chymotrypsin/ trypsin) / Serratiopeptidase and diarrhoea in two neonates who had received it via breast milk.

So this drug should be avoided, or not used for more than recommended 3-5 days by the obstetrician for a lactating mother.

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