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Dear Healthcare Professional,

**POTENTIAL MEDICATION ERROR WITH TOT’HEMA ORAL SOLUTION**

The National Pharmacovigilance Centre at the Food and Drugs Authority (FDA) wishes to inform healthcare professionals that it has become aware of the **potential** for wrong administration of Tot’hema Oral Solution through the parenteral route.

Tot’hema Oral Solution, registered by the FDA for prevention and treatment of iron-deficiency anemia is packaged in an amber colored ampoule for oral administration and indicated. Although no formal reports have been received, the FDA has received anecdotal reports of potential wrongful administration of this product through the parenteral route by some healthcare professionals.

The FDA therefore wishes to remind healthcare professionals to note that the product is for **ORAL USE ONLY**.

Meanwhile, the Marketing Authorization Holder, Laboratoire Innotech International is working with the FDA to put in place the underlisted **additional** Risk Minimization Measures (aRMMs) to prevent such errors.

1. Print boldly on the secondary package - “**Do Not Inject, For Oral Use Only**”
2. Provide training for healthcare professionals on the correct route of administration of Tot’hema Oral Solution
3. Provide Information, Education and Communication Materials (IE&C) for HCPs on correct administration of Tot’hema Oral Solution
4. Monitor the effectiveness of all Risk Minimisation Measures in place.

Healthcare professionals are therefore encouraged to report any such cases of wrong administration to the National Pharmacovigilance Centre, Food and Drugs Authority by completing the Adverse Reaction Reporting Form or call **024 431 0297** or send e-mail to [drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh).

Yours faithfully,

HUDU MOGTARI  
CHIEF EXECUTIVE OFFICER