

Medical Product Alert No. 01/ 2025
Unregistered Oxytocin Injection 10iu/ml (A-Tocin Injection and Derm Oxytocin Injection) in Ghana

Alert Summary

The Food and Drugs Authority (FDA), Ghana reports of two brands of **unregistered Oxytocin Injection 10iu/1ml (A- Tocin Injection and Derm Oxytocin Injection)** detected during Product Quality Monitoring activities in Pharmacies and Hospitals in some selected regions in Ghana. Oxytocin is a synthetic hormone that is used to induce or strengthen uterine contractions in pregnant women to aid in labour and delivery and to control postpartum bleeding.

The unregistered medicines did not meet specifications for **Assay** when tested in the FDA's Quality Control Laboratory. There is no manufacturer's address on the labels of **A-Tocin Injection** and the product is purported to be marketed by ACME Health Care Ltd. **Derm Oxytocin Injection** is manufactured by Shandong Shenglu Pharmaceuticals Ltd., North of Sihe Road, Sihe Street, Sishui County, Shandong, China.

How to identify the Unregistered Products

A-Tocin Injection

- A-TOCIN" is written in red and has **NAFDAC Reg. Number B4-2006**.
- The inscriptions on the ampoules are in blue ink.
- There is no manufacturer's address on the product
- Products have a temperature storage stated as "store in a cool place below **25°C**" which is not the required storage conditions for Oxytocin.

Derm Oxytocin Injection

- DERM OXYTOCIN INJECTION is written in bold on a yellow background.
- The product has **NAFDAC reg. C4-2001**
- The inscriptions on the transparent ampoules are in black ink.
- Products have a temperature storage stated as "store in a cool place below **25°C**" which is not the required storage conditions for Oxytocin.

Please refer to the attachment of this Alert for details of the unregistered products.

Risks

- Distribution of unregistered Oxytocin injection poses a serious public health risk. Oxytocin injection is also a temperature-sensitive product which quality, safety and efficacy can be compromised when not transported under the right condition during importation and distribution for sale.
- The storage conditions stated on the labels is not the required temperature for Oxytocin injection which may compromise the quality, safety and efficacy of the product.

- Usage of both A-Tocin and Derm Oxytocin Injections could result in treatment failures since the product has not been approved for the Ghanaian market.
- Analysis conducted on both samples indicates the products are substandard and could be injurious to the consumer.
- Users of A-Tocin and Derm Oxytocin Injections may experience side effects such as: heavy vaginal bleeding, dyspnea, seizures, tachycardia and bradycardia, neonatal seizure and neonatal jaundice.

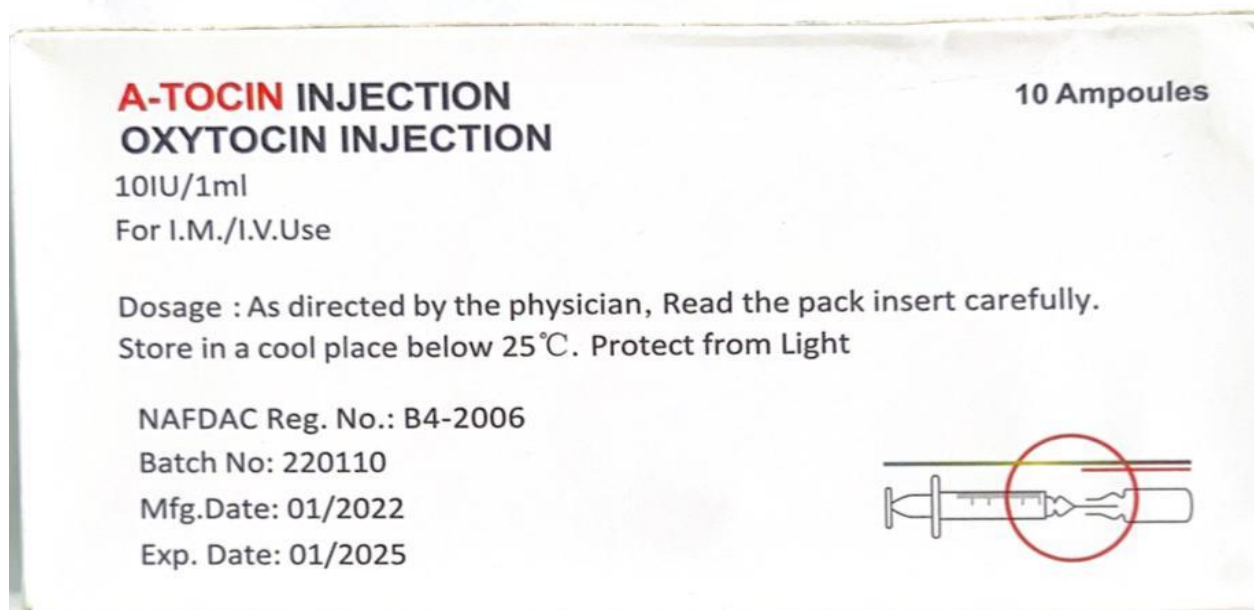
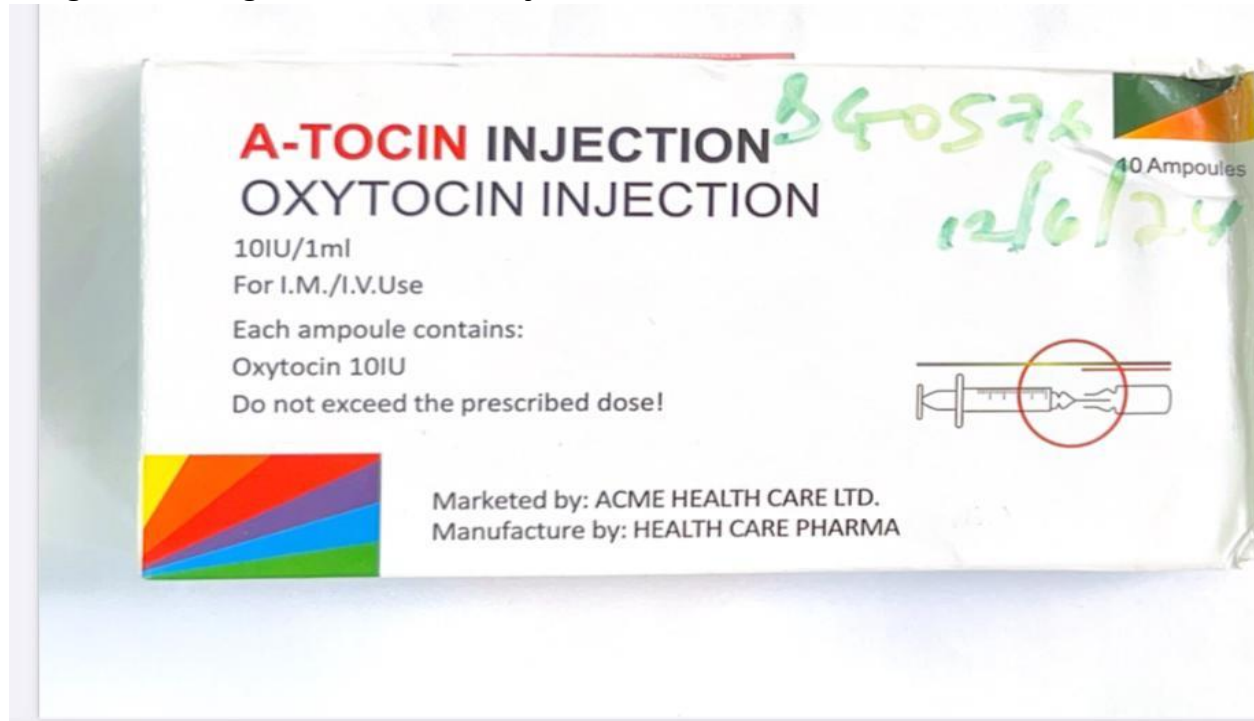
Advice to healthcare professionals, regulatory authorities and the public

The FDA is informing all healthcare professionals and the general public that the quality, safety and efficacy of the unregistered A-Tocin and Derm Oxytocin Injections cannot be guaranteed. Recall of these medical products are ongoing and investigations are also being conducted to identify the importers and distributors of these products.

If you are in possession of unregistered products, the FDA recommends that you do not use them and return them to the nearest FDA office or health facility. If you, or someone you know, has, or may have used the unregistered A-Tocin and Derm Oxytocin Injection, or suffered an adverse event or unexpected side-effect after use, seek immediate medical advice from a healthcare professional or contact the FDA in any of our offices or through our social media handles.

Product Details

Images of Unregistered A-Tocin Injection



Images of Information Panel of unregistered A-Tocin Injection



Images of Information on ampoules of A-Tocin Injection

DERM

1ml X 10Amps

OXYTOCIN INJECTION

10IU/ML

I.M./I.V.

Each Ampoule contains: Oxytocin 10IU

Marketed by: Derm Pharmaceuticals Ltd.
19, Alhaji Salami Street, Aguda Surulere, Lagos, Nigeria

NAFDAC REG. No.: C4-2001
Mfg. Date: 05/2023

Batch No.: 230528
Exp. Date: 05/2026

NAFDAC REG. No.: C4-2001
Mfg. Date: 06/2023

Batch No.: 230645
Exp. Date: 06/2026

Store in cool and dry place, below 25°C
Keep medicine out of the reach of children.

Images of Unregistered Derm Oxytocin Injections



Images of Information on ampoules of Derm Oxytocin Injection