FOOD AND DRUGS AUTHORITY GHANA

Public Assessment Report

VELLNATE-120 INJECTION 120mg

Artesunate

AFF0065/25

Udvell Therapeutics Pvt Ltd - 2 Floor, Opp Badminton Academy Doon University Road, Dehradun, Uttarakhand, 248001, India

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Administrative info

Dosage Form	Injection
Strength	120mg
Applicant's Name & Postal Address	Udvell Therapeutics Pvt Ltd - 2 Floor, Opp Badminton Academy Doon University Road, Dehradun, Uttarakhand, 248001, India
Manufacturer's Name & Address	Vellinton Healthcare - Village: Rampur Jattan, Trilokpur Road, Kala Amb Distt.: Sirmour (H.P.) – 173030, India, India
Local Agent	Paramount Therapeutics Ltd. - House no. 31, Near Dabis Hotel, Tabora-Accra Ga West, Greater Accra P.O. Box 17976, Accra, Greater Accra, Ghana

1. Part 1

1.1 Abstract

Based on the review of the data on quality, safety and efficacy, the application for Vellnate-120 Injection 120mg, indicated for the initial treatment of severe malaria in adults and children is approved.

1.2 Executive Summary

1.2.1 About the product

A comprehensive description of the indications and posology is given in the SmPC. This registration application concerns a generic application.

The marketing authorization has been granted pursuant to section 118 of the Public Health Act, Act 857.

2. Part 2a: All accepted presentations (Description of all accepted presentations and dosages, as given in the product dossier)

FDA Registration Number	Product Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package Size
FDA/SD.255-050789	VELLNATE-120	120mg	Injection	Intravenous	Glass vial	1 x 1 vial

Part 2b: Appearance of Product (Photograph of formulation (solid forms) or other product characteristics (liquid forms)

3. Part 3: Product information for the user (Patient Information Leaflet - PIL)

https://fdaghana.gov.gh/wp-content/uploads/2025/08/Vellnate-120-Injection-Artesunate-PIL.pdf

4. Part 4: Information for the health care provider (Summary of Product Characteristics– SmPC)

https://fdaghana.gov.gh/wp-content/uploads/2025/10/Vellnate-120-Injection-Artesunate-SmPC.pdf

5. Part 5: Labelling

5.1 Particulars to appear on the Outer Packaging (Secondary Package)

- **Name of the medicinal product**

Vellnate-120 Injection

- **Statement of active substance**

Each vial contains 120 mg artesunate powder for injection

- **List of excipients (excipient of safety concern)**

Artesunate powder for injection does not contain any excipients.
Solvent (sodium bicarbonate injection) contains sodium bicarbonate
Diluent (sodium chloride injection) contains sodium chloride and water for injection

- **Pharmaceutical form and contents**

Each box contains 1 vial of Artesunate for injection (120 mg), Sodium Bicarbonate Injection BP 1ml, and Sodium Chloride Injection BP 2.5ml.

- **Method and route of administration**

Intravenous use after reconstitution and dilution. Read the patient information leaflet before use.

- **Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the reach and sight of Children.

- **Other special warning(s), if necessary**

Discard the solution if it appears cloudy or precipitated after dilution and reconstitution.

- **Expiry date**

EXP {MM/YYYY}

- **Special storage conditions**

Store at a temperature below 30°C.

Protect from light & moisture.

- **Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate.**

N/A.

- **Name and address of the manufacturer**

Vellinton Healthcare
Address: Village-Rampur Jattan, Trilokpur Road Kala Amb, Sirmour (H.P.), 173030

- **Manufacturer's batch number**

Batch {number}

- **(Advice on) General classification for supply**

Medicinal product subject to medical prescription.

- **Instructions on use**

5.2 MINIMUM PARTICULARS TO APPEAR ON PRIMARY PACKAGE

- **Name of the medicinal product**

VELLNATE-120 INJECTION

- **Name of the manufacturer**

Vellinton Healthcare, India

- **Expiry date**

EXP {MM/YYYY}

- **Manufacturer's batch number**

Batch {number}

- **Other**

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Solvent ampoule

- **Name of the Medicinal Product**

Sodium Bicarbonate Injection

- **Name of the manufacturer**

Vellinton Healthcare, India

- **Expiry Date**

EXP {DD/MM/YYYY}

- **Manufacturer's Batch Number**

Batch {number}

- **Other**

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Diluent ampoule

- **Name of the medicinal product**

Sodium Chloride Injection

- **Name of the manufacturer**

Vellinton Healthcare, India

- **Expiry Date**

EXP {DD/MM/YYYY}

- **Manufacturer's Batch Number**

Batch {number}

- **Other**

6. Part 6: Scientific Overview and Discussion

6.1 Introduction

VELLNATE-120 INJECTION is white or almost white crystalline powder filled in 20 ml clear glass vial, sealed with grey butyl rubber stopper and 20 mm baby blue color flip-off seal. Each vial contains Artesunate 120mg. The injection is packed in Glass vial.

The are no excipients in this formulation.

6.2 Active Pharmaceutical Ingredient (API)

The active pharmaceutical ingredient is In-House. Artesunate Sterile is a white crystalline powder. Its form is a crystalline anhydrous form with moisture content of about 0.5%w/w which is soluble in ethyl acetate, practically insoluble in petroleum ether. The drug substance is an optically active compound and shows an optical rotation and may not show polymorphism.

Manufacturing process

The manufacturing process was presented with sufficient details. The active pharmaceutical ingredients have been adequately characterized, and acceptable

specifications have been adopted for the relevant materials and products (starting materials, intermediate products, solvents).

Quality control of active pharmaceutical ingredient

The pharmaceutical ingredient specification is considered adequate to control the quality. Batch analytical data demonstrating compliance with this specification have been provided.

Stability of active pharmaceutical ingredient

Stability data are provided on the active substance of three (3) batches stored below 25^0C. The currently acceptable retest period is 36 months when stored below 25^0C

6.3 Finished Pharmaceutical Product

Pharmaceutical development

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant FDA/ICH guidelines. The choice of packaging and manufacturing is justified.
The choice of the sterilization method is adequately justified

Manufacturing process

The manufacturing process consists of dispensing, sterilization, filling and sealing. The manufacturing process has been validated according to relevant FDA/ICH guidelines. Process validation data on the product has been presented for at least three production-scale batches in accordance with the relevant FDA guidelines.

Microbiological attributes

The drug product is routinely tested for sterility. Sterility requirements for drug products are granted by terminal sterilization.

Quality control of finished pharmaceutical products.

The finished product specifications (release and shelf-life) are adequate to control the relevant parameters for the dosage form. The test parameters include description, Identification, Average filled weight, uniformity of filled weight, clarity of solution, particulate matter, related substance, water content, bacteria endotoxins, sterility and assay. The proposed acceptance criteria at release and shelf-life have been justified and are considered appropriate for the quality control of the product. Batch analytical data from production scale batches manufactured at the proposed finished product manufacturing site have been reviewed. The data demonstrates compliance with the specification and also shows batch to batch consistency.

Stability of finished pharmaceutical products.

Stability data on the product have been provided on three production scale batches stored below 30^0C. The conditions used in the stability studies are according to the FDA/ICH stability guideline. The batches were stored in the proposed unit dose containers. All parameters remain within the specified limits. The proposed shelf-life of 32 months and storage conditions are justified.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies.

There are no substances of ruminant animal origin present in the product, nor have any been used in the manufacturing of this product, so a theoretical risk of transmitting TSE can be excluded.

7. Part 7: Steps taken for registration.

The application was submitted as a full review application procedure. It was first approved by the FDA Ghana on Tuesday, 21 May 2025.

8. Part 8: Steps taken following registration.

This is a first registration. The report will be updated at the next renewal date.