

National Center for Vector Borne Diseases Control

Technical Specification of Combi Blister Packs of ACT – SP for Different age group under NVBDCP

Description of Drug/Product:					
Age Groups =>	Infant i.e. < 1 year	1 – 4 Years	5 – 8 Years	9 – 14 Years	Adults
Age – group wise colour code of Combi Blisters =>	Pink Colour	Yellow Colour	Green Colour	Red Colour	White Colour
A) Description of Combi Blister Pack containing Artesunate (AS) and Sulphadoxine Pyremethamine (SP)	-3 tablets of Artesunate (25mg each) 1 Tab per day for 3 days	3 tablets of Artesunate (50 mg each) 1 Tab per day for 3 days	3 tablets of Artesunate (100mg each) 1 Tab per day for 3 days	3 tablets of Artesunate (150 mg each) 1 Tab per day for 3 days	3 tablets of Artesunate (200mg each) 1 Tab per day for 3 days
	1 tablet of Sulphadoxine Pyremethamine (250mg + 12.5mg) Single dose	1 tablet of Sulphadoxine Pyremethamine (500mg+25mg) Single dose	1 tablet of Sulphadoxine Pyremethamine (750mg+ 37.5mg) Single dose	2 tablets of Sulfadoxine Pyremethamine (500mg+ 25mg)	2 tablets of Sulphadoxine Pyremethamine (750mg+37.5mg) each or 3 tablets of Sulphadoxine Pyremethamine (500mg+25mg) each
B) Each Row - No. of tablets :	First Row (Day 1) One tablet of Artesunate (25 mg) and one tablet of Sulphadoxine Pyremethamine (250 mg+12.5 mg)	First Row (Day 1) One tablet of Artesunate (50 mg) and One tablet of Sulphadoxine Pyremethamine (500+25mg)	First Row (Day 1) One tablet of Artesunate (100mg) and one tablet of sulphadoxine Pyremethamine (750mg+37.5) mg	First Row (Day 1) One tablets of Artesunate (150 mg) and two tablets of Sulphadoxine Pyremethamine (500+25mg)	First Row (Day 1) One tablet of Artesunate (200 mg) and two tablets of Sulphadoxine Pyremethamine (750+37.5) mg each or three tablets of Sulphadoxine Pyremethamine (500+25) mg each
	Second Row (Day 2) One tablet of Artesunate (25mg)	Second Row (Day 2) One tablet of Artesunate (50mg)	Second Row (Day 2) One tablet of Artesunate (100mg)	Second Row (Day 2) One tablet of Artesunate (150mg)	Second Row (Day 2) One tablet of Artesunate (200mg)
	Third Row (Day 3) One tablet of Artesunate (25mg)	Third Row (Day 3) One tablet of Artesunate (50mg)	Third Row (Day 3) One tablet of Artesunate (100mg)	Third Row (Day 3) One tablet of Artesunate (150mg)	Third Row (Day 3) One tablet of Artesunate (200mg)
Caution	The blister strip should be superscribed that SP not to be given to children under 5 months				

A series of handwritten signatures and initials in blue ink are located at the bottom of the page, below the table. From left to right, they include: a signature that appears to be 'D. Das', another signature, 'Bh', 'Sandeep', 'Sandeep', 'Sandeep', 'Sandeep', 'Sandeep', 'Sandeep', and 'Sandeep'. There is also a date '1/3' written at the bottom right.

<p>C) Pharmacopeial Requirement</p>	<p>The product must comply with the latest version of Indian Pharmacopoeia (IP) or other applicable version.</p>
<p>D) Shelf Life/ Efficacy</p>	<p>Tablet Artesunate: Two years</p> <p>Tablet Sulfadoxine + Pyremethamine two years.</p> <p>Each Pack will bear shelf life of 2 years on the pack with manufacturing and expiry date.</p> <p>At least 5/6th of the minimum shelf life must remain at the time of delivery to the consignee. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.</p>
<p>E. Packing & Marking</p>	<p>All the packs in different groups will have definite colours as indicated above.</p> <p>The tablets will be placed in three rows with transparent top. Each row should be clearly marked as Day 1, Day 2 and Day 3 giving number of tablets in each row.</p> <p>Each pack should indicate dose schedule per kg body weight for both Tablet Artesunate and Tablet Sulphadoxine-Pyremethamine i.e. AS-4 mg/kg body weight (bw) and 25mg/ kg (bw) of Sulphadoxine + 1.25 mg per kg (bw) of Pyrimethamine respectively.</p> <p>Marking: Printing/markings on Blister/Catch cover/corrugated box and pack will be as per Drug & Cosmetics Act 1940 and rules made thereunder and as amended from time to time.</p> <p>Manufacturing and Expiry dates of Artesunate and Sulfadoxine-Pyremethamine tablets should be written separately on the Blister Pack/Catch Cover.</p> <p>Each Blister Strip will be stuffed in a paper catch cover. 25 Blister Strips will be placed in a pack and 100 such packs will be packed in a corrugated box. Each Blister Strip/Catch Cover/Pack and Box should be marked "NVBDGP, Dte. GHS SUPPLY- NOT FOR SALE".</p> <p>Supplies shall be securely packed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.</p>
<p>F. Labelling</p>	<p>The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.</p>

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