

## ANNOTATED SUMMARY OF PRODUCT (SmPC) CHARACTERISTICS TEMPLATE

### 1. NAME OF THE MEDICINAL PRODUCT

WIMAL PLUS JUNIOR

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Each Co-blister pack contains:**

**One Sulfadoxine and Pyrimethamine Dispersible Tablet 250/12.5mg**

Each Dispersible Tablet contains Sulfadoxine 250mg and Pyrimethamine 12.5mg

Product contains Lactose Monohydrate.

**Three Amodiaquine (as Hydrochloride) Dispersible Tablets 75mg**

Each dispersible tablet contains Amodiaquine Hydrochloride 98mg equivalent to Amodiaquine 75mg.

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Sulfadoxine and Pyrimethamine Dispersible Tablets description: White to off-white, round shaped flat bevel edged tablet, Scored on one side and plain on the reverse.

Amodiaquine (as Hydrochloride) dispersible Tablets description: Yellow, round shape flat, bevel edged tablet, plain on one side and scored on the reverse.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

This product is indicated for malaria prevention during the malaria season (seasonal malaria chemoprevention, SCM) in children aged 12-59 months.

#### 4.2 Posology and method of administration

##### Children aged 12-59 months

**Treatment should start at the beginning of the high transmission period and is given in 3day courses as follows,**

	Dose (child aged 12 -59 months)	
	Amodiaquine (as Hydrochloride) Dispersible tablet 75mg	Sulfadoxine and Pyrimethamine Dispersible Tablet 250/12.5mg
Day 1	2 Tablet	2 Tablet
Day 2	2 Tablet	
Day 3	2 Tablet	

The 3-day course is repeated after 1 month, for a maximum 4 courses during the high -transmission period.











