Appendix 5: SAEs recording form

3.4. Study ID: |__ |__||___||__ |__||___||__ |__||___|

3.5. Participant Initial _____

3.6. SAEs form between D1 and D15**; use the codes 1 = Severe, 2 = Very severe**

Severe effects

Days when serious side effects occurred
D0 D1 D2 D3 D4 D5 D6 D7 D8 D9 D10 D11 D12 D13 D14 D15 D30

4.3.1 Angioneurotic
oedema/anaphylactic shock
4.3.2 Anuresis

4.3.3 Seizures

4.3.4 Erythema multiforme

4.3.5 Epidermal necrolysis

4.3.6 Recurrent symptoms

4.3.7 Stevens Johnson Syndrome

4.3.8 Others

4.3.9 If other specify.....

.....

.....

AFTER COMPLETING QUESTIONS UNDER 4.3 AND 4.2, THE INVESTIGATOR SHOULD ANSWER THE FOLLOWING QUESTION; THE ANSWER WILL BE YES IF ANY SEVERE EFFECT IS REGISTERED

3.7. Did the interviewed participant experience a serious/severe adverse event after taking the 3 drugs?
1. Yes 2. No 99. unknown 3.8. If yes for 4.5, please list down……..

3.9. If yes for 4.5, please complete the Fever and serious adverse events **surveillance form appendix 2.**

4. Causality assessment criteria:

4.1. **Is the serious effect related to the therapy?** 1. Not related 2. Probably 3. Unlikely

4.1.1. What is your Arguments for decision…….
…… 4.1.2. Remarks/Observations regarding this serious adverse effect case management……
……

NOTE: ***Serious adverse effects will be treated and observed for 24 hours (maximum) by the physicians on the field. If there is no improvement, the subject will be transferred to the most appropriate health care facility***

Thank you for your collaboration

7.1 List of contraindications to look for: 1=Yes, 2=No

Contraindications	**1**	**2**

7.1.1. Pregnancy		
7.1.2. Breastfeeding		
7.1.3. Children less than 5 years of age (≤90cm)		
7.1.4. Allergy to one of the study drugs: azithromycin, Ivermectin, Abendazole		
7.1.5. Medicine intake: antiacids containing aluminium or magnesium, nelfinar, ergot derivatives		
7.1.6. Serious illness (systemic edema, severe dyspnea, etc.)		
7.1.7. Others…….. If others, please specify:		

DECISION REGARDING INCLUSION IN THE STUDY *: 1. Yes, 2. No*

7.2. Concomitant Treatments: codes; 0: Not administered 1: Administered; D=day

Concomitant Treatments														
Antalgic treatment: paracetamol														
Anti-inflammatory treatment: diclofenac														
Anti-malarial treatment: artemisin and quinine compounds														
Antibiotics treatment: all categories														

Local treatment (eyes, lymphoedema, skin, etc.)														
Solutes														
Corticoids														
Cardio-stimulants														
Anxiolytics														
Antihistaminics														

7.3. Concomitant Treatment: Number of days|___|___| days

7.4. Evolution: Favourable: 1. Yes 2. No