TPP for onchocerciasis– revised and approved version

Variable	Acceptable	Ideal
Indication	For the treatment of Onchocerciasis	For the treatment of Onchocerciasis
Product Description	Oral form, injection, intramuscular or subcutaneous injection	Oral form
Target population	All infected patients with the exception of pregnant women, children younger than 5 years.	All individuals who are at risk for onchocerciasis
Treatment regimen	• Oral dose, once or twice a day • Duration of treatment up to 14 days • One single im or sc injection or repeated after a week (2 injections) • One dose for adults and weight/age-adjusted or height-based dosing for children	• Oral dose, once a day, up to 3 days • One dosage for all ages
Efficacy	Superior to comparator in eliminating skin microfilariae at 24 months ~~with~~ with evidence of impacting adult worms (killing adults or embryos)	Superior to comparator in eliminating skin microfilariae at 24 months with evidence of impacting adult worms (killing adults or embryos)
Safety	**Adverse events** Minor and manageable side effects • Monitoring for AE manageable at local healthcare post • Moderate impact on activities of daily living • No severe Mazzoti reaction • No severe adverse ocular reaction **Population for restricted use at registration** Pregnancy women Lactating woman (duration according to PK of the drug) **Precaution/Warnings** • Concomittant infections (eg.loaisis) • Acute illness (eg. Fever, bacterial infection) **Use in specific populations**: • Pre-treatment assessment and careful post-treatment follow-up should be available for patients with *Loa-loa* coinfection. • Exclusion of high *Loa loa* mf/mL co-infected patients	**Adverse events** • No monitoring for AE required • No impact on activities of daily living • No Mazzoti reaction • No adverse ocular reaction **Population for restricted use at registration** • None **Precaution/Warnings** None **Use in specific populations:** • Safe for use in patients co-infected with *L. loa* No monitoring needed. (no rapid microfilariae activity)
	Drug-drug interactions: Manageable for individual case treatment	**Drug-drug interactions:** • No clinically significant drug-drug interaction with commonly used anti-parasitic and anti-infective drugs • No evidence for clinically significant, adverse interactions with long-term/chronic use drugs (e.g., anti-tuberculosis drugs, anti-retrovirals, contraceptives) And • No evidence for clinically significant, adverse interactions with commonly administered MDA drugs (e.g.ivermectin, praziquantel, other benzimidazoles, azithromycin), and anti-malarial drugs.
Shelf Life	3 years in zone IVb	More than 3 years in zone IVb