Prophylactic Trypanocide for Animal African Trypanosomosis (AAT)

GALVmed
Protecting Livestock – Improving Human Lives

Target Product Profile (TPP)

A safe and effective prophylactic product for ruminants and other livestock infected with common Trypanosome species (especially *T. congolense* and *T. vivax* including isolates resistant to diminazene and isometamidium)

Attribute	Ideal TPP (Wants)	Minimum TPP (Needs)
1 **Active Ingredient**	Novel agent with new mechanism of action. No cross- or side-resistance to existing product actives.	Novel agent. Side-resistance to existing veterinary products acceptable if overcome by greater intrinsic potency or speed of action.
2 **Indication for use**	Prevention and treatment of *T. congolense, T. vivax, T. brucei* and *T. evansi* infections, including strains resistant to existing trypanocides.	Prevention of *T. congolense* and *T. vivax* infections, including strains resistant to existing trypanocides.
3 **Target species**	Cattle, sheep, goat & other ruminants, horses, donkeys, pigs.	Cattle
4 **Route of administration**	Injectable (i.m. and s.c.) plus oral option for sheep.	Injectable (i.m. or s.c.)
5 **Formulation**	Injectable: Pre-formulated solution. Oral: Solid bolus or suspension/solution drench.	Injectable: Pre-formulated solution or suspension or sterile powder in vial for reconstitution
6 **Period of Protection**	Once in 6 months. If it also provides therapy then it should be provided from a single administration and at the same dose as prophylaxis.	Once in 2 months.
7 **Recommended time of treatment**	Before (or on) introduction to infected regions or at start of tsetse season. If also provides therapy then use at first clinical signs of disease or parasitaemia.	Before (or on) introduction to infected regions or at start of tsetse season.
8 **Expected efficacy**	Absence of parasitaemia and clinical signs, e.g. anaemia. [For Regulatory Studies: Absence of clinically significant parasitaemia, e.g. buffy coat method for duration of protection period, and normal haematocrit/PCV].	Absence of parasitaemia and clinical signs, e.g. anaemia. [For Regulatory Studies: Absence of clinically significant parasitaemia, e.g. buffy coat method for duration of protection period, and normal haematocrit/PCV].

Prophylactic Trypanocide for Animal African Trypanosomosis (AAT)

Attribute	Ideal TPP (Wants)	Minimum TPP (Needs)
9 Target animal safety	No clinically significant adverse drug reactions. Minimal administration site reactions. Safe for use in breeding animals (male and female) – demonstrated in target species.	No serious adverse drug reactions. Acceptable reactions at administration site. Safe for use in breeding animals (male and female) – demonstrated in laboratory animal studies.
10 Withdrawal period	Milk 0 days. Meat <21-28 days.	Meat <2 months. Not for use in cattle producing milk for human consumption. (No milk withdrawal period established).
11 Special requirements for animals	Compatible for concomitant use with common treatments e.g. ectoparasiticides, antimicrobials, anthelmintics and vaccines.	None stated.
12 Special requirements for persons	No special precautions required beyond good practice.	Routine personal protective equipment. No major hazard on accidental self-injection or pour-on.
13 Special requirements for environmental protection	No special precautions.	Minimal soil/water residues. Minimal restrictions on disposal of packaging.
14 Package size	1, 5, 10 and 50 doses packages.	10 dose packages.
15 Price to user	<US$2/dose (300 kg animal).	Higher prices than US$2/dose are a major challenge unless justified by value-added properties and include syringes, etc.
16 Storage requirements	Ambient temperature ≤40°C/75% RH.	Ambient temperature ≤30°C/ 75% RH* **FAO/WHO Guideline*
17 Shelf-life as packaged	≥3 years*	≥ 18 months* * *At world zone IVb for regulatory purposes*
18 Shelf-life after first opening	≤28 days	≥7 days for multidose vial