

Vaccine for Animal African Trypanosomosis (AAT)

Target Product Profile (TPP)

A safe and effective vaccine to prevent infection or clinical disease caused by *T. congolense* and *T. vivax* in ruminants.

Attribute	Ideal TPP (Wants)	Minimum TPP (Needs)
1 Antigen	Immunogen with <i>T. congolense</i> & <i>T. vivax</i> antigens.	Immunogen with <i>T. congolense</i> and/or <i>T. vivax</i> antigens.
2 Indication for use	For active immunisation of cattle, sheep, goats & camels against <i>T. congolense</i> & <i>T. vivax</i> .	For active immunisation of cattle against <i>T. congolense</i> and/or <i>T. vivax</i> .
3 Target species	Cattle, sheep, goats, equines & camels.	Cattle.
4 Recommended Dose	Same dose for cattle and sheep: 2ml.	≤5 ml (cattle).
5 Pharmaceutical form	Ready to use solution/ suspension.	Reconstituted injectable solution/ suspension.
6 Route of administration	Subcutaneous and intramuscular.	Subcutaneous or intramuscular.
7 Regimen – primary vaccination course	Single dose.	Maximum of two doses given 2 – 6 weeks apart.
8 Regimen – booster	Annual dose.	6 monthly booster.
9 Epidemiological relevance	Protection against <i>T. congolense</i> & <i>T. vivax</i> in affected regions.	Protection against <i>T. congolense</i> &/or <i>T. vivax</i> in affected regions.
10 Recommended age at first vaccination	From 1 – 2 months of age (as early as possible).	When other vaccines are applied (normally 3 – 4 months of age).
11 Onset of immunity	One week following primary vaccination.	2 – 3 weeks following primary vaccination.
12 Duration of immunity	Life time immunity.	Six months following first booster vaccination.
13 Expected efficacy	To prevent infection and transmission in 100% of the animals. [For registration studies: absence of parasitaemia and clinical signs, and sustained normal haematocrit].	To prevent disease in > 70% of vaccinated animals [For registration studies: prevention of clinical disease (no proportional decrease in PCV greater than 20%).]

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14 Expected safety	No injection site reactions and no pyrexia nor milk reduction.	Mild and transient injection site reactions and pyrexia lasting less than 14 days. Transient milk reduction.
15 Withdrawal period	Nil for milk and meat.	1 – 2 weeks at point of injection for meat.
16 Special requirements for animals	Vaccinate all animals.	Vaccinate only clinically healthy animals.
17 Special precautions for persons	No reaction on self-injection	No severe reaction after accidental self-injection.
18 Package size	<10, 50, 50, 100, 250 doses.	10 and/or 50 doses.
19 Price to end user (will be dependent on duration of immunity)	US\$1-2.00/dose to end user.	<US\$5/dose
20 Storage requirements	Stable at 30°C/75%RH for 24 months.	Stable at 2-8°C/75%RH for 24 months.
21 Shelf-life as packaged for sale	36 months.	18 months.
22 Shelf-life after first opening (in-use stability)	24 hours or greater.	1 hour.
23 In-use preservative for inactivated vaccines	No preservative required.	Any approved preservative.