

**ADVERSE EVENT REPORT FORM**Version 2.0
13-Dec-2021**FORM TO BE SENT TO:**AB SCIENCE
3 avenue Georges V, 75008 - PARISpharmacovigilance@ab-science.com
Fax : 33 1 47 20 10 82

EVENT TYPE	NAME AND ADDRESS OF SENDER	SERIOUSNESS
<input type="checkbox"/> Adverse reaction <input type="checkbox"/> Lack of efficacy <input type="checkbox"/> Off label use <input type="checkbox"/> Environmental problems <input type="checkbox"/> Infectious agent <input type="checkbox"/> Residues	Veterinarian <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other <input type="checkbox"/> Phone number: Fax number: E-mail:	<input type="checkbox"/> Serious <input type="checkbox"/> Not Serious <input type="checkbox"/> Death <input type="checkbox"/> Life threatening <input type="checkbox"/> Significant disability <input type="checkbox"/> Congenital anomaly <input type="checkbox"/> Other important medical condition

PATIENT(S) *Animal (s)* *Humain being(s)* (for human beings, fill only age and sex bellow)

Species	Breed	Sex	Statuts	Age/DOB	Weight (Kg)	Health status before start of Masivet
		F <input type="checkbox"/> M <input type="checkbox"/>	Neutered <input type="checkbox"/> Pregnant <input type="checkbox"/> Intact <input type="checkbox"/>			<input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor <input type="checkbox"/> Critical <input type="checkbox"/> Unknown

Medical history/Risk factors

SUSPECT DRUG (Masivet@)

Start date	Route	Dosage/Frequency	End date	Indication	Batch number- Expiry date

Masivet @ administered by: Veterinarian Animal owner Other
VETERINARY MEDICINAL PRODUCTS ADMINISTERED BEFORE THE ADVERSE EVENT*(if more products are administered concurrently than the number of boxes available, please duplicate this form)*

Medicinal Veterinary Product (VPM)	Route	Dosage/Frequency	Start date	Administered by: Veterinarian/Animal owner/Other	End date	Indication

Has the Health Authorities (HA) been informed?Yes No

SUSPECTED ADVERSE REACTION DATE / /	Time between first administration and event 	Number treated _____ Number reacted _____	Duration of adverse reaction
Evolution: Death <input type="checkbox"/> Euthanasia <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Recovered without sequelae <input type="checkbox"/> Ongoing <input type="checkbox"/> Date: / /			
DESCRIPTION OF THE EVENT – Indicate also if the reaction has been treated, how and with what was the result? 			
Causality assessment related to Masivet® and adverse reaction		Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unclassified <input type="checkbox"/> Unconclusive <input type="checkbox"/> Unlikely <input type="checkbox"/>	
Necropsie <input type="checkbox"/> File number : Investigations <input type="checkbox"/> :			
OTHER RELEVANT DATA (attach further papers if necessary (e.g. Investigations carried out, copy of necropsy report (if available) copy of medical report for human beings exposure or ongoing)			
HUMAN EXPOSURE CASE (if the reported case refers to human being, please also complete the details of exposure below.)			
• Contact with treated animal <input type="checkbox"/> • Oral ingestion <input type="checkbox"/> • Topical expositionn <input type="checkbox"/> • Others <input type="checkbox"/> Exposure dose:			
Date: Place: Name and signature of sender:			
Contact point (phone) (if different from number given on page 1)			

(*AB Science, represented by its Chief Executive Officer, is responsible for personal data, intended to record and evaluate event reports of adverse events within the scope of veterinary pharmacovigilance defined in Articles R.5141-94 to R.5141-110 of the French Public Health Code).
In accordance with the provisions of Regulation (EU) 2016/679 on the protection of individuals with regard to the processing of personal data and the data flow (GDPR) and the Data Privacy Protection and Rights - Act of 6 January 1978 amended, you have a right of access, rectification, limitation and, in certain cases, data erasure your private information. You may also, for legitimate reasons, forbid your private data processing.