

FORMULAIRE DE RAPPORT CONCERNANT LES EFFETS INDÉSIRABLES

(Pour les plaintes relatives à la qualité, allez à [la page 3](#))

Date de la notification initiale :

Date du suivi :

Questions relative à:

Contrefaçon, détournement, falsification Plainte de qualité ([page 3](#))

RAPPORTEUR

A savoir :

Vétérinaire/Pharmacien ou autre

Propriétaire/Patient humain

Nom :

Nom :

Pratique :

Adresse :

Adresse :

Tél. :

Tél. :

PATIENT(S)

Animal (animaux) Nom:

Être humain (*mentionnez ci-dessous seulement l'âge, sexe et poids*)

Espèce :

Race :

Statut :

Sexe :

Age :

Poids (kg):

	Vacciné/ Produit administré	Réaction	Récupéré	Euthanasie	Mort	Sous traitement	Blessure permanente	Inconnu
Nombre :	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date :	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Remarques :

Condition de santé au moment du traitement/Maladie déjà présente :

MÉDICAMENTS VÉTÉRINAIRES ADMINISTRÉS AVANT L'EFFET INDÉSIRABLE SUSPECTÉ

(si le nombre de produits administrés (à peu près au même temps) dépasse le 3, veuillez le mentionner sous la description)

	1	2	3
Dénomination du médicament vétérinaire administré			
Forme pharmaceutique & dosage (ex.: comprimés 100 mg)			
Numéro de lot			
Voie/site d'administration			
Dose / fréquence			
Date(s) de (première) vaccination(s)/administration			
<i>Si applicable :</i>			
Durée du traitement			
Date de commencement du traitement			
Date de fin du traitement			
Qui a administré le médicament vétérinaire? (vétérinaire, propriétaire, autre)			
Utiliser comme enregistré?	Oui Non	Oui Non	Oui Non
Pensez-vous que la réaction soit due à ce produit?	Oui Non	Oui Non	Oui Non

INFORMATION CONCERNANT L'EFFET INDÉSIRABLE OU LA MANQUE D'EFFICACITÉ SOUHAITÉ

Date de l'effet indésirable : Temps entre administration et réaction :
(en minutes, heures ou jours)

L'animal a été traité avant avec ce produit : Oui Non Inconnu Le vétérinaire a vu cette réaction avant : Oui Non Inconnu

L'animal a réagi avant à ce produit : Oui Non Inconnu L'animal a réagi sur un autre produit avant? : Oui Non Inconnu

DESCRIPTION DE L'INCIDENT: (HUMAIN OU ANIMAL)

Veuillez mentionner cet info additionnellement : La réaction indésirable a-t-elle été traitée, comment et avec quoi et avec quel résultat ? - Autres données importantes. (Éventuellement en pièce jointe, par exemple des résultats de laboratoire, des rapports de section, etc.)

Si le rapport concerne une réaction chez l'homme, veuillez également compléter les informations ci-dessous.

Enceinte : Oui Non Inconnu

Quantité/dose du médicament vétérinaire concerné :

Portez-vous des vêtements de protection ? (par exemple des gants): Oui Non Inconnu

FORMULAIRE DE PLAINTE QUALITÉ

Date de la notification initiale :

RAPPORTEUR

A savoir :

Vétérinaire/Pharmacien ou autre

Nom :

Pratique :

Adresse :

Tél. :

Propriétaire/Patient humain

Nom :

Adresse :

Tél. :

DONNÉES DU PRODUIT

Nom du produit - Présentation	Numéro de lot	Date de Péréemption
<input type="text"/>	<input type="text"/>	<input type="text"/>

AVEZ-VOUS PRIS DES PHOTOS DE DÉFAUT?

Oui, mail la photo à PharmacovigilanceMSDAHBenelux@merck.com

DESCRIPTIF DE LA PLAINTE :

ÉCHANTILLON

BELUX: Retourné au Grossiste?

Non Oui:

Nom du grossiste :

**VEUILLEZ AJOUTER CE FORMULAIRE
À LA RETOUR AU GROSSISTE STP.**

NL: Retourné à MSD Animal Health?

Non Oui:

Echantillon peut être envoyer
à l'adresse ci-dessous :

MSD Animal Health Nederland,
t.a.v. Denise Hendriks,
Antwoordnummer 11,
5830 VE Boxmeer

PRIVACY NOTICES:

Full Privacy notice DPOC and Medical Information:

When you contact MSD AH Nederland // MSD AH BV/SRL MSD processes personal data under this Privacy Notice and in accordance with applicable legislation, including the General Data Protection Regulation (2016/679; the "GDPR") and other applicable national data protection laws in The Netherlands - Belgium - Luxembourg.

MSD will collect your contact information of choice (i.e., email address and/or phone number) for the primary purpose of responding to your inquiry and documenting any Adverse Events or Product Quality Complaints reported by you. In addition, MSD will save: the details of your medical inquiry, the method used to contact us (e.g., email, phone), your role as a customer (e.g., animal owner, veterinary healthcare professional), and the product(s) and/or disease state pertaining to your question. We will also log the response we provide to the inquiry. These data are collected for statistical purposes and enable the company to identify information gaps and future research needs as well as improve communication about our products. For quality assurance purposes, and to ensure compliance with all rules and regulations, we likewise document how we provide answers to different types of customers and the appropriateness of our responses. This information will not be linked back to you and will be saved for the above purposes as long as there is a business or regulatory need to do so.

The above information is ultimately collected based on MSD's legitimate interest to ensure high quality customer service and enhance patient safety.

If you report an adverse event or other product experience which will need to be forwarded to regulatory authorities, we will collect relevant details about the animal (e.g., species, breed, age) and product (e.g., dose and formulation). Preferably, we will gather as much complementary information as possible to better understand the circumstances of the event. For instance, it is often essential for us to inquire about the animal's general medical history, including any prior health ailments, current conditions/diseases, and concomitant products administered. Again, the central purpose of requesting these details is to monitor the performance of our products, maximizing their safe and effective use in all patients.

The information that we collect is based on our company's legal requirements to document adverse and other reportable events, and it is intended for the interest of public and veterinary health. You decide how much data you choose to share with us. The quality of our service in responding to your inquiry will not be compromised if you choose not to share data.

Is data transferred or disclosed to third parties?

Since MSD is a global corporation, your data may be shared internally with the business units responsible for: processing adverse event reports, managing product quality complaints, and responding to veterinary information inquiries. These units could be located anywhere in the world.

Your data may be transferred to and processed by third-parties which perform services for MSD (data processors) to enable these companies to perform the services requested by MSD. Only the personal data that is necessary for the third party to fulfill the services will be supplied to these companies. All third-party providers must adhere to applicable written data processor agreements and implement appropriate technical and organizational measures for the protection of personal data.

If applicable, your data will also be reported to global regulatory authorities in an anonymized format as required by law and for the interest of public health.

We will not disclose personal data to any other third parties unless required to do so under the Data Protection Law or other laws or in order to establish, exercise, or defend legal claims.

Where is your data processed?

We primarily process personal data locally and on servers located in the United States, and as such we need to transfer your information to a location outside of the EU/EEA. The level of information protection in countries outside the EU/EEA may be lower than that offered within the EEA. Where this is the case, we will implement appropriate measures under the GDPR to ensure that your personal information remains protected and secure.

It is important to note that MSD complies with the EU-U.S. Privacy Shield Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information transferred from the European Union to the United States. MSD has certified to the U.S. Department of Commerce that it adheres to the Privacy Shield Principles. In addition, MSD has entered into Binding Corporate Rules, which have been approved in the European Union, that permit the transfer of personal information throughout the world to any other affiliate within the MSD group of companies (which includes a MSD affiliated company in the United States).

Your rights:

You have the right to request access to the personal data which MSD processes about you. Moreover, you have the right to request that incorrect or complete personal data is corrected. You also have the right to, at any time, withdraw your consent to the processing of your personal data, with future effect. If you revoke your consent, MSD will continue to process your personal data based on legal requirements of minimum criteria to report adverse events and save cases totally anonymized instead. If you do not wish to provide your data, the services provided by MSD will be unaffected to the extent possible.

Contact us:

MSD is the controller of the personal data for the purposes described above. The contact details of our offices can be found for NL at <https://www.my-msd-animal-health.nl/contact-customer-service/>, for BELUX at <https://nl.msd-animal-health.be/contacteer-ons/>

If you have any questions regarding MSD's processing of personal data, please feel free to visit <https://www.msdprivacy.com/nl/nl/index.html> or <https://www.msdprivacy.com/be/en/>.

If You Have Questions:

If you have questions or concerns regarding the processing of your personal data or want to exercise your privacy rights, please contact MSD AH (NL and BELUX) via MSD.AH.info@merck.com or by filling out the web form at <https://dsr.msd.com/DSR/Netherlands/Dutch/> or <https://dsr.msd.com/DSR/Belgium/English/>. Naturally, you also have the right, should you wish, to lodge a complaint with the <https://autoriteitpersoonsgegevens.nl/nl> or <https://www.dataprotectionauthority.be/citizen/homepage>.

Intervet Nederland B.V

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MSD Animal Health

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