zoetis Artwork Center / Louvain-la-Neuve / BELGIUM					LLN
GRAPHIST	Cécile Gavage	PRODUCT NAME	Duvaxyn WNV		COLOURS
CR NR	200001241	ITEM	LEAFLET	- / Z63	BLACK
DIR NR / V°	501473	NO GTIN NR			
COUNTRY (-IES)	ZA	NEW CODE	4001344 2	TECHNICLA MASTER / LAYOUT I009	
DATE(S) & VERSION(S) NR		OLD CODE		SIZE (mm)	KLEPS
29/06/2016 - v1		NA		105 x 250	10-2 / 60-1
01/07/2016-v2		DESCRIPTION OF REQUEST:			
		Product transfer to LLN			
DATAMATRIX CHECK		40013442		FONT SIZE(S)	7,5 pt

zoetis

For Animal Use Only

DUVAXYN® WNV

Reg. No. G4071 (Act 36 of 1947)

40013442

Inactivated vaccine emulsion against West Nile Virus infection for horses.

STORAGE INSTRUCTIONS
Store in the dark in a refrigerator between 2 °C – 8 °C. Do not freeze. Protect from light.

COMPOSITION
Each dose of 1 ml contains inactivated West Nile Virus, strain VM-2. RP* 1,0 – 2,2.
*Relative potency by *in vitro* method, compared to a reference vaccine that was shown to be effective in horses.
Contains MetaStim™ (SP Oil) adjuvant.

INDICATIONS
For the active immunisation of horses of 6 months of age or older against West Nile virus disease by reducing the number of viraemic horses. The onset of immunity is 3 weeks after the primary vaccination course. The duration of immunity is 12 months after primary vaccination.

WARNINGS
Do not vaccinate animals intended for slaughter for human consumption.
Keep out of reach of children, uninformed persons and pets.
Do not vaccinate unhealthy horses.

In case of accidental self injection, ingestion or spillage onto skin, seek medical advice immediately and show the package insert or label to the physician.

PRECAUTIONS
The vaccine can be used during pregnancy and lactation. Transient immunodepression may be observed during pregnancy and could interfere with vaccine effect.
Do not mix with any other veterinary medicinal product or other vaccines.
A small number of animals may show transient local reactions in the form of a mild, local swelling at the injection site post vaccination that resolve spontaneously within 1-2 days. It is sometimes associated with pain and mild depression. In some cases hyperthermia may occur for up to 2 days.
Consult a veterinarian if any symptoms persist.

Vaccination may interfere with existing sero-epidemiological surveys. However, since the IgM response following vaccination is infrequent, a positive IgM ELISA test result is a strong indicator of natural infection with West Nile Virus. If infection is suspected as a result of a positive IgM response, additional testing would need to be conducted to conclusively determine whether the animal was infected or vaccinated. No specific studies have been conducted to demonstrate absence of interferences from maternally-derived antibodies on vaccine take. It is therefore recommended not to vaccinate foals of less than 6 months of age.

DIRECTIONS FOR USE Use only as directed.
For intramuscular use. Administer 1 dose (1 ml) by deep intramuscular injection in the neck region, according to the following schedule:
Primary vaccination course
First injection from 6 months of age, second injection 3-5 weeks later.
Revaccination
A sufficient degree of protection should be achieved after an annual booster injection with a single dose although this schedule has not been fully validated.

PRESENTATION
2 x 1 ml prefilled syringes in a carton.

REGISTRATION HOLDER
Zoetis South Africa (Pty) Ltd
Co. Reg. No. 2012/001825/07
P.O. Box 783720, Sandton 2146
South Africa
Tel. (011) 245 3300
0860 ZOETIS (0860 963847)

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zoetis

Slegs Vir Dieregebruik

DUVAXYN® WNV

Reg. Nr. G4071 (Wet 36 van 1947)

Geïnaktiveerde entstof emulsie teen Wes Nyl Virusinfeksie in perde.

BERGINGSINSTRUKSIES
Berg in die donker in ŉ yskas tussen 2 °C – 8 °C. Moet nie bevries nie. Beskerm teen lig.

SAMESTELLING
Elke dosis van 1 ml bevat geïnaktiveerde Wes Nyl Virus, stam VM-2. RP* 1,0 – 2,2.
*Relatiewe potensie deur *in vitro* metode in vergelyking met ŉ verwysingsentstof wat doeltreffend bewys is in perde.
Bevat MetaStim™ (SP Olie) bevorderingsmiddel.

INDIKASIES
Vir die aktiewe immunisering van perde van 6 maande ouderdom of ouer teen Wes Nyl Virussiekte deur die aantal viremiese perde te verminder. Die aanvang van immuniteit is 3 weke na die primêre entingskursus. Die duur van immuniteit is 12 maande na primêre inenting.

WAARSKUWINGS
Moet nie diere, wat bestem is vir menslike verbruik, inent nie.
Hou buite bereik van kinders, oningeligte persone en diere.
Moet nie ongesonde perde inent nie.
In geval van toevallige selfinenting, inname of mors op vel, raadpleeg onmiddelik ŉ geneesheer en toon die voubiljet of etiket aan hom/haar.

VOORSORGMAATREËLS
Die entstof kan gedurende dragtigheid en laktasie gebruik word. Verbygaande immuunonderdrukking, wat waargeneem mag word tydens dragtigheid, mag entstofwerking belemmer.
Moet nie meng met enige ander veterinêre medisyne of ander entstowwe nie.
ŉ Klein aantal diere mag verbygaande lokale reaksies in die vorm van ŉ ligte, lokale swelling by die inspuitplek toon na inenting wat spontaan sal opklaar binne 1-2 dae. Dit word soms geassosieer met pyn en ligte depressie. In sommige gevalle mag hipertermie voorkom vir tot 2 dae. **Raadpleeg u veearts as enige simptome aanhou.**

Inenting mag bestaande sero-epidemiologiese opnames belemmer. Alhoewel die IgM reaksie na inenting nie dikwels voorkom nie, is ŉ positiewe IgM ELISA toetsresultaat ŉ sterk aanduiding van natuurlike infeksie met Wes Nyl Virus. Indien infeksie vermoed word as gevolg van ŉ positiewe IgM reaksie, moet addisionele toetse gedoen word om bo alle twyfel vas te stel of die dier besmet was of ingeënt is. Geen spesifieke studies is gedoen om die afwesigheid van belemmernis deur maternaal-verkrygde teenliggaampies op entingsopname te bepaal nie. Dit word daarom aanbeveel om nie vullens onder 6 maande ouderdom in te ent nie.

GEBRUIKSAANWYSINGS Gebruik slegs soos aangedui.
Vir binnespierse gebruik. Dien 1 dosis (1 ml) toe deur diep binnespierse inspuiting in die nekarea volgens die volgende skedule:
Primêre entingskursus
Eerste inspuiting vanaf 6 maande ouderdom gevolg deur ŉ tweede inspuiting 3-5 weke later.
Herinenting
ŉ Voldoende graad van beskerming sal bereik word na die jaarlikse versterkingsinspuiting met ŉ enkele dosis alhoewel hierdie skedule nog nie voldoende bevestig is nie.

AANBIEDING
2 x 1 ml voorafgevulde spuite in ŉ karton.

REGISTRASIEHOUER
Zoetis South Africa (Pty) Ltd
Mpy. Reg. Nr. 2012/001825/07
Posbus 783720, Sandton 2146
Suid-Afrika
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Document Approvals

Stephanie Kuhn	South Africa - MRO Lead 04-Jul-2016 09:24:40 GMT+0000

Francoise Bosschaert	Louvain-La-Nueve - Site QA 05-Jul-2016 10:22:12 GMT+0000

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