## VPA10484/022/001

## Parazole Dog/Cat 100 mg/ml Oral Suspension

VRA-S - Vet - G.I.18 - One-off alignment of the prinformation with version 9.0 (or the latest version of QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD template major update of the QRD templates in accordance Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2 G.I.18 Safety, Efficacy, Pharmacovigilance change One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates are in effect at the time that this one-off variation submitted) of the QRD templates i.e. major update QRD templates in accordance with Regulation (EU 2019/6, for veterinary medicinal products placed of	of the is ees i.e. with 2004 - es - ates ion is of the J) n the	23/06/25
market in accordance with Directive 2001/82/EC o Regulation (EC) No 726/2004	<u> </u>	
VNRA - Vet - B44 - Submission of a new or update Eur. CEP from an already approved manufacturer in non-sterile active substance, starting material, reagnintermediate, excipient - B44 Changes to the quality of the dossier: Submission of a new or updated Ph. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material reagent or intermediate used in the manufacturing profession of the active substance; — excipient	for a ent or cy part Eur.	10/06/25
VNRA - Vet - B3 a) - a) Deletion of a manufacturing for an active substance, intermediate or finished propackaging site, manufacturer responsible for batch site where batch control takes place, or supplier of starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a)  Vet - B3 a)  Changes to the quality part of the dossier: Deletion manufacturing site for an active substance, interme or finished product, packaging site, manufacturer responsible for batch release, site where batch cont takes place, or supplier of a starting material for an substance, reagent or excipient (when mentioned in dossier)	oduct, release, a of a ediate arol active	01/05/25
Vet - A1 a)  Vet - A1 a)  Vet - A1 a)  Vet - B44(Do not use)  VNRA - Vet - A1 a) - a) Change in the name or adcontact details of the marketing authorisation holder a) Administrative changes: Change in the name or or contact details of the marketing authorisation holder a) VNRA - Vet - B44 - Submission of a new or updated and the	er - A1 address older	16/05/24

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	Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	
Vet - F.II.e.1 z	VRA-R - Vet - F.II.e.1 z - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.1 z) Quality Changes - Container closure system - Change in immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	26/02/24
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	26/02/24
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.1 z) Quality Changes - Finished Product - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	26/02/24
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.1 z) Quality Changes - Finished Product - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	26/02/24
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.1 z) Quality Changes - Finished Product - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	26/02/24
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.1 z) Quality Changes - Finished Product - Manufacture - Replacement or addition of a manufacturing site for part or all of the	26/02/24

	manufacturing process of the finished product. Other	
	manufacturing process of the finished product - Other	
	changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - z) Other changes under this	
	code level e.g. variations outlined in section 6 and 7 of	
	EMA/CMDv/7381/2021 - F.II.b.1 z) Quality Changes -	
	Finished Product - Manufacture - Replacement or addition	26/02/24
	of a manufacturing site for part or all of the	
	manufacturing process of the finished product - Other	
	changes under this code level, e.g. variations outlined in	
	section 6 and 7 of EMA/CMDv/7381/2021	
	VRA-R - Vet - F.II.b.1 c) - c) Site where any	
	manufacturing operation(s) take place, except	
	batch-release, batch control, primary and secondary	
	packaging, for non-sterile medicinal products - F.II.b.1 c)	
Vet - F.II.b.1 c)	Quality Changes - Finished Product -Manufacture -	26/02/24
vet 1.11.0.1 c)	Replacement or addition of a manufacturing site for part	20/02/24
	or all of the manufacturing process of the finished product	
	- Site where any manufacturing operation(s) take place,	
	except batch-release, batch control, primary and	
	secondary packaging, for non-sterile medicinal products	
	VRA-S - Vet - F.II.e.2 z) - z) Other changes under this	
	code level e.g. variations outlined in section 6 and 7 of	
Vet - F.II.e.2 z)	EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes -	
	Container closure system - Change in the specification	26/02/24
	parameters and/or limits of the immediate packaging of	20/02/24
	the finished product - Other changes under this code level,	
	e.g. variations outlined in section 6 and 7 of	
	EMA/CMDv/7381/2021	
	VNRA - Vet - C6 - Introduction of a summary of the	
	PSMF or changes to the summary of the PSMF not	
Vet - C6	already covered elsewhere in the Annex to Regulation	
	(EU) 2021/17 - C6 Changes to the safety, efficacy and	10/07/22
	pharmacovigilance part of the dossier: Introduction of a	19/07/23
	summary of the PSMF or changes to the summary of the	
	PSMF not already covered elsewhere in the Annex to	
	Regulation (EU) 2021/17	
	VNRA - Vet - C1 - Change(s) in the name or address or	
	contact details of a qualified person for	
V . C1	pharmacovigilance (QPPV) - C1 Changes to the safety,	00/05/22
Vet - C1	efficacy and pharmacovigilance part of the dossier:	09/05/23
	Change(s) in the name or address or contact details of a	
	qualified person for pharmacovigilance (QPPV)	
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site	
	for an active substance, intermediate or finished product,	
	packaging site, manufacturer responsible for batch release,	
	site where batch control takes place, or supplier of a	12/12/22
	starting material for an active substance, reagent or	
	excipient (when mentioned in the dossier) - B3 a)	
	Changes to the quality part of the dossier: Deletion of a	
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	manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	
A.1	IAin - A.1 - A.1 Change in the name and/or address of the marketing authorisation holder - A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder	11/03/22