Bezpečnost uživatele

- Část I C – Podrobné a kritické souhrny
- Část III A – Zkoušky bezpečnosti a reziduí

1. Přesná identifikace přípravku
2. Farmakologie
3. Toxikologie
4. Další požadavky
5. Bezpečnost uživatele

Dana Halová

ÚSKVBL

15 March 2010
EMA/CVMP/543/03-Rev.1
Committee for medicinal products for veterinary use (CVMP)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guideline on user safety for pharmaceutical veterinary medicinal products

Adoption by CVMP for release for consultation	12 January 2005
Date of coming into effect	13 July 2005
Revision by CVMP Safety Working Party	27 February 2009
Adoption by CVMP for release for consultation	17 April 2009
End of consultation (deadline for comments)	31 August 2009
Agreed by CVMP Safety Working Party	4 February 2010
Adoption by CVMP	10 March 2010
Date for coming into effect	1 October 2010

This guideline replaces guideline the guideline on user safety for pharmaceutical veterinary medicinal products that came into effect on 13 July 2005 (EMEA/CVMP/543/03-FINAL)

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Guideline on user safety for pharmaceutical veterinary medicinal products

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seznam literatury by měl obsahovat jen relevantní a doložené texty článků

mg × µg

překlepy

NIELS HJØRTH AND JYTTE RØED-PETERSEN

zhodnocení možných expozic

Kvalitativní charakterizace rizika
MOE = NOAEL / expozice

Struktura bodu 4.5 SPC:

- A - riziko
- B – čemu se vyhnout pro minimalizaci rizika
- C – jak zabránit expozici
- D – co dělat v případě expozice

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Nový pokyn

19 April 2018
EMA/CVMP/SWP/721059/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline on user safety of topically administered veterinary medicinal products

Draft Agreed by Safety Working Party (SWP-V)	May 2016
Adoption by CVMP for release for consultation	16 June 2016
Start of public consultation	27 June 2016
End of consultation (deadline for comments)	31 December 2016
Agreed by SWP-V	February 2018
Adopted by CVMP	19 April 2018
Date for coming into effect	1 November 2018

This guideline will supplement the existing 'Guideline on user safety for pharmaceutical veterinary medicinal products' (EMA/CVMP/543/03-Rev.1).

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Guideline on user safety of topically administered veterinary medicinal products

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- **Kontakt s přípravkem**
  - Preaplikační fáze – p.o. dítě 12,5 kg, 10% balení, max. 5 ml a 2 cm obojku
    - Není riziko – dermální expozici nepočítat
    - Je riziko - dermální expozici počítat a balení upravit na rezistentní proti dětem
  - Aplikační fáze – dospělý 60kg
    - HTM (max. 1% max. dávky)
    - dermální (max. 10% max. dávky)

$$D = \frac{\mathrm{AR} * \mathrm{FA}}{\mathrm{BW}}$$

- **Kontakt s ošetřeným zvířetem**
  - Krátkodobý
    - Dermální
    - HTM
    - D + HTM
  - Dlouhodobý - dítě 12,5 kg, případně gravidní
    - Dermální
    - HTM
    - D + HTM

$$\mathrm{TR} = \frac{\mathrm{AR} * \mathrm{F}_{AR}}{\mathrm{SA}_{animal}}$$

$$\mathrm{DE}_{bw-corr} = \frac{\mathrm{TR} * \mathrm{SA}_{contact}}{\mathrm{BW}}$$

$$\mathrm{HR} = \frac{\mathrm{DE} * \mathrm{F}_h}{\mathrm{SA}_h}$$

$$\mathrm{OE} = \frac{\mathrm{HR} * \mathrm{SA}_m * \mathrm{HTM} * \mathrm{HIM}}{\mathrm{BW}}$$

+ Wipe test

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SCIENCE MEDICINES HEALTH

Nový pokyn 2

6 December 2018
EMA/CVMP/SWP/377245/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products

Agreed by Safety Working Party (SWP-V)	November 2016
Agreed by Efficacy Working Party (EWP-V)	December 2016
Agreed by Quality Working Party (QWP)	February 2017
Adoption by CVMP for release for consultation	16 February 2017
Start of public consultation	24 February 2017
End of consultation (deadline for comments)	31 August 2017
Agreed by EWP-V	30 May 2018
Agreed by QWP	28 September 2018
Agreed by SWP-V	23 October 2018
Adoption by CVMP	6 December 2018
Date for coming into effect	1 July 2020

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Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products

- Omezení potenciálního karcinogenního rizika spojeného s expozicí potenciálně mutagenním nečistám
- Identifikace, kategorizace, kvalifikace a kontrola mutagenních nečistot
- Doplnění:
- VICH GL10 – Nečistoty v nových vet. přípravcích
- VICH GL11 – Nečistoty v nových vet. látkách

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Reference:

- EMEA/CVMP/543/2003 Rev. 1 – User safety for pharmaceutical veterinary medicinal products
- EMA/CVMP/SWP/721059/2014 - Guideline on user safety of topically administered veterinary medicinal products
- EMA/CVMP/SWP/377245/2016 – Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products
- Notice to applicants, Veterinary medicinal products, Presentation and content of the dossier, Eudralex, volume 6B, 2015
- EMA VICH GL22, 23, 28, 31, 32, 33, 37, 54
- SMĚRNICE EVROPSKÉHO PARLAMENTU A RADY 2001/82/ES o kodexu Společenství týkajícím se veterinárních léčivých přípravků
- 378/2007 Sb. Zákon o léčivech
- 228/2008 Sb. Vyhláška o registraci léčivých přípravků