EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP assessment report for Rheumocam 330 mg granules in sachet for horses (EMEA/V/C/000121/X/0015)

International non-proprietary name: meloxicam

Assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.

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Product profile

Invented name:	Rheumocam
Active substances:	Meloxicam
Target species:	Horses
Pharmaceutical form:	Granules in sachet
Strength:	330 mg
Therapeutic indication:	Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in horses weighing between 500 and 600 kg.
ATCvet code:	QM01AC06
Pharmaco-therapeutic group:	Anti-inflammatory and anti-rheumatic products, non-steroids, oxicams
Applicant:	Chanelle Pharmaceuticals Manufacturing Ltd

Introduction

On 28 October 2013 Chanelle Pharmaceuticals Manufacturing Ltd submitted an application for an extension to the Community marketing authorisation for Rheumocam to the European Medicines Agency (the Agency) in accordance with Article 19 of Commission Regulation (EC) No. 1234/2008 and Annex I points 2(c) and 2 (d) thereof.

Rheumocam contains meloxicam and was first authorised for use in the European Union on 10 January 2008 under Article 13(1) of Directive/2001/82/EC, a generic application.

The product is currently available in different pharmaceutical forms (chewable tablets, solution for injection and oral suspension) for different target species (cattle, pigs, horses, dogs and cats).

This extension application is to add a new strength of meloxicam (330 mg) and a new pharmaceutical form (granules in sachet) for horses. The route of administration is in-feed use. The reference product is Metacam 15 mg/ml oral suspension for horses; no corresponding Metacam 330 mg granules is authorised.

The applicant applied for the following indication "alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders".

The rapporteur appointed was M. Holzhauser-Alberti and the co-rapporteur was E.-M. Vestergaard.

On 12 March 2015 the CVMP adopted an opinion and CVMP assessment report.

On 12 May 2015, the European Commission adopted a Commission Decision granting an extension to the marketing authorisation for Rheumocam.

Part 1 - Administrative particulars

Detailed description of the pharmacovigilance system

The applicant has provided a detailed description of the pharmacovigilance system (version 12) which fulfils the current legal requirements of Directive 2001/82/EC. Based on the information provided the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in the Community or in a third country.

Manufacturing authorisations and inspection status

The manufacturing site of the active substance is in the European Union (EU) and the manufacturing site for the finished product is Chanelle Pharmaceuticals Manufacturing Ltd, Ireland. Batch release for the EU will be carried out by Chanelle Pharmaceuticals Manufacturing Ltd, Ireland.

All relevant sites have valid manufacturing authorisations.

Good manufacturing practice (GMP) compliance of the manufacturer of the active substance is claimed by the applicant by a declaration from the qualified person at the site for batch release and relies on an on-site audit performed by Chanelle Pharmaceuticals Manufacturing Ltd, Ireland in November 2014.

Overall conclusions on administrative particulars

The detailed description of the pharmacovigilance system and the GMP certification of the manufacturing sites were considered in line with legal requirements.

Part 2 - Quality

Composition

Rheumocam 330 mg granules for horses, is a pale yellow granular powder for oral administration. This product has been formulated to be bioequivalent to Metacam 15 mg/ml oral suspension. Both contain the active ingredient meloxicam, however in different concentrations and with different excipients.

The proposed new pharmaceutical form contains the following excipients: glucose monohydrate (filler and sweetener), apple flavour (flavour), crospovidone (disintegrant) and povidone (binder). The excipients are considered typical for this type of dosage form and are therefore acceptable. A corresponding Metacam formulation is not available.

Container

Rheumocam 330 mg granules for horses is presented in paper foil sachets containing 1,500 mg of finished product and is available in a pack size of 100 sachets in a cardboard box. The finished product is a single-dose product.

Development pharmaceutics

Rheumocam 330 mg granules for horses, was developed to be bioequivalent to Rheumocam 15 mg/ml oral suspension. However, Rheumocam 15 mg/ml oral suspension was not considered to be an appropriate reference product as it is a generic and the applicant submitted during the procedure a new bioequivalence study with Metacam 15 mg/ml oral suspension as reference product. Both products Rheumocam 330 mg granules and Metacam 15 mg/ml oral suspension can be administered mixed with food, but the granules may be more readily mixed into food than the suspension. Furthermore, the granules are presented in sachets that allow administering the same amount of active substance to the horse from a smaller volume of packaging.

An apple flavour is included in the formulation, but the finished product is not considered palatable. This excipient is included into the formulation in order to facilitate the administration of the finished product.

The finished product is indented to be administrated mixed with food. There is no incompatibility of the product with the food used in the bioequivalence study. The type of food (typical muesli) used in the bioequivalence study is considered representative of food usually given to horses.

Comparative impurity data of Rheumocam 330 mg granules versus Metacam 15 mg/ml oral suspension were presented. The level of identified impurities, as well as the level of individual unknown and total impurities is similar between these two products.

Method of manufacture

The finished product is manufactured according to a standard process (wet granulation) at Chanelle Pharmaceuticals Manufacturing Ltd. in Ireland. The description of the manufacturing process and the level of detail provided are considered satisfactory.

Appropriate in-process controls have been set to monitor the manufacturing process and ensure it is controlled.

The validation of the manufacturing process has been satisfactorily conducted on two industrial scale batches of 10 kg which is the smallest commercial batch size for this product. The complete validation on

commercial scale batches will be performed at Chanelle Pharmaceuticals Manufacturing Ltd., Ireland, which is the manufacturing site declared for commercial batches. This is considered acceptable.

Control of starting materials

Active substance

The active substance, meloxicam, is described in the European Pharmacopoeia (Ph. Eur.). An active substance master file was provided and has been assessed previously for the initial marketing authorisation of Rheumocam. However, a new version of the restricted part has been provided and the changes proposed within this new version are acceptable.

The proposed retest period for the active substance is 5 years, stored in polyethylene bags in fibre drums. Results from storage of batches of the substance for up to 60 months at 25 °C/ 60% relative humidity (RH) and for 6 months at 40 °C/75% RH are available. No relevant changes were observed. The proposed retest period is considered acceptable.

Excipients

All the excipients are the subject of a monograph of the Ph. Eur. except the apple flavour for which supplier's data on its composition are provided. An appropriate specification has been set for this excipient. Certificates of analysis from the finished product and the excipients manufacturers have been provided for each component. The results comply with the specifications.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

None of the starting materials used for the active substance meloxicam or the finished product are risk materials as defined in the current version of the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3).

Transmissible spongiform encephalopathy (TSE) declarations for each component of the finished product (active substance and excipients) have been provided by the respective manufacturer and the manufacturer of the finished product.

Control tests during production

Not applicable.

Control tests on the finished product

The product specification includes tests for appearance (visual), identity and assay of meloxicam (HPLC), weight, moisture (Ph. Eur.), uniformity of dosage units (Ph. Eur.), identity of flavour (organoleptic), microbial purity (Ph. Eur.) and particle size distribution. The proposed test parameters and limits are considered acceptable.

The analytical methods used in the control of the finished product are validated, when necessary, and are considered acceptable.

The results of the analysis of two production scale batches of finished product were presented which comply with the proposed specification.

Stability

Results from stability studies with two production scale batches of the finished product are available at long term conditions (25 °C/60% RH) for 24 months and accelerated conditions (40 °C/75% RH) for 6 months.

The shelf life specification is the same as at release except that limits for related substances have been established at the end of shelf life.

Based on the stability data provided, extrapolation of long term data from 24 months up to 36 months is justified and the proposed shelf life of 3 years is considered acceptable.

No photostability study is presented. However, as the granules are filled into opaque sachets which are considered suitable for the protection of the finished product this is considered acceptable. After mixing into food, the finished product has to be administrated immediately and has not to be stored. A recommendation in this regard is included in the product information.

The proposed shelf life of 3 years without any special storage conditions is acceptable.

Overall conclusions on quality

The dossier provides a suitable description of the formulation and demonstrates that the manufacturing process leads to a stable product with consistent quality.

All the components of the finished product are the subject of a monograph in the Ph. Eur. except the apple flavour for which an appropriate specification has been set.

The finished product is manufactured by wet granulation which is a standard process. Complete process validation on commercial scale batches will be performed at the site of manufacture of the commercial batches.

Finished product specification limits at release and end of shelf life are appropriate and control appropriate parameters for this dosage form.

The finished product is a single-dose presentation containing 1,500 mg of granules (330 mg of meloxicam/sachet). It will be available in cardboard boxes containing 100 sachets.

Stability data for the active substance and dosage form are sufficient to support the claimed retest period and shelf life respectively.

Based on the review of the data on quality, the manufacture and control of Rheumocam 330 mg granules for horses are considered acceptable.

Part 3 – Safety

This extension application is to add a new strength (330 mg) and a new pharmaceutical form (granules in sachet) for the existing target species horses. In support of this application, an in vivo bioequivalence study in horses was provided with Rheumocam 15 mg/ml oral suspension but this product was not considered to be an appropriate reference product as it is a generic of Metacam. The applicant submitted during the procedure a new bioequivalence study with Metacam 15 mg/ml oral suspension as reference product (see part 4). This was considered an appropriate reference product.

Concerning Rheumocam 330 mg granules for horses, the quantitative composition in active substance is not the same as for the reference product and the pharmaceutical form is not identical (granules versus oral suspension).

However, both products are to be administered orally mixed with feed and the dose regimen is identical, 0.6 mg meloxicam/kg bodyweight (bw) once daily for 14 consecutive days. The CVMP considered that the same principles as for classical generic applications, concerning bioequivalence, could be applied to the assessment of this application.

Safety documentation

Pharmacodynamics

See Part 4.

Pharmacokinetics

See Part 4.

Toxicological studies

No toxicological studies were provided. This application is a line extension of a generic medicinal product and the toxicological profile of meloxicam does not need to be reassessed. This is considered acceptable as in support of the application, a bioequivalence study has been provided which demonstrated that Rheumocam 330 mg granules for horses and Metacam 15 mg/ml oral suspension for horses are bioequivalent.

Tolerance in the target species of animal

See Part 4.

User safety

The applicant has presented a user safety assessment that was conducted in accordance with the current CVMP Guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03-Rev.1).

The professional user will be the veterinary surgeon and relevant staff and animal handlers and the non-professional user will be the animal's owner. The most likely route of exposure is via accidental ingestion which can be considered as acute exposure.

As all excipients in the test product are commonly used in human and veterinary medicinal products and their toxicological profiles are well known, it can be assumed that they will not raise a toxicological concern. It is considered that the apple flavour does not pose any particular concern.

The proposed warning sentences resulting from the user safety assessment are the same as for the reference product Metacam 15 mg/ml oral suspension for horses.

The CVMP concluded that the product does not pose an unacceptable risk to the user when used in accordance with the summary of product characteristics (SPC).

Environmental risk assessment

A phase I environmental risk assessment was provided in line with line with the VICH GL6 on environmental impact assessment (EIAs) for veterinary medicinal products (VMPs) - Phase I (CVMP/VICH/592/98-FINAL). Given that the product is for the treatment of an individual or a small number of animals in a flock or herd, the environmental risk assessment can stop at Phase I.

Rheumocam 330 mg granules, is not expected to pose a risk for the environment when used according to the SPC.

Overall conclusions on the safety documentation

The applicant has provided a user safety assessment that was conducted in accordance with the current CVMP guideline on user safety for pharmaceutical veterinary medicinal products (EMEA/CVMP/543/03-Rev.1).

As all excipients are commonly used in human and veterinary medicinal products and their toxicological profiles are well known, it can be assumed that they will not raise a toxicological concern. The proposed warning sentences included in the SPC are considered appropriate to ensure the safety of the person who will administer the product. The CVMP concluded that the product does not pose an unacceptable risk to the user when used in accordance with the SPC.

Rheumocam 330 mg granules for horses, is not expected to pose a risk for the environment when used according to the SPC.

Residues documentation

The active substance of the product Rheumocam 330 mg granules for horses is meloxicam. This product is indicated in horses with a recommended dose of 0.6 mg/kg bw, once daily up to 14 days by oral route either mixed in feed or given directly into the mouth.

MRLs

The active substance in Rheumocam is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) 37/2010:

Pharmacologi-cally active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, *Equidae*	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	NO ENTRY	Anti-inflammatory agents / Nonsteroidal anti-inflammatory agents
		Bovine, caprine	15 µg/kg	Milk		

The excipients listed in section 6.1 of the SPC, with the exception of apple flavour, are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

Apple flavour is a branded excipient and, as such, is neither included in table 1 of the annex to Regulation (EU) No. 37/2010, nor in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009. The full qualitative and quantitative composition of the flavour was provided and the CVMP considers that this excipient does not pose a risk to the consumer.

Withdrawal periods

No residue depletion studies were provided.

The applicant referred to a bioequivalence study performed with Rheumocam 330 mg granules and Metacam 15 mg/ml oral suspension for horses. As bioequivalence with the reference product was shown, and as the product is to be administered orally, no new confirmatory local residue studies would be necessary. According to the CVMP Note for guidance: approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95 FINAL) and the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2) confirmatory local residue studies, in the case of a generic application, are required only for parenterally administered products via intramuscular or subcutaneous route.

The test and reference products were administered in the same way, e. g. mixed with the same amount of feed. From the results of this study, the bioequivalence between the two products is demonstrated.

The withdrawal period proposed by the applicant is the same as that of the reference product (meat and offal: 3 days) and is considered acceptable.

In addition, the following sentence is included in section 4.11 of the SPC: Not authorised for use in lactating animals producing milk for human consumption.

Overall conclusions on the residues documentation

The MRL status of the active substance and the excipients is considered to be fully documented. In particular, the full qualitative and quantitative composition of the apple flavour was provided and the CVMP considers that this excipient does not pose a risk to the consumer.

The proposed withdrawal period for meat and offal of 3 days is accepted as the bioequivalence with an appropriate reference product is demonstrated. The product is not authorised for use in lactating animals producing milk for human consumption.

Part 4 – Efficacy

This extension application is to add a new strength and pharmaceutical form of meloxicam, i.e. 330 mg of meloxicam per sachet in the form of granules, for the existing target species horses.

In support of this application, an in vivo bioequivalence study was provided with Rheumocam 15 mg/ml oral suspension in horses as reference product. The CVMP considered this study not acceptable as the chosen reference product was not appropriate.

A new bioequivalence study was performed in horses following single oral administration of 0.60 mg of meloxicam/kg bw between Rheumocam 330 mg granules for horses and an adequate reference product, Metacam 15 mg/ml oral suspension for horses. This good laboratory practice (GLP) study was satisfactory and performed according to the requirements of the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2). The test and reference products were administered mixed with the same amount of feed.

From the results of this study, the bioequivalence between the two products is demonstrated.

Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. In vitro and in vivo studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

Development of resistance

Not applicable.

Pharmacokinetics

A GLP-compliant bioequivalence study was performed in the Czech Republic in 2014 with 24 horses. The test and reference products were Rheumocam 330 mg granules for horses and Metacam 15 mg/ml oral suspension for horses respectively.

The study was performed according to the requirements in the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2).

It is a single-dose, two-period, two-sequence, cross-over bioequivalence study with a 15-day wash-out period.

The test and the reference products were administered at the recommended dose of 0.60 mg of meloxicam/kg bw mixed with the same amount of feed. The product was administered into the trough thoroughly mixed together with small amount of muesli feed (approximately 250 g) usually used at the test site. Consumption of the whole dose and its swallowing were checked. The whole administered product with muesli feed was consumed always within 2–3 minutes. A single dose of the product was administered at each period.

Blood samples were stored frozen and the sampling times were pre-dose and at appropriate time intervals post-dose. Physical examination and clinical observation focused on general tolerance, local tolerance and adverse events (AEs) of animals (general appearance, behaviour and appetite) were performed. No changes of clinical health, no local or general intolerance and no adverse events were observed.

From the results of this study, the bioequivalence between the two products was considered to be established on the basis of the mean area under the curve (AUC) falling in between the margins of the reference product (81.7%–113.2%; 90% CI) and C_{max} falling in between the margins of the reference product (83.1%–111.9%; 90% CI).

Dose determination/justification

Not applicable.

Target animal tolerance

No specific tolerance study has been conducted with the Rheumocam 330 mg granules for horses.

In the pivotal bioequivalence study with Metacam 15 mg/ml oral suspension for horses both products were administered mixed with feed and there were no issues with the administration. Apple flavour is present in the test product but not in the reference product Metacam but there were no differences reported in the bioequivalence study with the administration of both products. The presence of the apple flavour did not have a negative effect on the palatability.

Rheumocam 330 mg granules for horses, is a more concentrated formulation of meloxicam than Metacam 15 mg/ml oral suspension. One important side effect of local tolerance of NSAIDs is whether the active substance is carried to the right dorsal colon where it can exert a direct toxic effect (e.g. right dorsal colitis). This is well described for other types of NSAIDs. A more concentrated formulation of meloxicam could have a similar effect whereby significant amounts could be carried to the right dorsal colon and

exert a direct toxic effect. This is independent of the dose since a lower amount is needed, in a more concentrated formulation, to be carried to the right dorsal colon to exert the toxic effect.

The applicant provided a relevant review of published literature that shows no reports of any issues with tolerance with meloxicam when used in horses.

Furthermore, the tolerance of Rheumocam 330 mg granules for horses was followed in the bioequivalence study and no adverse effects were reported. Thus, this new more concentrated form of meloxicam can be expected to be well tolerated locally in the intestines of horses over time (14 days of consecutive administration is claimed).

In order to minimise the risk of intolerance due to a greater concentration of meloxicam section 4.9 of the SPC clearly states that "The product should be added to 250 g of muesli feed, prior to feeding", as per the conditions in the bioequivalence study.

The product is packaged as a single-dose sachet and as such administration to the horse cannot be done according to the bodyweight of the horse. Therefore, the use of the product is restricted, as a single-dose product, to adult horses weighing between 500 kg and 600 kg. This restriction allows a precise dosage for adult horses as for the reference product. Without this restriction the dosing band would be much greater than that for the reference product.

The information relating to contraindications, adverse effects, precautions for use, interactions and overdose included on the proposed SPC for Rheumocam 330 mg granules for horses is the same as that included on the SPC of the reference product.

Rheumocam 330 mg granules for horses is contraindicated in pregnant or lactating mares, in foals less than 6 weeks old and in horses suffering from gastrointestinal disorders because the safety is not documented.

Taking into account that the product is an oral dosage form, bioequivalence was tested versus Metacam 15 mg/ml oral suspension for horses where no adverse events or intolerance were reported, the toxicological profile of the active substance is well known and has been adequately characterised in the published literature and that the excipients are recognised as being non-toxic, the CVMP concluded that the absence of tolerance studies with Rheumocam 330 mg granules is acceptable.

Overall conclusion on efficacy

A GLP bioequivalence study was performed in horses following single oral administration of 0.60 mg of meloxicam/kg bw with Rheumocam 330 mg granules for horses and Metacam 15 mg/ml oral suspension for horses. The choice of the reference product is considered appropriate and the bioequivalence is accepted.

This bioequivalence study supports the indication "For the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses" as authorised for the reference product Metacam 15 mg/ml oral solution for horses.

Rheumocam 330 mg granules for horses is a single-dose product restricted to horses weighing between 500 kg and 600 kg in order to achieve the same dosing range as the reference product.

The CVMP concluded that the product is well tolerated when used according to the SPC.

Part 5 – Benefit-risk assessment

The application for Rheumocam 330 mg granules for horses is an extension application to add a new strength (330 mg) and a new pharmaceutical form (granules in sachet) for the existing target species horses.

The applicant based their application upon bioequivalence with Metacam 15 mg/ml oral suspension for horses.

The proposed indication is: Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

The proposed withdrawal periods for meat and offal of 3 days is accepted. The product is not authorised for use in lactating animals producing milk for human consumption.

Benefit assessment

Direct therapeutic benefit

The active substance, meloxicam, is a well-known non-steroidal anti-inflammatory drug in veterinary medicine. It is beneficial in the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in horses.

The evidence for the direct therapeutic benefit is considered established on the basis of bioequivalence to the reference product.

Additional benefits

The product is presented as a granules formulation with apple flavour to facilitate administration to horses and increases the range of available treatment possibilities.

Risk assessment

Potential risks were identified as follows:

Quality:

The formulation and manufacture of Rheumocam 330 mg granules for horses are well described and specifications set will ensure that product of consistent quality will be produced.

For the target animal:

The product should be administered as a single-dose product and only to horses weighing between 500 kg and 600 kg to prevent the risk of over- or under-dosing.

The same information and warnings as for the reference product are included in the product information for the safe use in the animals.

Additionally, Rheumocam 330 mg granules for horses is a more concentrated form of meloxicam than the reference product with the risk of the active substance being carried to the right dorsal colon where it can exert a direct toxic effect. In order to address local tolerance concerns in the gut of horses, the SPC and package leaflet indicate that the single-dose product should be mixed with a small portion (250 mg) of muesli feed, as per the bioequivalence study.

For the user:

The CVMP concluded that user safety for this product is acceptable when used as recommended and taking into account the safety advice in the SPC.

For the environment:

Rheumocam 330 mg granules for horses, is not expected to pose a risk for the environment when used according to the SPC.

For the consumer:

Apple flavour is an excipient which is not present in the reference product. The CVMP considered that this excipient does not pose a risk to the consumer.

The proposed withdrawal period for meat and offal of 3 days is accepted as bioequivalence with the reference product is demonstrated. The product is not authorised for use in lactating animals producing milk for human consumption.

Risk management or mitigation measures

Appropriate information has been included in the SPC to inform on the potential risks of this product relevant to the target animal, the user, the environment and the consumer and to provide advice on how to prevent or reduce these risks.

Evaluation of the benefit-risk balance

Rheumocam 330 mg granules for horses is beneficial in the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in horses

The formulation and manufacture of Rheumocam 330 mg granules for horses is well described and specifications set will ensure that product of consistent quality will be produced.

It is well tolerated by the target animals and presents an acceptable risk for users and the environment when used as recommended and appropriate warnings have been included in the SPC. A sufficient withdrawal period has been set.

Appropriate warnings have been included in the SPC and other product information.

The product has been shown to have a positive benefit-risk balance overall.

Conclusion on the benefit-risk balance

The overall benefit-risk evaluation for the product is deemed positive with a sufficiently clear and complete product information.

Conclusion

Based on the original and complementary data presented the CVMP concluded that the quality, safety and efficacy of Rheumocam 330 mg granules for horses are considered to be in accordance with the requirements of Directive 2001/82/EC.

Based on the CVMP review of the data on quality, safety and efficacy, the CVMP recommends the extension of the marketing authorisation for Rheumocam to include Rheumocam 330 mg granules for horses weighing between 500 and 600 kg.