

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 April 2003 (24.04.2003)

PCT

(10) International Publication Number
WO 03/033031 A1

(51) International Patent Classification⁷: **A61K 009/52**,
031/351, 033/04, A61P 33/00

(21) International Application Number: PCT/AU02/01426

(22) International Filing Date: 18 October 2002 (18.10.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PR 8390 19 October 2001 (19.10.2001) AU

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DOSAGE FORM, DEVICE AND METHODS OF TREATMENT

(57) **Abstract:** The present invention relates to a controlled dosage release element adapted to be inserted into and retained in the rumen of a ruminant animal. The element comprises: a) one or more discrete and predetermined amounts of at least a first formulation comprising at least a first active agent, the formulation being adapted to dissolve in rumen fluids at a rate such that dissolution of each of the one or more amounts of first formulation provides a short or pulsed episode of release of the first active agent into the rumen; and b) one or more predetermined amounts of at least a second formulation adapted to dissolve at a controlled rate in rumen fluids; wherein the one or more amounts of first formulation are provided at one or more predetermined locations within the element relative to said one or more amounts of second formulation for one or more delayed releases of at least the first active agent into the rumen at predetermined times before, during, after, or any combination thereof, of a predetermined extended time period defined by said second formulation. The invention also relates to a method for delivering at least a first active agent to the rumen of a ruminant animal in a delayed manner at one or more predetermined times after administration to the animal of a composition containing the active agent, the method comprising administering to the animal a controlled dosage release element according to the invention. The first active agent will typically be for the treatment, prophylaxis or both of a diseased or infested state in a ruminant animal, or for altering the physiological status of a ruminant animal.



WO 03/033031 A1