980225 0-2
RTMP's copy!

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61K 9/00, 9/20

A1

(11) International Publication Number: **WO 97/24109**

(43) International Publication Date: 10 July 1997 (10.07.97)

(21) International Application Number: PCT/EP96/05884

(22) International Filing Date: 20 December 1996 (20.12.96)

(30) Priority Data:
95203649.9 27 December 1995 (27.12.95) EP
(34) Countries for which the regional or international application was filed: DE et al.

(71) Applicant *(for all designated States except US)*: JANSSEN PHARMACEUTICA N.V. [BE/BE]; Turnhoutseweg 30, B-2340 Beerse (BE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: GILIS, Paul, Marie, Victor [BE/BE]; Janssen Pharmaceutica N.V., Turnhoutseweg 30, B-2340 Beerse (BE).

(81) Designated States: AL, AM, AU, BA, BB, BG, BR, CA, CN, CU, CZ, EE, GE, HU, IL, IS, JP, KG, KR, LC, LK, LR, LT, LV, MD, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: BIOADHESIVE SOLID DOSAGE FORM

(57) Abstract

The present invention is concerned with bioadhesive pharmaceutical compositions comprising a pharmaceutically effective amount of an active ingredient, from 80 % to 98.8 % (w/w) pre-gelatinized starch, and from 1 % to 10 % (w/w) of a hydrophilic matrix forming polymer, characterized in that the composition further comprises from 0.2 % to 5 % (w/w) alkali C_{16-22}alkyl fumarate as a lubricant; solid dosage forms such as tablets which are suitable for oral, nasal, rectal and vaginal administration; processes of preparing the compositions and solid dosage forms.