

NEW DRUGS

中国药学会系列期刊/《CAJ-CD》规范执行优秀期刊/美国《化学文摘》荷兰SCOPUS等国际著名检索系统收录
中国中文核心期刊 中国科技核心期刊 中国科学引文数据库来源期刊

中国新药杂志

二〇二一年

第三十卷

第七期

第577-672页

半月刊

CHINESE JOURNAL OF NEW DRUGS

ISSN 1003-3734
CN 11-2850/R
CODEN ZXZHA6

中国新药杂志



7

2021

Vol.30 | No.7

- 韩国细胞治疗产品监管政策及对我国的启示
- 新版《药品注册管理办法》修订内容研究与思考
- 单核/巨噬细胞载体药物递送系统的设计与进展
- 苯甲酸阿格列汀片在中国健康人体中的生物等效性研究
- 黄芩苷抗癫痫作用及对神经肽Y受体Y1在海马区表达的影响

www.newdrug.cn

ISSN 1003-3734



万方数据

国家药品监督管理局主管



•新药述评与论坛•

- 577 加拿大、韩国、新加坡和马来西亚新药注册申请监管程序对我国的启示·····陈丽钻, 孙爽, 胥煜, 等
- 584 韩国细胞治疗产品监管政策及对我国的启示·····李娜, 张晓

•新药注册与审评技术•

- 590 新版《药品注册管理办法》修订内容研究与思考·····王婧璨, 张晓东, 温宝书, 等
- 596 医疗产品紧急授权政策梳理及启示·····王雪, 左书凝, 许淑红, 等

•重大新药创制专项巡礼•

- 601 百日咳系列抗原的酶联免疫检测法建立及其在组分百日咳疫苗吸附原液中的应用·····陈雯, 雷念潮, 周以斯, 等

•综述•

- 607 左乙拉西坦在临床应用中疗效与安全性的研究进展·····杨黎, 董宪喆, 齐晓涟, 等
- 611 单核/巨噬细胞载体药物递送系统的设计与进展·····杨晗, 张娜, 刘永军
- 617 脑脊液中药物浓度测定方法研究进展·····董柳含, 蔡芸

•临床研究•

- 623 苯甲酸阿格列汀片在中国健康人体中的生物等效性研究·····金浩, 陈勇, 程俊霖, 等

•实验研究•

- 628 黄芩苷抗癫痫作用及对神经肽Y受体Y1在海马区表达的影响·····秦少坤, 平鑫, 刘书宁, 等
- 633 荷梗水提物对慢性应激所致抑郁小鼠学习记忆及蛋白激酶C表达的影响·····曹亚飞, 张延红, 芦晔, 等
- 639 薏苡素包合物的药动学及组织分布研究·····徐蓉蓉, 沈新宇, 胡荣, 等
- 644 一种莪术油复配消毒剂的抗菌效果和安全性研究·····王贺, 程钢, 黄颖, 等
- 649 GC-MS法测定药用复合膜中25种初级芳香胺的迁移量·····邹茹, 朱碧君, 常亮, 等
- 654 首批重组特立帕肽国家标准品的研制与标定·····张伟, 张慧, 吕萍, 等

•药物安全与合理应用•

- 660 PCSK9抑制剂依洛尤单抗和阿利西尤单抗不良反应文献分析·····舒冰, 张蕾, 沈爱宗
- 666 吉西他滨致放射回忆性肌炎文献分析·····朱玲娜, 汪龙, 程军, 等

- 577 The inspiration to China from new drug applications in Canada, South Korea, Singapore and Malaysia
CHEN Li-zuan, SUN Shuang, XU Yu, *et al*
- 584 Regulations of cell therapy products in Korea and the enlightenment to China
LI Na, ZHANG Xiao
- 590 Revisions of the new "Provisions for Drug Registration" in China and some considerations
WANG Jing-can, ZHANG Xiao-dong, WEN Bao-shu, *et al*
- 596 Analysis on emergency authorization policies of medical products
WANG Xue, ZUO Shu-ning, XU Shu-hong, *et al*
- 601 Establishment of enzyme-linked immunoassay for pertussis series antigen and its application in adsorbed stock solution of component pertussis vaccine
CHEN Wen, LEI Nian-chao, ZHOU Yi-si, *et al*
- 607 Research progress on efficacy and safety of levetiracetam in clinical application
YANG Li, DONG Xian-zhe, QI Xiao-lian, *et al*
- 611 The design and progress of monocyte/macrophage carrier drug delivery system
YANG Han, ZHANG Na, LIU Yong-jun
- 617 Progress of drug determination in cerebrospinal fluid
DONG Liu-han, CAI Yun
- 623 Bioequivalence study of alogliptin benzoate tablets in Chinese healthy volunteers
JIN Hao, CHEN Yong, CHENG Jun-lin, *et al*
- 628 The antiepileptic effect of baicalin and its effect on the expression of neuropeptide Y Y1 receptor in brain
QIN Shao-kun, PING Xin, LIU Shu-ning, *et al*
- 633 Effects of water extract of lotus petiole in chronic mild stress-induced depression mice: learning, memory and PKC expression
CAO Ya-fei, ZHANG Yan-hong, LU Ye, *et al*
- 639 Pharmacokinetics and tissue distribution of coixol-HP- β -CD clathrate
XU Rong-rong, SHEN Xin-yu, HU Rong, *et al*
- 644 Antibacterial effect of a turmeric oil compound disinfectant and its safety
WANG He, CHENG Gang, HUANG Ying, *et al*
- 649 GC-MS for the determination of migration of 25 primary aromatic amines in medicinal composite films
ZOU Qie, ZHU Bi-jun, CHANG Liang, *et al*
- 654 Preparation and calibration of the first batch of national standard recombinant teriparatide
ZHANG Wei, ZHANG Hui, LÜ Ping, *et al*
- 660 Literature analysis of adverse drug reactions induced by PCSK9 inhibitors: evolocumab and alirocumab
SHU Bing, ZHANG Lei, SHEN Ai-zong
- 666 Literature analysis of gemcitabine-induced radiation recall myositis
ZHU Ling-na, WANG Long, CHENG Jun, *et al*

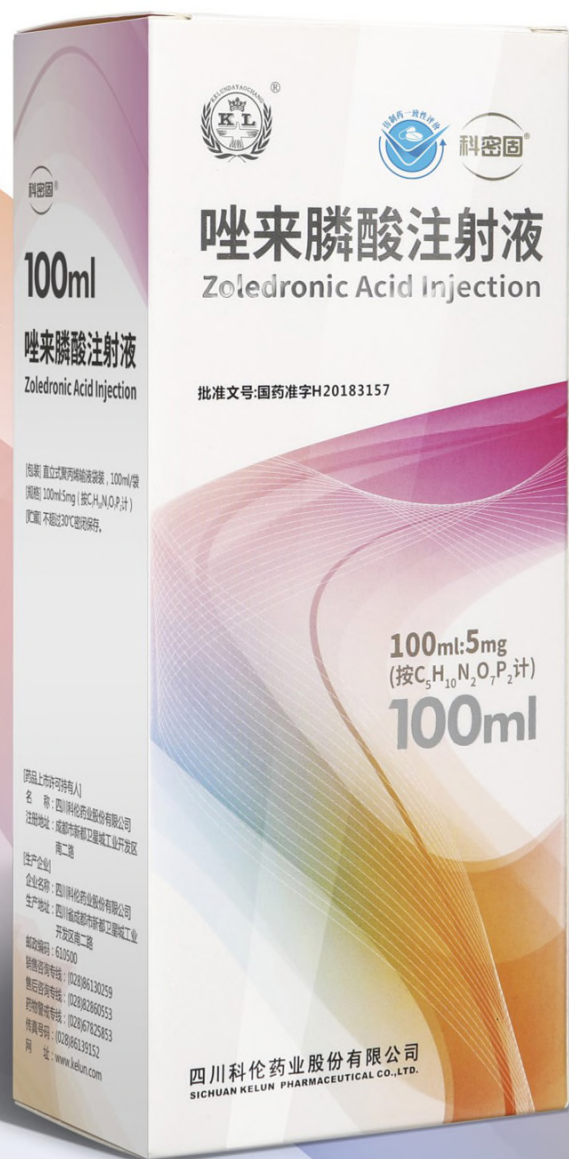
Directed by: National Medical Products Administration
Sponsored by: China Medical Science Press
China National Pharmaceutical Group Corp.
Chinese Pharmaceutical Association
Editor-in-Chief: SANG Guo-wei
Board Chairman: SHI Sheng-yi
Edited by: Editorial Board of Chinese Journal of New Drugs
Published by: Chinese Journal of New Drugs Co., Ltd.
Address: Room 317, No.3 Chengming Building, No.2 Xizhimen South Street, Xicheng District, Beijing 100035, China
Tel: (010)52722697 / 52722651 / 52723707

Website: <http://www.newdrug.cn>
E-mail: bianjibu@newdrug.cn
Printer: Beijing Kexin Printing Co., Ltd.
Domestic Distribution: Beijing Post Offices
Overseas Distribution: China International Book Trading Corp.
(P.O.Box 399 Beijing, China)
Domestic Subscription: Local Post Offices
Periodical Registration: ISSN 1003-3734 CN 11-2850/R
Publication Date: April 15, 2021
Copyright: 2021 by Chinese Journal of New Drugs Co., Ltd.



唑来膦酸注射液
Zoledronic Acid Injection

一年一次滴注, 治疗骨质疏松



简要说明书:

【通用名称】唑来膦酸注射液

【商标名】科密固®

【规格】100ml:5mg (按C₅H₁₀N₂O₇P₂计)

【适应症】用于治疗绝经后妇女的骨质疏松症; 用于治疗成年男性的骨质疏松症以增加骨量; 用于治疗Paget's病(变形性骨炎)。

【用法用量】对于骨质疏松症的治疗, 推荐剂量为一次静脉滴注5mg本品, 每年一次。

【不良反应】本品最常见的用药后症状包括(治疗绝经后妇女骨质疏松症的研究中的发生率): 发热(18.1%)、肌痛(9.4%)、流感样症状(7.8%)、关节痛(6.8%)、头痛(6.5%), 绝大多数出现于用药后3天内。这些症状绝大多数为轻到中度, 并在出现不良事件后3天内缓解。之后再使用本品时, 这些症状的发生率显著下降。如有需要, 可在给药后短时间内服用对乙酰氨基酚或布洛芬, 这样可以使本品给药后前3天内出现的用药后症状的发生率降低约50%。其余不良反应详见说明书。

【禁忌】对唑来膦酸或其他双膦酸盐或药品成份中任何一种辅料过敏者禁用。低钙血症患者、肌酐清除率<35 ml/min的严重肾功能损害患者、妊娠和哺乳期妇女禁用。其余禁忌详见说明书。

【生产企业】四川科伦药业股份有限公司

【批准文号】国药准字H20183157

详细信息请参考产品说明书

【本广告仅供医学药学专业人士阅读】 川药广审(文)第230201-00654号



科伦药业
KELUN PHARMACEUTICAL