

CHINESE JOURNAL OF NEW DRUGS

# 中國新药杂志

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



17  
2016  
Vol.25 | No.17

- 抗糖尿病中药专利分析  
心脏安全药理学评价新策略——CiPA  
Beagle犬灌胃给予二甲基乙酰胺/聚氧乙烯蓖麻油溶媒28 d重复给药毒性研究  
重组人-鼠嵌合抗CD20单抗IBI301食蟹猴急性毒性研究  
10 483份国家基本药物说明书老年用药信息标注情况调查分析

www.newdrug.cn

ISSN 1003-3734



国家食品药品监督管理总局主管



# 目 次

半月刊 1992年创刊

第25卷第17期 2016年9月15日出版

•新药述评与论坛•

1921 抗糖尿病中药专利分析·····耿胜燕, 欧阳雪宇, 周倩, 等

1928 我国药物研发协同创新机制初探·····张海燕, 李晓晴, 张晶

1933 索利那新治疗膀胱过度活动症的成本-效用分析·····范长生, 王建业, 廖利民, 等

•新药申报与审评技术•

1939 心脏安全药理学评价新策略——CiPA·····胡晓敏, 张子腾, 宗英, 等

•重大新药创制专项巡礼•

1946 Beagle犬灌胃给予二甲基乙酰胺/聚氧乙烯蓖麻油溶媒28 d重复给药毒性研究·····耿兴超, 王超, 彭茜, 等

•生物医药前沿•

1953 重组人-鼠嵌合抗CD20单抗IBI301食蟹猴急性毒性研究·····刘丽, 齐卫红, 林志, 等

•综述•

1960 FLT3抑制剂作用模式、构效关系及其临床研究进展·····郭晓星, 兰清源, 阮聪, 等

1967 PD-1/PD-L1在非小细胞肺癌的治疗研究进展·····塞丹, 陈晓品

1973 慢性乙型肝炎的抗病毒药物及靶点的研究进展·····毛水燕, 王晨, 杨悦

•临床研究•

1979 羟考酮与舒芬太尼用于全麻诱导时患者对双腔支气管导管插管反应和切皮反应的比较·····丁蕾, 陈冀衡

•中药大品种新进展专栏•

1984 龙黄降压胶囊质量标准研究·····张璐, 许红玮, 桂新景, 等

1990 丹参酮II<sub>A</sub>磺酸钠注射液体外改良溶血试验研究·····汤连升, 孙超, 张森, 等

•实验研究•

1994 利拉鲁肽对1-甲基-4-苯基吡啶离子诱导的PC12细胞氧化损伤的影响·····李碧蓉, 唐海林, 曹妍群, 等

2000 柚皮苷抑制TNF-α诱导的人脐静脉内皮细胞的氧化应激和炎症反应·····戴永国, 卢腾, 张可, 等

2007 头花蓼有效组分中3个成分在模式生物斑马鱼中的代谢研究·····梅朝叶, 向文英, 黄勇, 等

2014 淀粉源介孔碳材料改善非诺贝特溶出速率及口服生物利用度研究·····邱阳, 吴超, 蒋杰, 等

2021 载羟基喜树碱双嵌段共聚物纳米粒的制备与评价·····谢黎崖, 常迪, 侯振清, 等

2027 聚乙二醇两端修饰依托泊苷及人参皂苷Rh2的自组装胶束构建及其理化性质表征·····赵海军, 赵维英, 洪泽辉

•药物安全与合理应用•

2036 10 483份国家基本药物说明书老年用药信息标注情况调查分析·····徐磊, 雷静, 封宇飞

# CONTENTS

CHINESE JOURNAL OF NEW DRUGS

Founded in 1992, Semimonthly  
Volume 25, Number 17  
September 15, 2016

- 1921 Analysis of patents of antidiabetic traditional Chinese medicine GENG Sheng-yan, OUYANG Xue-yu, ZHOU Qian, *et al*
- 1928 Comments on collaborative innovation mechanism in drug research and development ZHANG Hai-yan, LI Xiao-qing, ZHANG Jing
- 1933 Cost-utility of solifenacin in the treatment of patients with overactive bladder syndrome FAN Chang-sheng, WANG Jian-ye, LIAO Li-min, *et al*
- 1939 A New strategy for pharmacological evaluation of cardiac safety——CiPA HU Xiao-min, ZHANG Zi-teng, ZONG Ying, *et al*
- 1946 A 28-day repeated dose toxicity study of co-solvent Dimethylacetamide/Cremophor EL (DMA/CrEL) in Beagle dogs GENG Xing-chao, WANG Chao, PENG Qian, *et al*
- 1953 Acute toxicity study of engineered chimeric murine/human anti-CD20 monoclonal antibody IBI301 in cynomolgus monkeys LIU Li, QI Wei-hong, LIN Zhi, *et al*
- 1960 Advances in the study of interaction mode, SAR and clinical trials of FLT3 inhibitors GUO Xiao-xing, LAN Qing-yuan, RUAN Cong, *et al*
- 1967 Research progress of PD-1/PD-L1 in the treatment of non-small cell lung cancer JIAN Dan, CHEN Xiao-pin
- 1973 Advances in antiviral drugs and targets for therapy of chronic hepatitis B MAO Shui-yan, WANG Chen, YANG Yue
- 1979 Comparison of oxycodone and sufentanil used for anesthesia induction in inhibiting responses to tracheal intubation with double-lumen endobronchial tube and skin incision DING Lei, CHEN Ji-heng
- 1984 Quality control of Longhuang Jiangya capsule ZHANG Lu, XU Hong-wei, GUI Xin-jing, *et al*
- 1990 Study on hemolytic effect of sulfotanshinone sodium injection *in vitro* TANG Lian-sheng, SUN Chao, ZHANG Sen, *et al*
- 1994 Effect of liraglutide on MPP<sup>+</sup>-induced oxidative injury in PC12 cells LI Bi-rong, TANG Hai-lin, CAO Yan-qun, *et al*
- 2000 Naringin inhibits TNF- $\alpha$  induced oxidative stress and inflammatory response in HUVECs DAI Yong-guo, LU Teng, ZHANG Ke, *et al*
- 2007 Metabolism of three components of effective fractions of *Polygonum capitatum* in zebrafish MEI Chao-ye, XIANG Wen-ying, HUANG Yong, *et al*
- 2014 The research of improving the dissolution rate and oral bioavailability of fenofibrate by starch-derived mesoporous carbon materials QIU Yang, WU Chao, JIANG Jie, *et al*
- 2021 Preparation and evaluation of HCPT-loaded amphiphilic block copolymer nanoparticles XIE Li-ya, CHANG Di, HOU Zhen-qing, *et al*
- 2027 Preparation and characterization of self-assemble micelles based on a novel polymer designed as polyethylene glycol-modified ginsenoside Rh2 and etoposide ZHAO Hai-jun, ZHAO Wei-ying, HONG Ze-hui
- 2036 Investigation on drug information for the elderly in 10 483 package inserts of national essential drugs XU Lei, LEI Jing, FENG Yu-fei

Directed by: China Food and Drug 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 1605, No.2 Ocean Cityscape, No.123 Zhongguancun Donglu,  
Haidian District, Beijing 100086, China

Tel: (010)80442198 / 82282300 / 80442188 / 80442189 / 82282326

Fax: (010)82282289

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: September 15, 2016

Copyright: 2016 by Chinese Journal of New Drugs Co.,Ltd.

乐松®贴剂

局部抗炎镇痛新选择

重拳出击  
有效镇痛

乐松

## 简要处方说明书：

【通用名】洛索洛芬钠贴剂

【规格】每贴7cm\*10cm，含洛索洛芬钠50mg。

【性状】本品为淡褐色至褐色膏体，涂布于背衬层上，膏体表面覆盖透明保护层。

【适应症】用于骨关节炎、肌肉痛、外伤导致肿胀疼痛。

【用法用量】1日1次，贴于患处。

【孕妇及哺乳期妇女用药】尚未确立安全性，建议权衡利弊。

【儿童用药】尚未确立安全性。

【老年用药】注意贴敷部位的皮肤状况。

【药物相互作用】暂无。

【禁忌症】对本品成分有过敏既往史者；患有阿斯匹林性哮喘或有其既往史者禁用。

【注意事项】支气管哮喘患者慎用。本品为对症治疗。不得用于损伤皮肤及粘膜、湿疹或发疹部位等。

【不良反应】主要有瘙痒、红斑、接触性皮炎等皮肤症状、胃不适等消化道症状以及ALT、AST等实验室检查值异常。

【贮藏】遮光，密封，不超过25℃保存。

【包装】铝塑复合袋包装。3贴/袋。

【有效期】24个月。

【批准文号】进口药品注册证号：H20140638 ( 50mg/贴 )

【国内联系单位】第一三共（中国）投资有限公司

地址：上海市南京西路1717号会德丰国际广场51楼

邮政编码：200040

联系电话：400-656-3228

传真号码：021-60397399

不良反应报告热线：021-60397322

禁忌症和不良反应具体内容详见说明书

注意：在处方前，请详细阅读参阅中国批准的完整说明书。详细处方资料备索。

本广告仅供医学药学专业人士阅读。沪药广审(文)第2016040144号



第一三共

中国 上海市 静安区 南京西路1717号 会德丰国际广场51楼 邮编：200040 电话：(86 21)6039 7200 传真：(86 21)6039 7397

国内定价：30.00元 国内统一刊号CN11-2850/R 邮发代号82-488 国外代号M4240