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# 中国实验血液学杂志

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# 中国实验血液学杂志

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【发明名称】：3-(取代二氢异吲哚酮-2-基)-2,6-哌啶二酮的合成方法及中间体

【专利号】：ZL 2011 1 0005625.3

【适应症】：本品与地塞米松合用，治疗曾接受过至少一种疗法的多发性骨髓瘤的成年患者。

25mg新增适应症：本品与地塞米松合用，治疗此前未经治疗且不适合接受移植的多发性骨髓瘤成年患者。

【禁忌】：1. 孕妇 2. 未达到所有避孕要求的可能怀孕的女性（见【注意事项】和【孕妇和哺乳期妇女用药】）。3. 对本品活性成分或其中任何辅料过敏者。

【不良反应】：1. MM-009和MM-010研究中复发/难治性多发性骨髓瘤患者的安全性数据总结  
(规格：5mg、10mg、25mg)

■最严重的不良反应包括：静脉血栓（深静脉血栓、肺栓塞）（见【注意事项】）。  
4级中性粒细胞减少（见【注意事项】）。

■最常见的不良反应为：疲乏（43.9%），中性粒细胞减少（42.2%），便秘（40.5%），腹泻（38.5%），肌肉痉挛（33.4%），贫血（31.4%），血小板减少（21.5%），和皮疹（21.2%）。测试数据详见说明书。

2. MM-021研究中复发/难治性多发性骨髓瘤中国患者的安全性数据总结  
(规格：5mg、10mg、25mg)

■最常见不良事件为贫血（121/199受试者，60.8%）、中性粒细胞计数减少（82/199受试者，41.2%）、中性粒细胞减少（71/199受试者，35.7%）和白细胞计数减少（66/199受试者，33.2%）。

3. 其他不良反应（规格5mg、10mg、25mg）：静脉血栓栓塞、深静脉血栓和肺栓塞（见【注意事项】）、血液和淋巴系统疾病、心脏疾病、内分泌疾病、眼科疾病、胃肠道疾病、全身性疾病和给药部位反应、检查、神经系统疾病、精神疾病、生殖系统和乳腺疾病、呼吸系统、胸廓和纵膈疾病、皮肤和皮下组织疾病详见说明书。

4. 此前未经治疗且不适合接受移植的多发性骨髓瘤患者的安全性数据总结（MM-020）  
(规格25mg)

■腹痛、肺炎、败血症、皮疹和深静脉血栓，测试数据详见说明书。

【注意事项】：详见说明书。



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