

Certificate of registration of Human Growth Hormone for Injection (10IU)
in the country of origin (China)

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安徽省药品监督管理局
药品再注册批准通知书

受理号: CYSZ2000541皖

通知书编号: 2020R002979

药品名称	药品通用名称: 注射用重组人生长激素 英文名/拉丁名: Recombinant Human Growth Hormone for Injection		
商品名称	安苏萌		
主要成分	重组人生长激素		
剂型	注射剂	申请事项	境内生产药品再注册
规格	10IU/3.33mg/支	注册分类	治疗用生物制品
药品注册标准编号	YBS00032020	原药品批准文号	国药准字S20093034
包装规格	1支/盒	药品有效期	24个月
审批结论	经审查, 本品符合《药品注册管理办法》的有关规定, 同意再注册。		
上市许可持有人	名称: 安徽安科生物工程(集团)股份有限公司 地址: 合肥市长江西路669号高新区海关路K-1		
生产企业	名称: 安徽安科生物工程(集团)股份有限公司 地址: 合肥市长江西路669号高新区海关路K-1		
药品批准文号	国药准字S20093034	药品批准文号有效期	至2025-10-14
主送	安徽安科生物工程(集团)股份有限公司		
抄送	合肥市市场监督管理局		
备注	建议继续完成国家药品监督管理局药品注册批件(批件号: 2020S00065)中要求研究的内容。		



Translation:

ANHUI MEDICAL PRODUCTS ADMINISTRATION
Notice of approval for drug re-registration

Acceptance number: CYSZ000541WAN Notification number: 2020R002979

Drug Name	INN: Recombinant Human Growth Hormone for Injection English name / Latin name: Recombinant Human Growth Hormone for Injection		
Trade name	Ansomone		
Active ingredient	Recombinant Human Growth Hormone		
Dosage form	Lyophilized powder for injection	Application items	Re-registration of domestic products
Specification	10IU/3.33mg/vial	Registration classification	Therapeutic biological products
Drug registration standard number	YBS00032020	Original drug approval number	GYZZS20093034
Packing specification	1 vial/box	Validity period of drug	24 months
Conclusion of examination and approval	After examination, this product conforms to the relevant provisions of the measures for the administration of drug registration, and it is agreed to be registered again.		
Marking Authorization Holder	Name: Anhui Anke Biotechnology (Group) Co., Ltd Address: Haiguan Road K-1, High&New Development Zone, No.669, West Chang jiang Road, Hefei City		
Manufacturer	Name: Anhui Anke Biotechnology (Group) Co., Ltd Address: Haiguan Road K-1, High&New Development Zone, No.669, West Chang jiang Road, Hefei City		
Drug approval number	GYZZS20093034	Period of validity	Until 14/10/2025
Main sending	Anhui Anke Biotechnology (Group) Co., Ltd		
Make a copy for	Hefei market supervision and Administration Bureau		
Note	It is suggested to complete the contents required in the approval document for drug registration of the State Drug Administration (approval document No.: 2020S00065).		

ANHUI MEDICAL PRODUCTS ADMINISTRATION

15/10/2020