

85+30



### 云南省药品监督管理局 药品再注册批件

原始编号: Z53021103

受理号: YZZ2018174滇

批件号: 2020R001037

药品名称	药品通用名称: 云南白药气雾剂 汉语拼音: Yunnan Baiyao Qiwuji		
剂型	气雾剂		
规格	云南白药气雾剂每瓶装85g, 含药液65g; 云南白药气雾剂 保险液每瓶装30g, 含药液14g	药品分类	中药
药品标准	国家食品药品监督管理局标 准YBZ00122016	药品有效期	36 个月
药品生产企业	名称: 云南白药集团股份有限公司 生产地址: 云南省昆明市呈贡新区云南白药集团股份有限公司		
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。		
药品批准文号	国药准字Z53021103	药品批准文号有效期	2025-06-15
附件	-----		
主送	云南白药集团股份有限公司		
抄报	国家药品监督管理局		
抄送	-----		
备注			





云南白药®

### 云南白药气雾剂说明书

OTC 外  
乙类

请仔细阅读说明书并按说明使用或在药师指导下购买和使用  
孕妇禁用;酒精过敏者禁用;对云南白药过敏者禁用;本品含草乌(制)、雪上一枝蒿(制)

**【药品名称】**

通用名称:云南白药气雾剂  
汉语拼音:Yunnan Baiyao Qiwuji

**【成份】** 国家保密方,本品含草乌(制)、雪上一枝蒿(制),其余成份略。

**【性状】** 云南白药气雾剂为非定量阀门气雾剂,在耐压容器中的药液为淡黄色至黄棕色的液体;喷射时,有特异香气。云南白药气雾剂保险液为非定量阀门气雾剂,在耐压容器中的药液为黄色至黄棕色的液体;喷射时,有特异香气。

**【功能主治】** 活血散瘀,消肿止痛。用于跌打损伤,瘀血肿痛,肌肉酸痛及风湿疼痛。

**【规格】** 云南白药气雾剂每瓶装85克,含药液65克;云南白药气雾剂保险液每瓶装30克,含药液14克。

**【用法用量】** 外用,喷于患处。使用云南白药气雾剂,一日3~5次。凡遇较严重闭合性跌打损伤者,先喷云南白药气雾剂保险液,若瘀伤肿胀仍不缓解,可间隔1~2分钟重复给药,一天使用不得超过3次。喷云南白药气雾剂保险液间隔3分钟后,再喷云南白药气雾剂。

**【不良反应】** 上市后监测数据显示本品可见以下不良反应:皮疹、瘙痒、皮肤潮红等。

**【禁忌】** 1. 孕妇禁用。2. 酒精过敏者禁用。3. 对本品过敏者禁用。4. 皮肤及黏膜破损、化脓者禁用。5. 禁止内服。

**【注意事项】**

1. 本品只限于外用,切勿吸入口、眼、鼻,使用后即洗手。
2. 如果出现不良反应或疑似不良反应,应立即停用,并去医院就诊。
3. 小儿、年老体弱者、心脏病患者、经期妇女应在医师指导下使用。
4. 使用云南白药气雾剂,保险液时先振摇,喷嘴离皮肤5~10厘米,喷射时间应限制在3~5秒钟,以防止局部冻伤。
5. 皮肤过敏者停用。
6. 皮肤受冻者停用。
7. 本品含草乌(制)、雪上一枝蒿(制),请仔细阅读说明书并按说明使用或在药师指导下购买和使用。
8. 严格按药品说明书用法用量使用,不宜长时间、大面积使用。
9. 本品开封后应在7天以内,如用药超过7天,应向医师咨询。
10. 使用时勿动火,切勿受热,应置于阴凉处保存。
11. 请勿将本品置于微波炉、烤箱。
12. 请勿用及于本品的气雾剂。
13. 本品含酒精(酒精),用药期间不得与头孢菌素类(如头孢唑肟、头孢唑啉、头孢他啶等)、甲硝唑、替硝唑、酮康唑、咪唑类(如甲流西那唑)结构的药物联合使用,以免导致双硫仑样反应。
14. 使用本品时,宜同时服用含半夏、瓜蒌、瓜蒌子、瓜蒌皮、天花粉、川贝母、浙贝母、平贝母、伊贝母、湖北贝母、白薇、白及或其制剂。
15. 对酒精及本品过敏者禁用,过敏体质者慎用。
16. 本品性状发生改变时禁止使用。
17. 儿童必须在成人监护下使用。
18. 请将本品放在儿童不能接触的地方。
19. 如正在使用其他药品,使用本品前请咨询医师或药师。

**【药物相互作用】** 如与其他药物同时使用可能会发生药物相互作用,详情请咨询医师或药师。

**【贮藏】** 密封,置阴凉处(不超过20℃)。

**【包装】** 铝塑包装,云南白药气雾剂1瓶;云南白药气雾剂保险液1瓶。

**【有效期】** 36个月

**【执行标准】** 国家食品药品监督管理局标准YB200122016

**【批准文号】** 国药准字Z53021103

**【说明书修订日期】**

**【上市许可持有人及生产企业】** 云南白药集团股份有限公司

生产地址:云南省昆明市呈贡新区云南白药集团股份有限公司

邮政编码:650500

电话号码:4001000538

传真号码:0871-66226885

注册地址:云南省昆明市呈贡区云南白药(集团)有限公司

网址:www.yunnanbaiyao.com.cn

如有问题可与生产企业联系



云南白药集团股份有限公司  
YUNNAN BAIYAO GROUP CO., LTD.

### Yunnan Baiyao Aerosol Instruction Manual

Please read the instruction carefully and follow the instruction to use or purchase and use under the guidance of pharmacist. It is contraindicated in pregnant women, alcohol allergy and individuals with an allergic reaction to Yunnan Baiyao; it contains AconitiKusnezoffii Radix Cocta and AconitiBrachypodi Radix Cocta.

**[Pharmaceutical Name]** Yunnan Baiyao Aerosol

**[Ingredients]** National Secret Formula. It contains AconitiKusnezoffii Radix Cocta and AconitiBrachypodi Radix Cocta, other ingredients are omitted.

**[Description]** A aerosol with non-metered-dose valve system; the drug liquid in the pressure-resistant container is a light yellow to yellowish brown colored liquid, with special fragrance by spraying.

**[Function and Indications]** Promoting blood flow to eliminate blood stasis, promoting subsidence of swelling and analgesic; used for treatment of traumatic injury, swelling and pain caused by stagnated blood, aching pain of muscle and painful rheumatic arthritis, etc.

**[Administration and Dosage]** External used, to spray on wounds, use Yunnan Baiyao Aerosol, 3-5 times daily. For serious trauma without skin injuries, apply Yunnan Baiyao Aerosol Insurance Liquid to injured part firstly. If serious pains can not be alleviated, 1-2 minutes later, reapply it, it is recommended to apply for no more than 3 times one day. Spray Yunnan Baiyao Aerosol on wounds after using Yunnan Baiyao Aerosol Insurance Liquid for 3 minutes.

**[Adverse reactions]** Monitoring data after marketing showed that the product has the following adverse reactions: skin rash, pruritus, facial flush, etc.

**[Contraindications]** 1. It is contraindicated in pregnant women.

2. It is contraindicated in alcohol allergy.
3. It is contraindicated in individuals with an allergic reaction to Yunnan Baiyao.
4. It is contraindicated in defective or pusulent skin and mucous membrane.
5. It is not to be taken orally.

**[Precautions]**

1. This Aerosol is used externally only, never spray into mouth, eye, nose; washing hands immediately after use.
2. If adverse reactions or suspected adverse reactions occur, discontinue immediately, and go to the hospital for treatment.
3. Children, the elderly and weak people, patients with heart disease, ulcers and menstruating women should use under the guidance of physician.
4. Shake can of Yunnan Baiyao Aerosol, Insurance Liquid firstly then use it, and hold the can 5-10cm away from the trauma applying time for spraying would be controlled in 3-5 seconds in order to avoid getting external skin frozen.
5. Discontinue use for people with skin allergies.
6. Don't use on broken skin.
7. It contains AconitiKusnezoffii Radix Cocta and AconitiBrachypodi Radix Cocta, please carefully read instruction manual and use it according to the instruction manual, or purchase and use it under the guidance of the pharmacist.
8. Use strictly according to the usage and dosage of the drug instructions, not suitable for long time and large area.
9. The time of self-medication should be within 7 days, if longer than 7 days, consult physician.
10. When it is just in use, keep away from flame and never let it to be heat.
11. Don't massage or rub after using.
12. Don't use and store upside down.
13. It contains ethanol (alcohol), and should not be used in combination with cephalosporins (such as cephazolin, cefuroxime, cefazidime, etc.), metronidazole, tinidazole, ketoconazole, furozolidone and other drugs containing the structure of methioniazole during the medication period, so as not to lead to disulfiram-like reaction.
14. When using this medicine, it is not suitable to take Pinelliae Rhizoma, Trichosanthis Fructus, Trichosanthis Semen, Trichosanthis Pericarpium, Trichosanthis Radix, Fritillariae Cirrhosae Bulbus, Fritillariae Thunbergii Bulbus, Fritillariae ussuriensis Bulbus, Fritillariae Pulidiflorae Bulbus, Fritillariae Hupehensis Bulbus, Ampelopsis Radix, Bletillae Rhizoma and its preparations at the same time.
15. Be forbidden for those with allergic to alcohol and this products, be careful for those with allergic constitution.
16. Don't continue to use it after the character of drug changed.
17. To obtain the guardianship from adults when children use it.
18. Keep out of reach of children.
19. To consult physician and pharmacist before using it if other drugs are being used.

**[Drug interactions]** None of such experiment has been performed, nor reliable references are available. Concomitant use of other drugs may produce interactions. Consult the doctor or pharmacist for details.

**[Specification]** Yunnan baiyao aerosol is 85g per bottle, containing 65g of liquid, Yunnan Baiyao Aerosol Insurance Liquid is 30 grams per bottle, containing 14g of liquid.

**[Storage]** Keep upright in a cool dry place (not exceeding 20°C).

**[Package]** Packed in aluminum in containing one bottle of Yunnan Baiyao Aerosol and one bottle of Yunnan Baiyao Aerosol Insurance Liquid.

**[Validity]** Three years.

**[Execution standard]** The standard of State Food and Drug Administration YB200122016

**[Approval document number]** GYZ No.Z53021103.

**[Revision date of specification]** June 16, 2020

**[Marketing Authorisation Holders and Producer]** Yunnan Baiyao Group Co., Ltd.

Address: Yunnan Baiyao Group Co., Ltd., Chenggong New District, Kunming, Yunnan Province, China.

Postal code 650500

Phone number: 4001000538

Fax number: 0871-66226885

Registered address: Number 3686 in Baiyao Street, Chenggong District, Kunming City, Yunnan Province.

Web site: www.yunnanbaiyao.com.cn

If have any questions, contact the manufacturer

XB00100206

成品尺寸: 130x185mm

85+30

### 云南省药品监督管理局 药品再注册批件

原始编号: Z53021103

受理号: CYZZ2018174滇

批件号: 2020R001037

药品名称	药品通用名称: 云南白药气雾剂 汉语拼音: Yunnan Baiyao Qiwuji		
剂型	气雾剂		
规格	云南白药气雾剂每瓶装85g, 含药液65g; 云南白药气雾剂保险液每瓶装30g, 含药液15g	药品分类	中药
药品标准	国家食品药品监督管理局标准YBZ00122016	药品有效期	36个月
药品生产企业	名称: 云南白药集团股份有限公司 生产地址: 云南省昆明市呈贡新区云南白药集团股份有限公司		
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。		
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备注			

