

# Expert consensus on the clinical application of Xuanfei Baidu granule

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## Abstract

Xuanfei Baidu granule is an effective prescription for COVID-19, which is modified from classical famous prescriptions. In order to further standardize clinician's rational use of Xuanfei Baidu granule, enhance clinical efficacy, improve rational medication level, and let it play a more significant role, the frontline clinical experts are invited for discussion on the major functions, usage, adverse reactions, and considerations of Xuanfei Baidu granule to form the consensus. The consensus is that: Xuanfei Baidu granule has the efficacy of promoting the lung and resolving dampness, clearing heat and removing pathogenesis, purging the lung and depoisoning; it can be used for the treatment of patients with mild, moderate, and heavy COVID-19 and other common upper respiratory tract infectious diseases such as influenza; acute tracheitis and bronchitis and community-acquired lower respiratory tract infectious diseases all belong to damp-toxin constraint in the lungs, Xuanfei Baidu granule can relieve cough, expectoration, and other symptoms caused by an acute exacerbation of the chronic obstructive pulmonary disease, with definite clinical efficacy and good safety. According to the principles of evidence-based medicine, this expert consensus will be updated regularly.

**Keywords:** Clinical application, COVID-19, Expert consensus, Xuanfei Baidu granule

## Introduction

The Xuanfei Baidu granule is an innovative medicine developed by the academician Zhang Boli and Professor Liu Qingquan with their team in the clinical practice of fighting against COVID-19, with the combination of classical prescriptions and modern components of modified traditional Chinese medicine (TCM) theory with modifications. It diffuses and purges the lungs, resolves dampness, clears heat and removes pathogenesis, and detoxifies, thereby playing an important role in treating COVID-19, hence its inclusion into the “three TCM drugs and three herbal formulas” for fighting COVID-19 in China<sup>[1]</sup>.

A large sample, multicenter TCM syndrome investigation showed that COVID-19 belongs to the “plague” category of TCM, and “damp-toxin constraint in the lung”

is its core pathogenesis, with clinical features of concurrent morbidity<sup>[2]</sup>. When it comes to the core pathogenesis of “damp toxin”, the basic treatment principle is resolving dampness and detoxifying, repelling foulness, and resolving turbidity, so the prescriptions that diffuse lungs and resolve dampness, clear heat and remove pathogenesis, purge and detoxify the lung, and repel foulness with aromatics should be adopted.

The Xuanfei Baidu granule is mainly composed of Ephedrae Herba (Mahuang), Gypsum Fibrosum (Shigao), Atractylodis Rhizoma (Cangzhu) (stir-baked with bran), Pogostemonis Herba (Guanghuoxiang), Artemisiae Annuae Herba (Qinghao), Polygoni Cuspidati Rhizoma et Radix (Huzhang), Verbenae Herba (Mabiancao), Coix Seed (Yiyiren), Phragmitis Rhizoma (Lugen), Descurainiae Semen Lepidii Semen (Tinglizi), Armeniacae Semen Amarum (Kuxingren), Citri Grandis Exocarpium (Huajuhong), and Glycyrrhizae Radix et Rhizoma (Gancao). It is modified from the five famous classical prescriptions including the Maxingshigan decoction in the *Treatise on Cold Damage Diseases* (Shāng Hán Lùn, 伤寒论), Maxingyigan and Tingli Dazao Xiefei decoctions from the *Synopsis of the Golden Chamber* (Jīn Kuì Yào Luè, 金匱要略), Reed Rhizome decoction from the *Medical Secrets from the Royal Library* (Wài Tái Mì Yào, 外台秘要), and Priceless Qi-Righting powder from the *Prescriptions of the Bureau of Taiping People's Welfare Pharmacy* (Tài Píng Huì Mǐn Hé Jì Jú Fāng, 太平惠民和剂局方). Moreover, abrotani herba, which is bitter, slightly spicy, and cold is added to enhance its ability to repel foulness with aromatics and clear the damp toxins in the blood. To prevent damp toxins from causing blood stasis joint stasis of toxins and blood, and to prevent exacerbation of the disease, this prescription substitutes the peach seed in Reed Rhizome decoction with Polygoni Cuspidati Rhizoma et Radix (Huzhang)

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and vervain (Mabiancao). Peach seed mainly enters the heart and liver channel, while Polygonum cuspidatum and vervain can enter the lung channel, thus making them more applicable to lung diseases. Moreover, Polygoni Cuspidati Rhizoma et Radix (Huzhang) and vervain can effectively promote blood circulation to remove meridian obstruction; thus, it can cure blood stasis caused by damp toxins at the beginning, preventing exacerbation of the disease, and preventing disease progression. Modern research has shown that Polygonum cuspidatum and vervain prevent the inflammatory factors and reduce the inflammation of the small airways.

The Xuanfei Baidu granule has been widely applied since it was launched. In the *Diagnosis and Treatment Protocol for COVID-19 (Trial 9th Version)* issued by the National Health Commission of the People's Republic of China and National Administration of Traditional Chinese Medicine, Xuanfei Baidu granule is the recommended medication for moderate cases in the clinical treatment. Moreover, in Sichuan, Guizhou, Liaoning, Hebei, and other provinces, Xuanfei Baidu granule is also recommended for treating patients with moderate COVID-19 clinical manifestation.

To further standardize clinicians' rational use of Xuanfei Baidu granule and enhance clinical efficacy, the frontline clinical experts were invited to discuss the major functions, usage, adverse reactions, and considerations of Xuanfei Baidu granule. We formed this consensus with the aim of providing clinicians with a reference to the rational use of Xuanfei Baidu granule.

### Basis for developing the consensus

With reference to relevant guidelines and clinical literature in combination with expert clinical treatment experience, this consensus involves discussions on the major functions, therapeutic principle and method, usage and dosage, adverse reactions, considerations, and combination medication of Xuanfei Baidu granule, to form recommendations and consensual suggestions for clinical issues in its application. Meanwhile, in full consideration of the early-stage clinical evidence and experiences, recommendations and suggestions on this consensus were formed. It mainly includes consensus recommendations or suggestions, basic information on the Xuanfei Baidu granule, and suggestions regarding clinical applications and safety.

### Disease diagnosis

#### TCM syndrome differentiation

COVID-19 belongs to the "plague" category of TCM. Its core pathogeneses are "dampness" and "toxin" with different concurrent syndromes and prognosis such as cold, fever, pathogeneses into nutrient blood or injury to yang-qi or yin-fluid<sup>[3]</sup>. The basis for differentiation of its core syndrome, "damp-toxin constraint in the lung" is: fever, cough with little sputum, yellow sputum, oppression and shortness of breath, abdominal distension, and constipation. The tongue body is dark red in color, and tongue shape is enlarged. The coating is yellow and

greasy or dry. The pulse is slippery and rapid or wiry and slippery<sup>[4]</sup>.

Plague diseases have strong infectivity and epidemicity. Besides COVID-19, severe acute respiratory syndrome (SARS) and influenza belong to the plague category.

#### Western medicine diagnosis

The ICD11 code of COVID-19 is U07.100×002. The diagnosis of COVID-19 shall refer to the *Diagnosis and Treatment Protocol for COVID-19 (Trial 9th Version)* issued by the National Administration of Traditional Chinese Medicine and National Health Commission of the People's Republic of China. The key points of the diagnosis are as follows: diagnosis shall be based on comprehensive analysis of historical epidemiology, clinical manifestations, and laboratory examination; a positive COVID-19 nucleic acid test is the primary standard of confirmed cases<sup>[4]</sup>;

#### Classification criteria

According to the *Diagnosis and Treatment Protocol for COVID-19 (Trial 9th Version)*, COVID-19 is clinically classified into mild, ordinary, severe, and critical cases. Here, we list the criteria for each classification: (1) Mild case: mild clinical symptoms, with no manifestations of pneumonia on imaging. (2) Ordinary case: fever, respiratory symptoms, with manifestations of pneumonia on imaging.

Severe case: obvious clinical symptoms, such as shortness of breath, respiratory rate  $\geq 30$  times/min; at rest, finger oxygen saturation  $\leq 93\%$  during air inhalation; arterial partial pressure of oxygen (PaO<sub>2</sub>)/oxygen inhalation concentration (FiO<sub>2</sub>)  $\leq 300$  mmHg (1 mmHg = 0.133 kPa); in high altitude areas (over 1,000 m), PaO<sub>2</sub>/FiO<sub>2</sub> should be corrected according to the following formula: PaO<sub>2</sub>/FiO<sub>2</sub>  $\times [760/\text{atmospheric pressure (mmHg)}]$ ; progressive worsening of clinical symptoms and lung imaging showing significant progression of lesions  $>50\%$  in 24 to 48 h.

Critical case: those requiring mechanical ventilation upon respiratory failure, or subject to shock, or requiring intensive care unit upon a combination of other organ failure.

### Formation of consensus recommendations and suggestions

According to a literature search in the system, four clinical studies<sup>[5-8]</sup> and two case reports<sup>[8-9]</sup> were included. Based on literature studies in combination with the clinical practice concerns, a list of expert opinions was formed, and 23 frontline clinical experts were consulted to give their opinions in the form of a questionnaire. In the second round, 66 experts were consulted *via* correspondence. Finally, the opinions of experts were collected in a meeting to form the expert consensus and recommendations by discussion.

Finally, the following consensus recommendations on the clinical application scope and effects of Xuanfei Baidu granule were formed (Tables 1 and 2).

**Table 1**  
**Consensus recommendation for Xuanfei Baidu granule in treating respiratory diseases based on clinical evidence**

No.	Consensus items	Strength of recommendation
1	Xuanfei Baidu granule is suitable for the treatment of mild and ordinary COVID-19.	Strong recommendation
2	Xuanfei Baidu granule can shorten the hospitalization time and the conversion time of nucleic acid tests turning negative, and improve the symptoms of fever, cough, pharyngeal discomfort, dyspnea, fatigue, anorexia, and diarrhea in the treatment of mild and ordinary COVID-19.	Strong recommendation
3	Xuanfei Baidu granule is suitable for the treatment of severe COVID-19.	Weak recommendation
4	Xuanfei Baidu granule can reduce mortality; reduce utilization rate of antibiotics, hormones, vasopressin, and mechanical ventilation; improve the inflammatory reaction and clinical symptoms; and promote the absorption of pulmonary inflammation in the treatment of severe COVID-19.	Weak recommendation

Strong recommendation: Clearly show that the benefits of interventions outweigh the disadvantages or the disadvantages outweigh the benefits; Weak recommendation: The advantages and disadvantages are uncertain or the evidence of high or low quality shows that the advantages and disadvantages are equal.

**Table 2**  
**Summary items of consensus recommendations reached in this document**

No.	Consensus items	Strength of recommendation
1	Xuanfei Baidu granule can be used to treat respiratory diseases with the syndrome of damp-toxin constraint in the lung.	Recommended
2	Xuanfei Baidu granule can also be used for acute and chronic tracheitis and bronchitis, upper respiratory tract infection, influenza, pneumonia, bronchiectasis with infection, and acute outbreak of COPD.	Recommended
3	The usage and dosage of Xuanfei Baidu granule in the treatment of COVID-19 for adult patients is 10 g, twice daily, 7–14 d for a treatment course. The drug can be stopped when the patient's symptoms are relieved.	Recommended
4	The dosage of Xuanfei Baidu granule for children is 5 g, twice daily, for no more than 7 d over a treatment course.	Recommended
5	Xuanfei Baidu granule can be administered in combination with other drugs to treat COVID-19.	Recommended
6	Xuanfei Baidu granule can improve symptoms such as cough, fever, expectoration, shortness of breath, throat discomfort, fatigue, anorexia, associated with respiratory infectious diseases, such as pulmonary infection.	Recommended
7	Xuanfei Baidu granule can be used to treat respiratory infectious diseases in children, such as upper respiratory tract infections, influenza, acute tracheitis and bronchitis.	Recommended
8	Xuanfei Baidu granule can improve the symptoms of fever, cough, expectoration, breath suppression, shortness of breath and throat discomfort caused by infectious respiratory diseases in children.	Recommended
9	Xuanfei Baidu granule may cause adverse reactions such as nausea, diarrhea, palpitation, flatulence, or stomach discomfort, which are mild and do not require special treatment. If the adverse reactions do not resolve, the drug should be stopped.	Recommended
10	Diseases caused by damp-heat stagnation of the lungs can be found in community-acquired pneumonia and other infectious pulmonary diseases, acute tracheitis and bronchitis, upper respiratory tract infection, COPD, bronchiectasis with infection, influenza, and other diseases.	Recommended
11	Xuanfei Baidu granule should not be administered to patients with yin deficiency of liver and kidney.	Not recommended
12	Xuanfei Baidu granule is safe for the treatment of COVID-19.	Recommended

COPD: Chronic obstructive pulmonary disease.

### Indications

Xuanfei Baidu granule can promote lung health and resolve dampness, clear heat and remove pathogeneses, purge the lung, and detoxify. It can treat patients with mild, ordinary, and severe COVID-19; other common upper respiratory tract infectious diseases such as influenza; and acute tracheitis, bronchitis, and community-acquired lower respiratory tract infectious diseases that all belong to damp-toxin constraint in the lung. It can relieve cough, expectoration, and other symptoms caused by an acute exacerbation of the chronic obstructive pulmonary disease.

### COVID-19

Xuanfei Baidu granule can be used for the treatment of mild and ordinary COVID-19 (consensus recommendation: strongly recommended); and for severe COVID-19 (consensus recommendation: weakly recommended).

Xuanfei Baidu granule can shorten the hospitalization time and the conversion time of the nucleic acid tests becoming negative, and improve the symptoms of fever, cough,

pharyngeal discomfort, dyspnea, fatigue, anorexia, and diarrhea in the treatment of ordinary COVID-19 (consensus recommendation: strongly recommended).

Studies have shown<sup>[6]</sup> that Xuanfei Baidu granule in combination with conventional therapy can shorten the conversion time for nucleic acid tests turning negative and reduce the hospitalization time of patients infected with the Omicron strain of COVID-19. It can improve cough, expectoration, throat discomfort, dry mouth, and other symptoms within 7 d of medication. The elimination rates of symptoms at 7 d were as follows: expectoration (38.78%), throat discomfort (55.29%), dry mouth (64.10%), cough (31.94%), and fever (100%), with no exacerbation or death.

Xuanfei Baidu granule can lower mortality, improve the inflammatory reaction (reduce white blood cell counts and procalcitonin), improve clinical symptoms (fever, cough, chest distress, dyspnea and tachypnea, head and body pain, anorexia, poor appetite, and fatigue), and promote pulmonary inflammation absorption in the treatment of severe COVID-19 (consensus recommendation: weak)<sup>[5,9–10]</sup>.

### Other infectious diseases of the lung

Xuanfei Baidu granule can also be used for upper respiratory tract infections, influenza, acute and chronic tracheitis and bronchitis, bronchiectasis with infection, acute attacks of chronic obstructive pulmonary disease, community-acquired pneumonia, and other infectious diseases of the lungs, which are caused by the damp-toxin constraint in the lung, as identified by TCM (Consensus recommendation: recommended).

### Usage and dosage

(1) The usage guidelines for Xuanfei Baidu granule to treat COVID-19 patients are as follows: a 10 g dose with boiled water, twice daily for 7 to 14 d until the symptoms disappear. (2) The usage guidelines for Xuanfei Baidu granule to treat children infected with COVID-19 is as follows: a 3 g dose, twice for children aged 4 to 6; a 5 g dose, twice daily for children aged 7 to 14 until the symptoms disappear (no longer than 7 d).

### Combination medication

Xuanfei Baidu granule can be used in combination with other medicines to treat of COVID-19. Please notice the medicine interactions and adverse reactions during combination medication.

As Xuanfei Baidu granules contain Glycyrrhizae Radix et Rhizoma (Gancao), according to the principles of Chinese herbal medicine incompatibility, it should not be taken together with Chinese medicinal formulae or Chinese patent medicines containing alga, EUPHORBIAE PEKINENSIS RADIX (Jingdaji), Kansui Radix (Gansui), or Genkwa Flos (Yuanhua).

### Safety

Xuanfei Baidu granule shows no increased risk in the treatment COVID-19, and has a good safety profile.

### Adverse reactions

In clinical practice, Xuanfei Baidu granule may cause adverse reactions such as nausea, diarrhea, palpitation, flatulence, or stomach discomfort, which are mild and do not require special treatment. If the adverse reactions do not resolve, the drug should be discontinued.

### Contraindications

Patients allergic to Xuanfei Baidu granule and its ingredients should use it with care; pregnant women, lactating women and infants (under 3 years old) should use it with care.

### Precautions

(1) The product should not be used by patients with yin deficiency of the liver and kidney, which is indicated in the instructions, but it is not supported by clinical evidence. Further observation is needed for clarification. (2) Patients with hepatic and renal insufficiency should take the product with care. (3) Patients with tachycardia should use the medicine with care. (4)

It is forbidden to overdose, administer repeatedly or for a long time. (5) After taking medicine, to have rest and avoid cold or greasy foods. (6) As ephedra is contained in the prescription, athletes should take it with care. (7) Patients with the abnormal liver function shall take it under the guidance of a doctor, and have their liver function tested during medication. (8) Patients with cold deficiency, diarrhea, or who pass stool more than three times daily during medication should take it under the guidance of the doctor.

### Discussion

Scholars in China and abroad have carried out a series of studies on the characteristics and mechanism of Xuanfei Baidu granule in treating COVID-19. Some researchers have analyzed the “three TCM drugs and three herbal formulas” including Xuanfei Baidu granule, and concluded that they could not only relieve symptoms such as fever, cough, fatigue, expectoration, diarrhea, but also shorten the conversion time of nucleic acid tests turning negative, prevent exacerbation of the disease, improve computer tomography (CT) image characteristics, relieve lung inflammation, regulate clinical biochemical indexes, and reduce a series of complications<sup>[1]</sup>.

Clinical research shows that Xuanfei Baidu granule in combination with Western medicine can profoundly relieve the clinical symptoms of COVID-19 patients such as fever, cough, fatigue, or anorexia, and improve immunity and anti-inflammatory effects<sup>[8]</sup>.

Xuanfei Baidu decoction can relieve mild and moderate symptoms of patients such as fever, cough, anorexia, and fatigue, preventing the condition from further worsening<sup>[11]</sup>. Furthermore, clinical research has also revealed that Xuanfei Baidu decoction can not only accelerate the elimination of numerous typical symptoms, but also promote the recovery in white blood cell and lymphocyte counts to the baseline, improve the inflammatory reaction and significantly reduce the sedimentation rate of red blood cells<sup>[8,12]</sup>.

Pharmacological research has shown that Xuanfei Baidu decoction can obviously inhibit weight loss and the immune organ index of mice induced by cyclophosphamide; improve the pathological structure of the liver, spleen, and thymus of immunosuppressed mice; enhance the levels of cytokines, IgG and IgM antibodies in serum, and the expression level of inflammatory factors in the spleen; promote the proliferation of spleen cells of immunosuppressed mice; and increase the proportion of CD4<sup>+</sup> and CD8<sup>+</sup> T cells in spleen cells, which suggests that Xuanfei Baidu decoction is involved in immune regulation and improves immune function<sup>[13]</sup>. A mouse model of pulmonary fibrosis bleomycin treated with Xuanfei Baidu decoction showed that this medicine could effectively protect the alveolar structure, reduce the cellular changes of lung, improve the infiltration of inflammatory cells, and inhibit the thickening of the blood vessel wall and collagen deposition; furthermore, after network pharmacology and protein–protein interaction analysis, we found that the above effects were related to inhibition of the activation of interleukin (IL)-6/STAT3 signaling pathway, preventing the differentiation of M2 macrophages, and downregulating the overexpression of inflammatory factors such as IL-6 and transforming

growth factor (TGF)- $\beta$ <sup>[14]</sup>. The model of acute lung injury induced by lipopolysaccharide LPS showed that Xuanfei Baidu decoction can improve the pathological changes of lung tissue in mice, downregulate the levels of inflammatory factors IL-6, tumor necrosis factor (TNF)- $\alpha$ , and IL-1 $\beta$  in serum and alveolar lavage fluid of mice, and also inhibit the infiltration of macrophages and neutrophils<sup>[15-17]</sup>. Its mechanism is related to the inhibition of programmed death (PD)-1/IL17A pathways<sup>[15]</sup> and the polarization of proinflammatory macrophages by increasing mitochondrial fusion and inhibiting the activation of NLRP3 inflammatory bodies mediated by nuclear factor kappa-B (NF- $\kappa$ B) and mitogen-activated protein kinase (MAPK) pathways<sup>[16-17]</sup>. In addition, Xuanfei Baidu decoction can also improve weight loss, spleen index, disease activity index, TNF- $\alpha$  level, and colon tissue injury of mice with acute colitis. Further studies have found that its mechanism is related to the inhibition of NF- $\kappa$ B pathway, downregulation of Th1/Th2 ratio, and remodeling of intestinal immunity<sup>[18]</sup>.

In terms of chemical composition, the main effective substances in several types of Xuanfei Baidu decoction were identified by ultra-high performance liquid chromatography, including ephedrine, glycyrrhizic acid, or amygdalin<sup>[14]</sup>. Wang et al.<sup>[19]</sup> carried out the network pharmacological analysis and inferred that Xuanfei Baidu decoction could inhibit the replication and invasion of the virus by combining luteolin,  $\beta$ -sitosterol, and other main active ingredients with virus receptors, thereby enhancing anti-inflammatory activity, oxidation resistance, and regulation of the immunity by regulating the core targets of IL-6, MAPK3, MAPK1, IL-1 $\beta$ , CCL2, EGFR, and NOS2. Xue et al.<sup>[20]</sup> carried out the network pharmacology analysis and found that there are 10 medicinal materials related to the lung channel in Xuanfei Baidu decoction, among which 167 active ingredients and 242 potential targets were selected. The core drugs include *Glycyrrhizae Radix et Rhizoma*, *Ephedrae Herba*, *Artemisiae Annuae Herba*, *Verbenae Herba*, and *Polygonum Cuspidatum*. The core ingredients include quercetin, stigmasterol, kaempferol, luteolin, and isorhamnetin; the core targets include AKT1, IL-6, TP53, VEGFA, and TNF. The mechanism may be related to the PI3K-Akt, HIF-1, and TNF signaling pathways. Moreover, more than 60 ingredients and metabolites were detected in plasma of animals that were intragastrically administered with Xuanfei Baidu decoction, and more than 50 ingredients and metabolites were distributed in lung tissues, among which the active ingredients polydatin, isoliquiritin, ephedrine, kaempferol, atracylenolide I, and verbascoside are closely related to the negative regulation of inflammation-induced macrophage activation and the reduction of lung inflammation<sup>[16]</sup>.

## Conclusions

To sum up, this expert consensus was formed mainly based on the existing evidence with reference to the consensus of relevant domestic guidelines and clinical literature and in combination with frontline clinical medication experience. It was followed with discussions on the major functions, usage, dosage, adverse reactions, and considerations of Xuanfei Baidu granule. We aimed to provide clinicians with a reference to the rational use

of Xuanfei Baidu granule. According to the principles of evidence-based medicine, this expert consensus will be updated regularly.

## Conflict of interest statement

The authors declare no conflict of interest.

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## Author contributions

Qingquan Liu, Yuhong Huang, Hongchun Zhang, Chengxiang Wang, Qing Miao, and Wenke Zheng were drafters; Boli Zhang, Enxiang Chao, Tangchun Wu, and Huahao Shen were steering committee experts; Junhua Zhang, Fengwen Yang, Jinhui Tian, and Xinyao Jin were methods experts.

## Ethical approval of studies and informed consent

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