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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Treatment of Acute Upper Respiratory Infection

Shufeng Jiedu Capsule is indicated for the treatment of acute upper respiratory infection (AURI) due to some bacteria or virus infection in adult illness who have symptom such as fever; headache; pharyngalgia; nasal obstruction; cough and some related symptoms due to AURI.

1.2 Limitations of Use

The following points should be considered before initiating treatment or prophylaxis with Shufeng Jiedu Capsule:

- There is no evidence for efficacy of Shufeng Jiedu Capsule in the treatment of illness patients with body temperature over 39.1°C, total number of white blood cells $> 10 \times 10^9/L$, and neutrophile granulocyte $> 80\%$.
- Patients with Conjunctival Fever or Herpetic Pharyngitis; furthermore, Gestation and Nursing Mothers didn't enrolled in the Shufeng Jiedu Capsule clinical trials.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Considerations

- Shufeng Jiedu Capsule was recommended to be taken after meals.
- Treatment may be better begin after found symptoms appearance due to AURI.

2.2 Standard Dosage - Treatment of Influenza

The recommended oral dose of Shufeng Jiedu Capsule for treatment of AURI in adults is three times daily, 4 capsules each time.

3 DOSAGE FORMS

Capsules: 0.52 g / capsule. Equivalent to 2.7 g decoction

4 CONTRAINDICATIONS

Shufeng Jiedu Capsule is contraindicated in patients with known serious hypersensitivity to product or any component of the product.

5 WARNINGS AND PRECAUTIONS

This product contains the extracts of *Polygonum cuspidatum*, *Herba Patriniae*, *Radix Isatidis*, etc. After taking the drug, symptoms such as diarrhea, loose stools, and yellow urine are the manifestations of drug treatment. The symptoms can be relieved by themselves after stopping the drug.

6 ADVERSE REACTIONS

Monitoring data shows that the product can see the following adverse reactions:

- Nausea, Vomiting;
- Abdominal Pain, Diarrhea, Bloating, Acid Reflux;
- Rash, Itching;
- Dizziness, Chest Tightness, Allergic Reactions, etc.

The most common adverse reactions are nausea and vomiting.

Table 1 Monitoring data of Frequent Adverse Events in patients nearly eighty million accepted Shufeng Jiedu Capsule treatment from 2015 year to 2019 year.

Adverse Event	Number of case
Nausea and Vomiting	415
Abdominal Pain, Diarrhea, Bloating	42
Acid Reflux	5

Rash, Itching	84
Allergic Reactions	26
Dizziness	14
Chest Tightness	8
Others	96

6.1 Clinical Trials Experience

A total of 224 subjects (111 patients in experiment group and 113 patients in control group) who participated in adult controlled clinical trials for the treatment of acute upper respiratory infection (AURI) were treated with Shufeng Jiedu Capsule. Security Result: The experiment group has one case with Nausea, which is probably concerned with the medicine.

7 DRUG INTERACTIONS

No research in this area.

8 USE IN SPECIFIC POPULATIONS

8.1 Pediatric Use

After administering 4g/kg or 6g/kg Shufeng Jiedu Capsule to 10-day-old mice for 14 days, the rats were found to be well tolerated. There was drug-related loose stools, slow weight gain, and slight increase in weight/coefficient of liver, spleen and kidney of male animals, no other drug-related toxicity was seen. The DOSAGE of 4g/kg or 6g/kg is equivalent to 19 times or 28.6 times the DOSAGE of a 1-month-old infant; equivalent to 25 times or 37.5 times the DOSAGE of a 3.5-year-old child.

After administering 6g/kg Shufeng Jiedu Capsule to 24-day-old rats for 14 days, the rats were found to be well tolerated. There was a drug-related color change in urine, and no other drug-related toxicity was observed. The DOSAGE of 6g/kg is equivalent to 37.5 times the DOSAGE of 3.5-year-old children; equivalent to 46.1 times the DOSAGE of 9.5-year-old children.

8.2 Pregnancy

Gavage of Shufeng Jiedu Capsules has no obvious toxicity on the development of mother rats and fetuses. The DOSAGE without observable damage is 7.2g/kg, which is equivalent to 81 times of the clinical human DOSAGE (calculated by 70kg of human body weight, clinical The human DOSAGE is 0.089g/kg/day).

9 OVER-DOSAGE

At present, there has been no experience with overdose.

10 DESCRIPTION

10.1 General Information

Shufeng Jiedu Capsule was composed of eight list as below:

Table 2 Latin Names, common name and Medicinal plant part of each herbs

Plant Latin Names	Common Names and plant part	Medicinal plant part
Polygonum cuspidatum Sieb.et Zucc.	Polygonum cuspidatum	Root
Forsythia suspensa (Thunb.) Vahl	Forsythia	Fruit
Isatis indigotica Fort.	Radix Isatidis	Root
Bupleurum chinense DC.	radix bupleuri	Root
Patrinia scabiosifolia Fischer ex Treviranus	Herba Patriniae	Herb
Verbena officinalis L.	Vervain	Herb
Phragmites communis Trin.	Reed	Rhizome
Glycyrrhiza uralensis Fisch.	Liquorice	Root

The product is made by mixing the dry extracts and the volatile oils of the herbs.

11 CLINICAL PHARMACOLOGY

11.1 Mechanism of Action

Shufeng Jiedu Capsule is Anti-bacterial and Antiviral drug.

11.2 Pharmacokinetics

No research in this area.

12 NONCLINICAL TOXICOLOGY OR PHARMACOLOGY

Shufeng Jiedu Capsule had a significant reduction in mortality in *Staphylococcus aureus* infection^[1].

Shufeng Jiedu Capsule were a broad-spectrum antibacterial that inhibited all 18 species of bacteria^[1].

The combination of Shufeng Jiedu Capsule and oseltamivir improved survival rates, attenuated clinical symptoms, induced weight gain, alleviated lung damage, and significantly reduced IL-1 β and IL-18 levels in serum and BALF, as well as reduced the expression levels of NLRP3-associated components and viral titers in lung homogenates^[2].

Shufeng Jiedu Capsule also alleviated PAK induced lung injury in KM mice. A complex network containing 15 pathways related to inflammation regulated by 16 types of components from six types of herbs via 29 proteins^[3].

13 CLINICAL STUDIES

13.1 Pre-Market Clinical Trails

- **Period II:** Western medicine clinic: the test group with 112 cases has 54.46% of recovery and 78.57% of significant effect; the contrast group with 114 cases has 47.37% of recovery and 74.56% of significant effect. TCM symptom: the test group with 112 cases has 55.36% of recovery and 78.57% of significant effect;

the contrast group with 114 cases has 46.49% of recovery and 73.68% of significant effect.

- **Period III:** Western medicine clinic: the test group with 350 cases has 46.30% of recovery and 74.90% of significant effect; the contrast group with 115 cases has 40.00% of recovery and 69.60% of significant effect. TCM symptom: the test group with 350 cases has 40.57% of recovery and 74.29% of significant effect; the contrast group with 115 cases has 46.96% of recovery and 78.26% of significant effect.
- **Security Result:** The test group has one case with naupathia, which is probably concerned with the medicine.

13.2 Post-market Clinical Trails

13.2.1 Treatment on AURI

A randomize-controlled double-blind test (240 patients, treatment group 120 cases; control group 120 cases) indicated that in treating acute upper respiratory infection of wind-heat syndrome, Shufeng Jiedu Capsules could lower body temperature quickly and improve clinical symptoms with good safety^[4].

13.2.2 Treatment on Sepsis

Another RCT test (combination group, 66 cases; single antibiotics group 63 cases) indicated that combination of antibiotics and Shufeng Jiedu Capsules in the treatment of sepsis is superior to routine antibiotic treatment since combination therapy reduces the inflammatory response and improves prognosis for septic patients ^[5].

13.2.3 Treatment on COVID-19

Shufeng Jiedu Capsules combined with Arbidol in the treatment of common-type COVID-19 can effectively promote the improvement of patients' clinical symptoms and it's safe. The combination of traditional Chinese and Western allopathic medicine is worth promoting in the clinical treatment of COVID-19 ^[6].

13.3 Review Literature

Shufeng Jiedu Capsule was associated with a significant reduction in treatment failure, from 20.1 to 8.3% (11 trials; 815 patients; relative risk 0.43, 95% confidence

interval [CI] 0.30 to 0.62), and duration of hospital stay (2 trials; 79 patients; mean difference−4.32 days, 95% CI−5.89 to−2.75 days) in the treatment of AECOPD. No significant difference in adverse events was found between Shufeng Jiedu Capsule and control groups^[7].

Meanwhile, another research suggests that Shufeng Jiedu Capsule in combination with usual care appears to shorten the duration of fever, cough and sore throat of AURTIs, and improve cure rate within 5 days of treatment. The use of Shufeng Jiedu Capsule is safe.

14 HOW SUPPLIED/STORAGE AND HANDLING

Air-proof package.

15 PACKAGE AND EXPIRY

- Package: Aluminium-plastic blister package. 12 capsules / sheets × 3 sheets / box.
- Expiry: 24 months.

16 EXECUTIVE STANDARD

The first supplement to the 2015 edition of “Chinese Pharmacopoeia”, The YBZ00652009 Standard by State Food and Drug Administration. Approved Document No. Guoyaozhunzi Z20090047; Approved Date: January 4, 2009

Manufacturer

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Contact the manufacturer if you have any questions

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17 REFERENCE

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