

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

XiaoYao Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 720mg tablet contains:

90mg extract (as dry extract) of the combination of dried bupleurum root (*Bupleurum Chinese* DC) and dried white peony root (*Paeonia lactiflora* Pall), corresponding to 243~477mg of dried bupleurum root and 243~477mg of dried white peony root.

320mg extract (as dry extract) of the combination of dried angelica sinensis root (*Angelica sinensis* (Oliv.) Diels), dried atractylodes rhizome (*Atractylodes macrocephala* Koidz) and dried liquorice root/rhizome (*Glycyrrhiza glabra* L. and/or *Glycyrrhiza inflata* Bat. and/or *Glycyrrhiza uralensis* Fisch.), corresponding to 256~352mg dried angelica sinensis root, 256~352mg dried atractylodes rhizome and 224~288mg dried liquorice root/rhizome.

Extraction solvent: Water.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Light yellow, capsule shaped, film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product for relief of symptoms of mental stress and exhaustion, such as low mood and decreased appetite. The indication is exclusively based on traditional use and not on clinical evidence.

4.2 Posology and method of administration

Posology

Adults take two film-coated tablets twice daily (up to four film-coated tablets per day).

Method of administration

Once in the morning and once in the evening with a glass of water.

It is recommended that to take XiaoYao Tablets after meal.

Tablets are for oral use only.

Paediatric patients

Safety and efficacy of XiaoYao Tablets have not been established in children and

adolescents below the age of 18 years. No data is available.

Duration of use

The maximum duration of use is 2 weeks.

If the symptoms do not improve or worsen after use of XiaoYao Tablets, or if side effects mentioned in section 4.8 are observed, a doctor should be consulted.

4.3 Contraindications

Do not use in case of known hypersensitivity to the herbal substances of XiaoYao Tablets or to any of the excipients listed in section 6.1.

Co-administration with drugs that affect blood clotting (such as warfarin), see section 4.5.

Co-administration with monoamine oxidase inhibitor (MAOIs, such as moclobemide), see section 4.5.

4.4 Special warnings and precautions for use

Do not exceed the recommended dose.

The safety and efficacy of XiaoYao Tablets in children under 18 years of age have not been established. XiaoYao Tablets use is therefore not recommended in this group.

Diabetics are advised not to take this medicine because of a possible effect on blood sugar levels.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of XiaoYao Tablets and blood-thinning drugs (such as warfarin) may increase the risk of bleeding. Co-administration of medicines that affect blood clotting is contraindicated (see 4.3)

Concomitant use with monoamine oxidase inhibitors (MAOIs, such as moclobemide) is contraindicated (see 4.3).

Concomitant use of XiaoYao Tablets and contraceptives is not recommended based on possible estrogen-like effect of this product.

Concomitant use of XiaoYao Tablets and carbamazepine may increase the side effects of carbamazepine.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no documented data on the use of components of XiaoYao Tablets in pregnant women. Results from animal studies are insufficient (see section 5.3). As a precautionary measure, the use of XiaoYao Tablets during pregnancy is therefore not recommended.

Breastfeeding

It is not known whether components of XiaoYao Tablets are excreted in breast milk. A risk to the child cannot be ruled out. The use of XiaoYao Tablets during the period of

breastfeeding is therefore not recommended.

Fertility

There is no known data on the effect of using XiaoYao Tablets on fertility in humans.

4.7 Effects on ability to drive and use machines

No studies have been done on the effect on the ability to drive or on the ability to operate machines. As far as is known, XiaoYao Tablets under normal dose have no effect on the ability to drive or use machines.

4.8 Adverse reactions

No adverse events have been reported in Europe for the current use of XiaoYao Tablets. Adverse events stated in this section have been reported in clinical studies with Xiaoyao preparations performed in China.

The adverse events are presented below per system organ class and frequency.

Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1.000$, $< 1/100$), rare ($\geq 1/10.000$, $< 1/1.000$) and very rare ($< 1/10.000$).

- Gastrointestinal disorders: nausea, dry mouth, diarrhea, stomach discomfort; uncommon.

- General disorders: fatigue; uncommon.

If adverse reactions occurred, it is recommended to stop taking this medicine and consult a doctor.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via The Netherlands Pharmacovigilance Centre Lareb at www.lareb.nl.

4.9 Overdose

No cases of overdose have been reported.

In the event of an overdose, patients may experience an increased chance of an undesirable effect. If symptoms develop, medical advice should be sought.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data do not indicate a special risk for people when using XiaoYao Tablets at the recommended dosage.

XiaoYao Tablets were found to be not genotoxic in an Ames test.

No carcinogenicity studies have been conducted with XiaoYao Tablets. Data on reproduction toxicity of the five herbs from XiaoYao Tablets are limited.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet cores:

Microcrystalline cellulose

Levomenthol

Magnesium stearate

Film coating:

Titanium Dioxide (E171)

Polyvinyl Alcohol-part Hydrolysed (E1203),

Talc (E553b),

HPMC 2910/Hypromellose (E464),

Macrogol/PEG (E1521),

Iron Oxide Yellow (E172),

Iron Oxide Red (E172),

Iron Oxide Black (E172).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

This medicine has a shelf life of 36 months in the sealed package.

The shelf life after opening is 1 month.

6.4 Special precautions for storage

Store below 30°C in original packaging. Keep out of sight and reach of children.

6.5 Nature and contents of container

White HDPE tablet container with PE seal and HDPE screw cap.

One tablet container contains 60 tablets.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Tasly Healthcare Deutschland GmbH,
Bahnhofstraße 8,
30159 Hannover, Germany

8. MARKETING AUTHORISATION NUMBER(S)

RVG 126209

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

23 August 2021