



St. John's Wort Red Oil Capsules

Active ingredient: St. John's Wort extract

Soft capsules

To be taken by adults

Read the entire information leaflet carefully; it contains important information for you. This medicinal product is available **without a prescription**. However, St. John's Wort Red Oil Capsules must be used according to the instructions to achieve the best possible results.

- Keep this information leaflet. You may want to reread it at a later date.
- Ask your pharmacist if you need any additional information or advice.
- Please inform your doctor or pharmacist if you are seriously affected by one of the listed side effects or if you notice side effects that are not included in this information leaflet.
- Consult a doctor or another person qualified in a healing profession if your complaints continue to worsen or if there is no improvement after 14 days.

This information leaflet contains:

1. What are St. John's Wort Red Oil Capsules and what are they used for?
2. What must I be aware of before taking St. John's Wort Red Oil Capsules?
3. How should St. John's Wort Red Oil Capsules be taken?
4. What are the possible side effects?
5. How should St. John's Wort Red Oil Capsules be stored?
6. Additional information

1. WHAT ARE ST. JOHN'S WORT RED OIL CAPSULES AND WHAT ARE THEY USED FOR?

St. John's Wort Red Oil Capsules are a traditional plant-based medicinal product.

Area of use:

Traditionally used to relieve temporary mental fatigue.

This medicine is a traditional medicine that is exclusively registered on the basis of years of application for the application areas.

2. WHAT MUST I BE AWARE OF BEFORE TAKING ST. JOHN'S WORT RED OIL CAPSULES?

St. John's Wort Red Oil Capsules must not be taken:

If you are allergic to St. John's wort, soya, peanuts, ponceau 4R (E124), or to any other component of St. John's Wort Red Oil Capsules.

Special care is necessary when taking St. John's Wort Red Oil Capsules:

Intensive UV radiation (long periods of sunbathing, sun lamps and solariums) should be avoided when taking St. John's Wort Red Oil Capsules.

In the case of on-going symptoms or the occurrence of side effects not listed in this information leaflet, you should consult a doctor or another qualified health professional.

Please note the following when taking St. John's Wort Red Oil Capsules together with other medicines:

Investigations on reciprocal effects of St. John's Wort Red Oil Capsules with other medicines have not been carried out.

Please notify your doctor or pharmacist if you take other medicinal products or have recently been taking other medicinal products, even if they are not prescription medicines.

When taking St. John's Wort Red Oil Capsules together with food and drink:

There are no known side effects with food and drink.

Pregnancy and lactation:

St. John's Wort Red Oil Capsules should not be taken during pregnancy and lactation, as sufficient research has not yet been conducted in this field.



Children and young people:

Insufficient research has been conducted into children and youngsters under 18 years of age taking this medicinal product. It should, therefore, not be given to children and youngsters under the age of 18.

Fitness to drive and operate machinery:

Appropriate investigations on fitness to drive and ability to operate machinery have not been carried out.

Important information about certain other components contained in St. John's Wort Red Oil Capsules:

Warning note: This medicinal product contains ponceau 4R (E124), which can cause allergic reactions in people who are especially sensitive to this substance.

3. HOW SHOULD ST. JOHN'S WORT RED OIL CAPSULES BE TAKEN?

Always take St. John's Wort Red Oil Capsules as described in the instructions in this information leaflet. Please consult your doctor or pharmacist if you are unsure.

Dose: The normal dose for adults is 1 soft capsule 2 times daily.

Use of this medicinal product by children and youngsters under 18 years of age is not recommended due to insufficient research. Insufficient data is available for concrete dosage recommendations for limited liver or bladder kidney function.

Type of application: Please swallow the capsules whole with sufficient fluid, preferably with a glass of water.

Duration of use: Consult a doctor or another person qualified in a healing profession if your complaints last longer than two weeks whilst taking St. John's Wort Red Oil Capsules.

Please consult your doctor or pharmacist if you feel that the St. John's Wort Red Oil Capsules are having too great or too little an effect.

What to do if you take too many St. John's Wort Red Oil Capsules:

If you accidentally take one or two more dosages than instructed it will generally not have any harmful effect. In this case, continue taking the capsules as described in the dosage instructions, or as prescribed by your doctor.

If you have taken a significant overdose of this medicinal product it can cause known side effects such as stomachache, nausea and diarrhoea. In this case please inform your doctor. Your doctor can decide on the best course of action.

Seizures and confusion have been reported after taking 4.5 g of dry St. John's wort extract daily over a period of 2 weeks and an additional intake of 15 g of dry extract shortly before hospitalisation.

After taking massive overdoses, the skin should be protected from sunlight and other UV light sources for a period of 1 to 2 weeks due to possible increased photosensitivity.

If you forgot to take St. John's Wort Red Oil Capsules:

Do not take a double dose; instead take the dose as described in this information leaflet or as instructed by your doctor.

If you stop taking St. John's Wort Red Oil Capsules:

It is generally considered harmless to stop the treatment or to end it prematurely.

If you have any further questions about taking this medicinal product please consult your doctor or pharmacist.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

As is the case with all medicinal products, St. John's Wort Red Oil Capsules can have side effects, but they do not necessarily affect everyone.

The following frequency data is taken as a basis for the assessment of side effects:

Very often:	more than 1 in 10 people treated
Common:	1 to 10 people treated from 100
Occasional:	1 to 10 people treated from 1,000
Rare:	1 to 10 people treated from 10,000



Very rare: less than 1 people treated from 10,000
Unknown: Frequency cannot be assessed based on available data

Possible side effects:

Gastrointestinal side-effects, allergic skin reactions, fatigue and anxiety can occur.
The frequency of occurrence is not known. Persons with a light skin may react with symptoms similar to a heavy sunburn.

Other possible side effects:

Phospholids from soya beans can very rarely cause an allergic reaction. Ponceau 4R (E124) cause allergic reactions.

Please inform your doctor or pharmacist if you are seriously affected by one of the listed side effects or if you notice side effects that are not included in this information leaflet.

Reporting side effects:

Please inform your doctor or pharmacist if you notice side effects. This also applies to side-effects not stated in this leaflet. You can register any side-effects directly with Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de.

By reporting any side effects, you can make a contribution towards more information being available on the safety of this medicinal product.

5. HOW SHOULD ST. JOHN'S WORT RED OIL CAPSULES BE STORED?

Keep all medicines out of the reach and sight of children.

You may not use the medicine after the expiry date stated under "for use until" on the folding box or blister packaging. The use by date relates to the last day of the month in question.

Storage conditions:

Do not store above 25 °C.

6. ADDITIONAL INFORMATION

Contents of St. John's Wort Red Oil Capsules:

Active ingredient: St. John's Wort extract

1 soft capsule contains: 221 mg extract of St. John's Wort (0.10-0.13:1), extracting agent: corn oil

The other ingredients are:

Refined Corn Oil, Phospholipids from Soya Beans, Gelatine, Glycerol, Purified Water, Ponceau 4R (E124).

Packet sizes available: Original packet with 120 soft capsules.

This information leaflet was last updated in February 2021.

Art. No. 171

PB1221

For risks and side effects please read the information leaflet and consult your doctor or pharmacist.