

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Karmamood St John's Wort tablets

Boots St John's Wort Mood Lift tablets

Simply Supplements Mood Boost St John's Wort tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

250 mg of extract (as dry extract) from St John's wort aerial parts (*Hypericum perforatum* L.)(3.5-6:1)(equivalent to 875 – 1500 mg of St John's wort).

Extraction solvent: Ethanol 60% v/v.

Each film-coated tablet contains: Lactose monohydrate (11 mg).(See 'Section 4.4 Special warnings and precautions for use')

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Film-coated tablet.

Round, ochre, film-coated tablets, free from ruptures.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

A traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety, based on traditional use only.

#### 4.2 Posology and method of administration

For oral use only.

For adults and the elderly, take 1 tablet daily. The tablets should be swallowed whole with a little liquid. The tablets should not be chewed.

If symptoms worsen, or do not improve after 6 weeks, a doctor or a qualified healthcare practitioner should be consulted.

The use in children or adolescents under 18 years is not recommended (See 'Section 4.4 Special Warnings and Precautions for Use').

#### 4.3 Contraindications

Hypersensitivity to the active ingredient or any of the excipients.

Patients with known dermal photosensitivity or patients undergoing phototherapy or any photodiagnostic procedures.

Concomitant use with any of the medicines included in Section 4.5. This is because St John's wort (*Hypericum perforatum*) has been shown to induce the cytochrome P450 isoenzymes CYP1A2, CYP2C19, CYP2C9 and CYP3A4 as well as transport protein P-glycoprotein. This results in pharmacokinetic interactions with a large number of medicines including leading to a possible decrease in the effectiveness of those medicines.

In addition, pharmacodynamic interactions have also been identified with antidepressants, particularly the SSRI antidepressants and with the triptan group of medicines.

#### 4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If symptoms worsen, or do not improve after 6 weeks, a doctor or a qualified healthcare practitioner should be consulted.

The use in children or adolescents less than 18 years old is not recommended due to lack of adequate data and medical advice should be sought.

This product is intended for relief of symptoms of slightly low mood and mild anxiety. Patients with signs and symptoms of depression should seek medical advice for appropriate treatment.

In very rare cases, particularly in light-skinned persons, sun burn type reactions on skin areas exposed to strong sunlight may occur due to photosensitisation by St John's wort. Persons using this product should avoid excessive sunbathing or the use of sunbeds or solariums.

This product should be discontinued at least 10 days prior to elective surgery due to the potential for interactions with medicinal products used during general and regional anaesthesia (see Section 4.5).

Each film-coated tablet also contains: Lactose monohydrate (11 mg).

Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

#### 4.5 Interaction with other medicinal products and other forms of interaction

Substances in St John's wort (*Hypericum perforatum*) have been shown to induce the cytochrome P450 isoenzymes CYP1A2, CYP2C19, CYP2C9 and CYP3A4 as well as the transport protein P-glycoprotein. This results in pharmacokinetic interactions with a large number of medicines leading to a potential decrease in the effectiveness of those medicines.

The concomitant use of ciclosporin, tacrolimus for systemic use, Amprenavir, indinavir and other protease inhibitors, irinotecan and warfarin is contraindicated.

Special care should be taken in case of concomitant use of all drug substances the metabolism of which is influenced by CYP1A2, CYP3A4, CYP2C9, CYP2C19 or P-glycoprotein (e.g. amitriptyline, fexofenadine, benzodiazepines, methadone, simvastatin, digoxin, finasteride), because a reduction of plasma concentration is possible.

Users of oral contraceptives taking St John's wort (*Hypericum perforatum*) may experience intracyclic menstrual bleeding and risk of contraception failure is increased.

Clinically significant pharmacodynamic interactions have also been identified with the SSRI antidepressants, and the triptan group of medicines used to treat migraines. Due to the increased risk of undesirable effects associated with these interactions this product should not be used concomitantly with these types of medicines.

Therefore this product should not be taken concomitantly with the medicines included in the table below:

Co-administered drug	Interaction	Recommendations concerning co-administration
<b>Anaesthetics /pre-operative medicines</b>		
Fentanyl,	Reduced blood levels with risk	Based on the elimination half-

propofol, sevoflurane, midazolam	of therapeutic failure.	lives of hypericin and hyperforin this product should be discontinued at least 10 days prior to elective surgery.
<b>Analgesics</b>		
Tramadol	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Antianginals</b>		
Ivabradine	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Anti-arrhythmics</b>		
Amiodarone	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Antibacterials</b>		
Erythromycin, clarithromycin, telithromycin	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Anticoagulants</b>		
warfarin, acenocoumarol	Reduced anticoagulant effect and need for increased dose	Do not take with this product.
<b>Antidepressants</b>		
<b>Tricyclics</b> eg. amitriptyline, clomipramine  <b>MAOIs</b> eg. moclobemide  <b>SSRIs</b> eg. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline,  <b>Others</b> eg. duloxetine, venlafaxine	Increased serotonergic effects with increased incidence of adverse reactions.	Do not take with this product.
<b>Antiepileptics</b>		
All drugs in this class including:  carbamazepine phenobarbitone phenytoin primidone sodium valproate	Reduced blood levels with increased risk of frequency and severity of seizures.	Do not take with this product.
<b>Antifungals</b>		
itraconazole, voriconazole	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Antimalarials</b>		
artemether lumefantrine	Reduced blood levels with risk of therapeutic failure.	<b>Do not take with this product.</b>
<b>Anti-parkinsons</b>		
rasagiline	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Antipsychotics</b>		

aripiprazole	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Antivirals</b>		
<b>HIV protease inhibitors:</b> amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir	Reduced blood levels with possible loss of HIV suppression.	Do not take with this product.
<b>HIV non-nucleoside reverse transcriptase inhibitors:</b> efavirenz, nevirapine, delavirdine	Reduced blood levels with possible loss of HIV suppression	Do not take with this product.
<b>Anxiolytics</b>		
bupirone	Increased serotonergic effects with increased incidence of adverse reactions.	Do not take with this product.
<b>Aprepitant</b>	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Barbiturates</b>		
butobarbital, phenobarbital	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Calcium channel blockers</b>		
amlodipine, nifedipine verapamil, felodipine	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Cardiac glycosides</b>		
digoxin	Reduced blood levels and loss of control of heart rhythm or heart failure.	Do not take with this product.
<b>CNS Stimulants</b>		
methyl phenidate	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Cytotoxics</b>		
irinotecan, dasatinib, erlotinib, imatinib, sorafenib, sunitinib, etoposide, mitotane	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Hormonal contraceptives</b>		
Oral contraceptives  Emergency Hormonal Contraception  Hormonal implants, injections  Transdermal patches, creams etc.  Intra-uterine devices with hormones	Reduced blood levels with risk of unintended pregnancy and breakthrough bleeding.	Do not take with this product.

<b>Hormone Replacement Therapy</b>		
Hormone Replacement Therapy: Oral Trandermal patches, gels Vaginal rings	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Hormone antagonists</b>		
exemestane	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Diuretics</b>		
eplerenone	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>5HT agonists</b>		
almotriptan,eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan	Increased serotonergic effects with increased incidence of adverse reactions.	Do not take with this product.
<b>Immunosuppressants</b>		
cyclosporin, tacrolimus	Reduced blood levels with risk of transplant rejection.	Do not take with this product.
<b>Lipid regulating drugs</b>		
simvastatin, atorvastatin	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Lithium</b>		
	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Proton pump inhibitors</b>		
lansoprazole, omeprazole	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Theophylline</b>		
	Reduced blood levels and loss of control of asthma or chronic airflow limitation.	Do not take with this product.
<b>Thyroid hormones</b>		
thyroxine	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.
<b>Oral hypoglycaemic drugs</b>		
gliclazide	Reduced blood levels with risk of therapeutic failure.	Do not take with this product.

#### 4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No studies on the effects on fertility have been performed.

#### 4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

#### **4.8 Undesirable effects**

Gastrointestinal disorders including dyspepsia, anorexia, nausea, diarrhoea, constipation; allergic skin reactions such as rash, urticaria, pruritis; fatigue and restlessness have been reported. The frequency is not known.

Fair-skinned individuals may react with intensified sunburn-like symptoms under intense sunlight or strong ultra-violet (UV) irradiation.

Other adverse reactions that have been reported include headaches, neuropathy, anxiety, dizziness and mania.

If other adverse reactions not mentioned above occur, a doctor, pharmacist or a qualified healthcare practitioner should be consulted.

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continual monitoring of the benefit/risk of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store.

#### **4.9 Overdose**

There are no data on human overdose with St John's wort.

After the intake of up to 4.5g dry extract per day for 2 weeks and additionally 15g dry extract just before hospitalization seizures and confusion have been reported.

Where a large overdose has occurred, phototoxic reactions may occur. The skin of the patient should be protected for one week from UV irradiation and sunlight. Outdoor activities should be restricted and clothes and/or sun block preparations used to protect the skin from sunlight. Symptomatic and supportive measures should be taken as appropriate.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Herbal medicinal product for the treatment of depressive disorders.

ATC code: N06AP01

The active constituents of St John's wort have not been definitively established. However, the phloroglucinol constituent, hyperforin, and the hypericin group of constituents, are thought to play an important role in its activity.

### **5.2 Pharmacokinetic properties**

The active ingredients of St John's wort can interact with other medicinal agents in two ways. Firstly, active ingredients in St John's wort that themselves are metabolised in the liver by the CYP3A4 isoenzyme, increase (induce) the activity of this enzyme so that it accelerates the elimination of other medicinal agents which are degraded by the same pathway. This leads to a consequent reduction in the plasma concentration and effectiveness of these other substances. Secondly, the active ingredients in St John's wort, like other type SRI or SSRI medicinal agents with an antidepressant action, can raise the concentration of serotonin in certain parts of the central nervous system so that this neurotransmitter can sometimes reach toxic levels, particularly when drugs containing St John's wort are combined with other antidepressants

### **5.3 Preclinical safety data**

Reverse mutation assays (Ames test) on bacteria indicated that the product was not mutagenic in *Salmonella typhimurium* (strains TA 98, TA 100, TA 102, TA 1535 and TA 1537) mutation assays with or without metabolic activation.

Adequate tests on reproductive toxicity have not been performed. Tests on carcinogenicity have not been performed.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose monohydrate  
Calcium hydrogen phosphate dihydrate  
Cellulose, powdered  
Silica, colloidal anhydrous

#### **Tablet core:**

Cellulose, powdered  
Magnesium Stearate  
Silica, colloidal anhydrous  
Sodium starch glycolate (type A)  
Stearic acid

#### **Film-coating:**

Eudragit E 100  
Hypromellose  
Macrogol 6000  
Talc  
Titanium dioxide E 171  
Iron oxide hydrate E 172 (= yellow iron oxide)

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Original packages contain 28, 30, 56, 60, 90, 120 film-coated tablets.

The film-coated tablets are packed in PVC/PVDC aluminium blisters and inserted into a carton together with the package leaflet.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

No special requirements

**7 MARKETING AUTHORISATION HOLDER**

Schwabe Pharma (UK) Ltd  
Alexander House  
Mere Park  
Dedmere Road  
Marlow  
Buckinghamshire  
SL7 1FX

**8 MARKETING AUTHORISATION NUMBER(S)**

THR 23056/0011

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

24/11/2016

**10 DATE OF REVISION OF THE TEXT**

24/04/2024