

# PROFESSIONAL INFORMATION

## Releaf Curcumin 185



SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

**Releaf Curcumin 185 (soft gel capsules).**

### COMPOSITION:

Each soft gel capsule contains:

NovaSOL<sup>®</sup> Liquid solubilisate of curcumin extract from Curcumin

(*Curcuma longa* L. (Turmeric rhizome extract)).

500 mg

Inactive ingredients are: Gelatin, Sorbitol, Glycerol E422, Purified Water.

Sugar free.

### CATEGORY AND CLASS:

Category of medicine: D

Class: D 3.5 Connective Tissue Medicines (Others)

Complementary Medicine: Western Herbal

### PHARMACOLOGICAL ACTION:

#### Pharmacodynamic properties:

**Releaf Curcumin 185** contains NovaSOL<sup>®</sup> Liquid solubilisate of curcumin extract from Curcumin (*Curcuma longa* L. (Turmeric rhizome)): A Liquid solubilisate of curcumin extract with 6% Curcuminoids of a spice that is traditionally used to relieve joint pain and inflammation associated with osteoarthritis. Curcumin is an antioxidant which exerts multiple benefits throughout the body, including suppressing pro-inflammatory chemicals. Curcumin is usually poorly absorbed from the gastrointestinal tract. However, NovaSOL<sup>®</sup> solubilising nanotechnology gives curcumin unique properties resulting in faster absorption and 185 times (bioavailability factor curcumin AUC, 24H) improved bioavailability than standard Curcumin extract.

#### Pharmacokinetic properties:

The active ingredient in this formulation is well known. Pharmacokinetic studies have not been conducted on **Releaf Curcumin 185**.

### INDICATIONS:

**Releaf Curcumin 185**, which is 185 times more bioavailable than standard Curcumin extract, is used to assist with the relief of joint pain and inflammation associated with osteoarthritis. **Releaf Curcumin 185** is a powerful antioxidant.

### CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Not recommended during pregnancy and/or lactation.

Contraindicated in patients with gallstones or a bile obstruction.

Contraindicated in patients with stomach ulcers or excess stomach acid.

Contraindicated in patients with bleeding disorders.

Contraindicated in patients with diabetes or hypoglycaemia.

Contraindicated in patients with iron deficiency.

Contraindicated in patients with gastroesophageal reflux disease (GERD/GORD).

Contraindicated in women with hormone-sensitive conditions.

### WARNINGS and SPECIAL PRECAUTIONS:

Curcumin may cause gallbladder contractions, dyspepsia, distension and gastroesophageal reflux. It can have an anticoagulant and antiplatelet effect, a hypoglycaemic effect, mild oestrogenic effects and may stimulate menstrual flow and the uterus. Caution in patients trying to conceive.

#### Effects on the ability to drive and use machinery:

No studies on the effect of **Releaf Curcumin 185** on the ability to drive or operate machinery were performed. It is unlikely that **Releaf Curcumin 185** would affect the ability to drive or operate machinery.

### INTERACTIONS:

Adverse effects have not become known with the simultaneous ingestion of **Releaf Curcumin 185** and food and drink.

Curcumin may cause gallbladder contractions and should be administered with care to patients with gallstones or gallbladder disease.

It may also have an anticoagulant and antiplatelet effect and might cause an increased risk of bleeding. Therefore, **Releaf Curcumin 185** should be administered with care to patients with bleeding disorders. Discontinue use of **Releaf Curcumin 185** at least two weeks before surgery and do not use it perioperatively. **Releaf Curcumin 185** should not be used with other treatments or herbs that might have an anticoagulant and antiplatelet effect as this might increase the risk of bleeding. Such treatments and herbs include aspirin, fluidione, clopidogrel, dalteparin, enoxaparin, heparin, ticlopidine, warfarin, angelica, clove, danshen, garlic, ginger, ginkgo, Panax ginseng, red clover, willow and others.

Curcumin can reduce levels of blood glucose and glycosylated haemoglobin (HbA1C) in diabetics and might contribute to hypoglycaemia. Therefore, **Releaf Curcumin 185** should not be taken with other treatments or herbs that have a hypoglycaemic effect such as glimepiride, glyburide, insulin, pioglitazone, rosiglitazone, chlorpropamide, glipizide, tolbutamide, devil's claw, fenugreek, garlic, guar gum, horse chestnut, Panax ginseng, psyllium and Siberian ginseng.

Research has shown that high levels of curcumin may bind with iron and prevent iron absorption. Use **Releaf Curcumin 185** with caution in patients with iron deficiency.

Curcumin should be administered with care to patients with gastroesophageal reflux disease as it may cause adverse gastrointestinal effects including dyspepsia, distension and gastroesophageal reflux.

Curcumin inhibits the binding of 3h-estradiol or beta-galactosidase with the oestrogen receptor, in which case **Releaf Curcumin 185** might have mild oestrogenic effects and might interfere with hormone replacement therapy. In the event of oestradiol treatment or irradiation, curcumin counteracts proliferation of cervical and breast cancer cell lines and might have an anticancer effect against hormone-sensitive cancers. However, curcumin might also worsen hormone-sensitive conditions such as breast, uterine, and ovarian cancer, as well as endometriosis and uterine fibroids. Administer **Releaf Curcumin 185** with caution to women with hormone-sensitive conditions.

Curcumin might affect the activity of the cytochrome P450 1A1 (CYP1A1) enzyme and could also affect the treatment of drugs metabolised by this enzyme. These would include drugs such as chlorzoxazone, theophylline and bufuralol. Avoid using **Releaf Curcumin 185** in conjunction with these treatments.

Additionally, curcumin might also inhibit the cytochrome P450 1A2 (CYP1A2) enzyme and might increase the levels of drugs metabolised by this enzyme. These would include drugs such as clozapine, cyclobenzaprine, flvoxamine, haloperidol, imipramine, mexiletine, olanzapine, pentazocine, propranolol, tacrine, zileuton, zolmitriptan and others. Avoid using **Releaf Curcumin 185** in conjunction with these treatments.

Inhibition of cytochrome P450 3A4 (CYP3A4) enzyme may occur, which might increase the levels of tacrolimus, calcium channel blockers, chemotherapeutic agents, antifungals (ketoconazole, itraconazole), glucocorticoids, alfentanil, cisapride, fentanyl, lidocaine, losartan, fexofenadine, midazolam and others. Avoid using **Releaf Curcumin 185** in conjunction with these treatments.

Curcumin might enhance the oral bioavailability of docetaxel and paclitaxel. Also, curcumin might increase the blood levels of norfloxacin and sulfasalazine and might affect the effects and adverse effects of these treatments. **Releaf Curcumin 185** should not be administered in combination with these treatments.

P-glycoprotein expression and activity might be inhibited by curcumin, which might increase the adsorption of P-glycoprotein substrates. Treatments that might be affected include some chemotherapeutic agents (etoposide, paclitaxel, vinblastine, vincristine, vindesine), antifungals (ketoconazole, itraconazole), protease inhibitors (amprenavir, indinavir, nelfinavir, saquinavir), H2 antagonists (cimetidine, ranitidine), some calcium channel blockers (diltiazem, verapamil), digoxin, corticosteroids, erythromycin, cisapride, fexofenadine, cyclosporine, loperamide, quinidine and others. Avoid using **Releaf Curcumin 185** in conjunction with these treatments.

Taking curcumin for six days prior to taking talinolol can decrease the bioavailability of this treatment when taken together. Avoid using **Releaf Curcumin 185** prior to and in combination with talinolol.

### HUMAN REPRODUCTION:

#### Pregnancy and lactation:

Not recommended for use in pregnancy and lactation.

Consult a healthcare professional for further information.

#### Fertility:

Curcumin may have mild oestrogenic effects and may stimulate menstrual flow and the uterus. Caution in patients trying to conceive.

### DOSAGE AND DIRECTIONS FOR USE:

Adults: For moderate symptoms of joint pain and inflammation: Take 1 soft gelatin capsule once daily. For severe symptoms of joint pain and inflammation: Take 1 soft gelatin capsule twice daily.

If the symptoms worsen or persist, please consult your healthcare practitioner.

Do not use later than the expiry.

### SIDE EFFECTS:

#### Blood and the lymphatic system disorders:

*Frequent:* An increased risk of bleeding.

#### Metabolism and nutrition disorders:

*Frequent:* Hypoglycaemia.

#### Gastrointestinal disorders:

*Frequent:* Dyspepsia, diarrhoea, distension, gastroesophageal reflux, nausea and vomiting.

#### Hepato-biliary disorders:

*Frequent:* Gallbladder contractions.

#### Skin and subcutaneous tissue disorders:

*Frequent:* Allergic dermatitis.

### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

There is a chance that large doses of curcumin might cause an atrioventricular heart block.

Do not exceed the maximum recommended dose.

Treatment of overdose is symptomatic and supportive.

### IDENTIFICATION:

A 10 mm oval clear soft gelatin capsule containing a yellowish orange oil.

### PRESENTATION:

30's: The capsules are available in white 175 mL PET containers, with a white PP cap and an induction seal.

### STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C. Keep the container tightly closed. Protect from light. KEEP OUT OF REACH OF CHILDREN.

### REGISTRATION NUMBER:

TO BE ALLOCATED.

**Releaf Curcumin 185** has not been evaluated by the SAHPRA for its quality, safety or intended use. **Releaf Curcumin 185** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**  
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## PATIENT INFORMATION LEAFLET

This leaflet tells you about **Releaf Curcumin 185**.

Western Herbal Medicine

SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

**Releaf Curcumin 185 (soft gel capsules).**

Read all of this leaflet carefully because it contains important information for you. **Releaf Curcumin 185** is available without a doctor's prescription. Nevertheless, you still need to use **Releaf Curcumin 185** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Do not share **Releaf Curcumin 185** with any other person.

Ask your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve.

### WHAT Releaf Curcumin 185 CONTAINS:

Each capsule contains:

Active substances are:

NovaSOL<sup>®</sup> Liquid solubilisate of curcumin extract from Curcumin

(*Curcuma longa* L. (Turmeric rhizome extract)).

500 mg

Inactive ingredients are: Gelatin, Sorbitol, Glycerol E422, Purified Water.

Sugar free.

### WHAT Releaf Curcumin 185 IS USED FOR:

**Releaf Curcumin 185**, which is 185 times more bioavailable than standard Curcumin extract, is used to assist with the relief of joint pain and inflammation associated with osteoarthritis. **Releaf Curcumin 185** is a powerful antioxidant.

### BEFORE YOU TAKE Releaf Curcumin 185:

**Do NOT take Releaf Curcumin 185:**

- If you are allergic to any of the ingredients.
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding") (see "HOW TO TAKE Releaf Curcumin 185").

### Take special care with Releaf Curcumin 185:

Curcumin may cause gallbladder contractions, indigestion, bloating and gastroesophageal reflux disease (GERD/GORD). It can have a blood thinning and antiplatelet effect and might reduce blood sugar levels. It might have mild oestrogenic effects and may stimulate menstrual flow and the uterus. Caution when trying to conceive (fall pregnant).

**Releaf Curcumin 185** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

### Please consult your doctor or pharmacist prior to use if you:

- have gallstones or a bile obstruction.
- have stomach ulcers or excess stomach acid.
- have bleeding disorders.
- have diabetes or low blood sugar levels.
- are diagnosed with an iron deficiency.
- have gastroesophageal reflux disease (GERD/GORD).
- are a woman and have hormone-sensitive conditions.

### Releaf Curcumin 185 with food and drink:

There are no known side effects to taking **Releaf Curcumin 185** with food and drink.

### Pregnancy and breastfeeding:

Do not use **Releaf Curcumin 185** during pregnancy or while you are breastfeeding your baby, as safety and efficacy have not been established.

**If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.**

### Driving and using machinery:

No studies on the ability to drive or use machinery have been performed. It

