

**CATALYST JOINT AND MUSCLE PROTECT AND REPAIR WITH UC-II® AND CARNIPURE®****COMPLEMENTARY MEDICINE: COMBINATION PRODUCT**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR WITH UC-II® AND CARNIPURE® capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Carnipure® (L-Carnitine)	250 mg
<i>Boswellia serrata</i> Roxb. ex Colebr. (Boswellia) [Gum, standardised to 65 % boswellic acid]	60 mg
<i>Curcuma longa</i> L. (Turmeric) [Root, standardised to 95 % curcumin]	60 mg
UC-II® (collagen type II)	20 mg

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsule.

White capsules containing yellow/orange coloured powder.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR can assist with joint health or inflammation and PROTECT muscle tissue repair.

4.2 Posology and method of administration

Adults: Take 2 capsules once daily.

Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to boswellia, collagen type II, turmeric, L-carnitine or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use**Surgery:**

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR may interfere with blood glucose control in diabetic patients, and decrease platelet aggregation and increase the risk of bleeding in patients (see section 4.5). Patients should therefore be advised to discontinue CATALYST JOINT AND MUSCLE PROTECT AND REPAIR at least 2 weeks prior to any surgical procedures.

Gallstones, gallbladder disease, stomach ulcers or excess stomach acid:

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR should be used with caution in patients with gallstones, gallbladder disease, stomach ulcers or excess stomach acid.

Seizures:

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR might increase the seizure frequency or severity in patients with a history of seizures. Caution is advised in patients with seizure disorders.

Liver or kidney disease:

Patients with liver or kidney disease should consult with a health care provider before taking CATALYST JOINT AND MUSCLE PROTECT AND REPAIR.

4.5 Interaction with other medicines and other forms of interaction**Anticoagulant or antiplatelet medicines:**

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects (see section 4.4).

Antidiabetic medicines:

Concomitant use of CATALYST JOINT AND MUSCLE PROTECT AND REPAIR with antidiabetic medicines or herbal supplements may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR can cause side effects, such as headaches or dizziness, and can affect the ability to drive a vehicle and use machines. Caution is advised when driving a vehicle or operating machinery until the effects of CATALYST JOINT AND MUSCLE PROTECT AND REPAIR are known.

4.8 Undesirable effects

CATALYST JOINT AND MUSCLE PROTECT AND REPAIR is generally well tolerated.

Nervous system disorders:

Less frequent: headache, dizziness, seizures

Gastrointestinal disorders:

Frequent: constipation, dyspepsia, diarrhoea, distension, gastro-oesophageal reflux, nausea, vomiting, abdominal pain

Skin and subcutaneous tissue disorders:

Less frequent: itching

General disorders and administration site conditions:

Less frequent: oedema, general weakness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of CATALYST JOINT AND MUSCLE PROTECT AND REPAIR is important. It allows continued monitoring of the benefit/risk balance of CATALYST JOINT AND MUSCLE PROTECT AND REPAIR. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and PROTECTive.

5. PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Category and class: D 33.7 Combination Product.

Mechanism of action:

Collagen helps to assist joint health and joint inflammation. Curcumin has antioxidant properties and helps to relieve inflammation. Boswellia has anti-inflammatory, analgesic, and anti-arthritis effects, and is commonly used for pain and inflammation associated with arthritis. L-Carnitine has antioxidant and anti-inflammatory properties. It plays a role in the muscle recovery process by reducing muscle tissue damage.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Magnesium stearate (E572)
Microcrystalline cellulose (E460(i))
Silicon dioxide (E551)
Vegetable capsule (containing hypromellose (E551) and titanium dioxide (E171)).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.
Protect from light and moisture.

6.5 Nature and contents of container

175 mL amber PET jars with white flip top lids with a white shrink sleeve.
Pack size: 60 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6
10 Church Street
Durbanville 7550

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

February 2021.