

The Real Thing Joint Revolution Capsules

Complementary Medicine. Health Supplement.

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

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

THE REAL THING JOINT REVOLUTION CAPSULES contains MSM (methylsulfonylmethane) 333,34 mg, glucosamine sulphate sodium chloride 250 mg, chondroitin sulphate sodium 133,34 mg, Hyal Joint® (sodium hyaluronate) 13,34 mg and collagen type II 2 mg per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING JOINT REVOLUTION CAPSULES contains:

	Per capsule	Per 3 capsules	Per 6 capsules
MSM (methylsulfonylmethane)	333,34 mg	1000 mg	2000 mg
Glucosamine sulphate (marine)	250 mg	750 mg	1500 mg
Chondroitin sulphate (bovine)	133,34 mg	400 mg	800 mg
Hyal Joint® (sodium hyaluronate) (poultry)	13,34 mg	40 mg	80 mg
Native collagen type II (poultry)	2 mg	6 mg	12 mg

The inactive ingredients include dicalcium phosphate, Aerosil (silicone dioxide), magnesium stearate (palm oil), gelatine (bovine) capsule shell. The capsules are sugar free. For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

THE REAL THING JOINT REVOLUTION CAPSULES is a clear, hard gelatine capsule shell containing an off-white to beige powder with speckles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING JOINT REVOLUTION CAPSULES is a health supplement that helps with-

- Joint health, helps to support the mobility of joints, and may help to support healthy knees;
- Relief of joint pain, helps to protect against the deterioration of cartilage, and is a factor in maintaining good cartilage and/or joint health; joint mobility and joint comfort.

Supplementation should not replace a healthy, balanced and varied diet.

4.2 Posology and method of administration

Adults 18 years and older: Take 3 to 6 capsules orally once a day with a glass of water. Not to be taken at bedtime. Gastrointestinal upset can be alleviated by taking divided doses with meals. Advise person to use for a minimum of one month to experience the benefits. Consult a healthcare practitioner for prolonged use.

Paediatric population

THE REAL THING JOINT REVOLUTION CAPSULES is not indicated in paediatrics. It is not suitable for use in children.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Advise the person to consult a relevant healthcare practitioner if symptoms worsen.

Use with caution or avoid if:

- you are allergic to shellfish. There is a theoretical concern that glucosamine products derived from seafood may cause allergic reactions in people who are sensitive to shellfish;
- you are allergic to other collagen-containing products in the form of gelatine and bovine collagen products.

4.5 Interaction with other medicines and other forms of interaction

THE REAL THING JOINT REVOLUTION CAPSULES affecting other products:

Do not use together with warfarin or other anticoagulant therapy.

4.6 Fertility, pregnancy and lactation

Advise the person to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding.

Contra-indicated as there is insufficient reliable data to support the safe use of these supplements during pregnancy or lactation. No fertility data is available.

4.7 Effects on ability to drive and use machines

THE REAL THING JOINT REVOLUTION CAPSULES may have a minor influence on the ability to drive and use machines due to possible undesirable effects.

4.8 Undesirable effects

a. Summary of the safety profile

THE REAL THING JOINT REVOLUTION CAPSULES is generally well tolerated at recommended oral doses. Gastro-intestinal effects are the most commonly documented undesirable effects for these active ingredients.

b. Tabulated list of adverse reactions

Methylsulfonylmethane (MSM):

Immune system disorders

May increase allergy symptoms.

Nervous system disorders

Headache, fatigue, insomnia and difficulty concentrating.

Gastrointestinal disorders

Nausea (common), diarrhoea (common), bloating (common), mild gastrointestinal discomfort (common), constipation or indigestion.

Skin and subcutaneous disorders:

Pruritus.

Glucosamine:

Immune system

Allergic reactions in sensitive individuals (rare), including pruritis, erythematous rash, rash, urticaria, lip oedema, angioedema, dyspnoea, gait disturbance, somnolence, hypotension, anaphylaxis.

Nervous system disorders

Drowsiness and headache.

Eye disorders

Ocular dryness in older persons, increased intraocular pressure.

Respiratory, thoracic and mediastinal disorders

Asthma exacerbation with glucosamine-chondroitin products.

Gastrointestinal disorders

Epigastric and abdominal pain, cramps (common), heartburn (common), diarrhoea (common), nausea (common), dyspepsia, vomiting, constipation (common), bloating (common) and flatulence. Oral dryness in older persons.

Hepato-biliary

Hepatotoxicity (rare).

Skin and subcutaneous tissue disorders

Itching, fingernail and toenail toughening with an increased rate in growth.

Chondroitin:

Nervous system disorders

Headache (rare) following treatment with a combination of oral chondroitin sulphate and glucosamine sulphate.

Gastrointestinal disorders

Nausea (common), bloating (common), abdominal pain (common), diarrhoea (common), constipation (common), dyspepsia (common) and epigastric burning.

Hepato-biliary disorders

Combination of glucosamine and chondroitin sulphate may cause acute liver injury (rare).

Skin and subcutaneous tissue disorders

Eyelid oedema, lower limb oedema, alopecia, skin rash.

Musculoskeletal and connective tissue disorders.

Hyaluronic acid:

Reports of hypersensitivity and anaphylaxis (rare) have been reported.

Collagen:

Nervous system disorders

Headache (uncommon), dizziness (uncommon) and insomnia (uncommon).

Gastrointestinal disorders

Constipation (common), nausea (common), vomiting (common), abdominal pain (common), anorexia (uncommon).

Hepato-biliary disorders

Liver function abnormalities, including elevated transaminase levels (uncommon).

Skin and subcutaneous disorders

Itching.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

Alternatively, suspected adverse reactions may be reported directly to the Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone (021) 701-0244 or e-mail adr@therealthing.co.za

4.9 Overdose

With an overdose, side effects can be precipitated and/or be of increased severity. In the event of overdosage stop taking the supplement. Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

THE REAL THING JOINT REVOLUTION CAPSULES belongs to category D Complementary Medicines, Health Supplements, class 34.12 Multiple Substance Formulation. MSM is a source of sulphur for the synthesis of the amino acids cysteine and methionine.

Glucosamine is an amino sugar. N-acetyl glucosamine is the acetylated derivative of the amino sugar glucosamine, which is a constituent of cartilage proteoglycans. Glucosamine is required for the synthesis of glycoproteins, glycolipids, and glycosaminoglycans (also known as mucopolysaccharides) such as hyaluronic acid. These carbohydrate-containing compounds are found in tendons, ligaments, cartilage, synovial fluid, mucous membranes, structures in the eye, blood vessels and heart valves. Glucosamine is also a component of heparin.

Chondroitin sulphate is a glycosaminoglycan (also known as a mucopolysaccharide). It is manufactured from bovine cartilage. It is endogenously found in cartilaginous tissues of most mammals and serves as a substrate (building material) for the formation of joint matrix structure.

Glucosamine and chondroitin together have synergistic benefits on cartilage metabolism. Hyal-Joint® (sodium hyaluronate) is a natural extract of chicken combs with a high content of hyaluronic acid. Hyaluronic acid is a polysaccharide chain of repeating disaccharide units. It is found throughout the human body where it serves as part of the supporting structure in the extracellular space. It is found most abundantly in human cartilage, synovial fluid (responsible for providing its viscoelasticity and lubricating properties), skin and the aqueous humour of the eye. Hyaluronic acid has been used for numerous joint disorders.

Collagen type II is derived from chicken cartilage. It is the main structural protein in cartilage. It is also found in other types of connective tissue.

5.2 Pharmacokinetic properties

Methylsulfonylmethane (MSM) crosses the blood-brain barrier and is found in brain tissue and cerebrospinal fluid. MSM is excreted via urine.

Glucosamine is absorbed from the small intestine. It has a bioavailability of about 26 % with oral glucosamine, indicating extensive first-pass metabolism of glucosamine by the liver.

Glucosamine is incorporated into plasma proteins during first pass metabolism, and unbound glucosamine is concentrated in the articular cartilage. It is thought to be mainly excreted in the urine, while some may also be excreted in the faeces. Elimination may be delayed with renal insufficiency.

Chondroitin is absorbed relatively fast after oral administration. Bioavailability is moderate (12 to 24 %). It is excreted mainly via urine.

No information is available on hyaluronic acid other than it has a half-life of 2,5 – 5,5 minutes, and is eliminated from circulation through uptake and biotransformation in the liver and spleen.

Insufficient reliable information is available regarding the pharmacokinetics of collagen type II.

Paediatric population

No information is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The inactive ingredients include –

- Aerosil (silicone dioxide)
- dicalcium phosphate
- magnesium stearate (palm oil)
- gelatine (bovine) capsule shells.
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6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING JOINT REVOLUTION CAPSULES have a shelf life of 2 years when stored in a cool, dry place, at or below 25 °C.

6.4 Special precautions for storage

Store in an airtight container protected from light. ^{2(u)} Protect from heat and moisture. ^{2(v)}

6.5 Nature and contents of container

THE REAL THING JOINT REVOLUTION CAPSULES are packed in a 200 ml amber glass bottle with a non-child resistant 45 mm polyethylene black screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 90 capsules. The bottle is packed in a round core carton fitted with a white insert lid.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

The REAL THING FOOD SUPPLEMENTS (PTY) LTD

9 Westlake Drive

Westlake 7945, Cape Town

Telephone: 021-701 0244

Email: info@therealthing.co.za