

SCHEDULING STATUS:

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM:

Rejuvenesse® Cartiflex™ Extra, tablets

COMPOSITION:

Each Rejuvenesse® Cartiflex™ Extra tablet contains:	
Glucosamine Hydrochloride	750 mg
Methylsulfonylmethane (MSM)	200 mg
Ascorbic Acid (Vitamin C)	60 mg

Other ingredients: Ethylenediaminetetraacetic acid (EDTA) disodium, butylhydroxytoluene, silicon dioxide, citric acid, vinylpyrrolidone-vinyl acetate copolymer, polyvinylpyrrolidone, maize starch, magnesium stearate. Coating contains: shellac solution, castor oil, beige colourant. Sugar free.

CATEGORY AND CLASS:

Complementary medicines: Health Supplements. Category D. 34.12 Multiple substance formulation.

PHARMACOLOGICAL ACTION:**Glucosamine hydrochloride:**

Glucosamine hydrochloride is one of the salt forms 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); these carbohydrate-containing compounds are found in tendons, ligaments, cartilage, synovial fluid, mucous membranes, and structures in the eye, blood vessels, and heart valves. Glucosamine stimulates metabolism of chondrocytes in the articular cartilage and synovial cells in the synovial tissues.

Methylsulfonylmethane (MSM):

MSM is a source of sulphur for the amino acids cysteine and methionine. Incorporation of MSM-derived sulphur into methionine is regulated by a limiting step involving micro-organisms in the intestinal lumen. Preliminary research suggests MSM might inhibit degenerative changes in joints in animal models of osteoarthritis. It might also stabilize cell membranes, slow or stop leakage from injured cells and scavenge hydroxyl free radicals which trigger inflammation.

Ascorbic acid (Vitamin C):

Some potentially beneficial effects of vitamin C are attributed primarily to antioxidant and free radical scavenging effects. Vitamin C readily undergoes reversible oxidation and reduction in the body. Vitamin C decreases oxidants in gastric juice, lipid peroxidation, and oxidative DNA and protein damage. Damage by reactive oxygen species are thought to be a contributing factor to a number of diseases, including osteoarthritis. Researchers theorize that antioxidants such as vitamin C might protect against some diseases associated with oxidative damage.

INDICATIONS:

Rejuvenesse® Cartiflex™ Extra is a health supplement for joint and cartilage support.

CONTRA-INDICATIONS:

Avoid in people with known allergy or sensitivity to the ingredients.

Glucosamine might increase the anticoagulant effects of warfarin and increase the risk of bruising and bleeding. Patients taking warfarin should avoid using Rejuvenesse® Cartiflex™ Extra.

Do not use if pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS:

Glucosamine might exacerbate asthma by an unidentified allergic mechanism. Use Rejuvenesse® Cartiflex™ Extra cautiously in patients with asthma.

Glucosamine might interfere with blood glucose control during and after surgical procedures. Patients should discontinue Rejuvenesse® Cartiflex™ Extra at least 2 weeks before elective surgical procedures.

Theoretically, glucosamine might induce resistance to antimetabolic chemotherapy. Exercise caution with this combination.

Patients with medical conditions should seek advice from a health care practitioner.

INTERACTIONS:

Glucosamine might increase the anticoagulant effects of warfarin and increase the risk of bruising and bleeding. Rejuvenesse[®] Cartiflex[™] Extra should be avoided by patients taking warfarin. Theoretically, glucosamine might induce resistance to antimetabolic chemotherapy.

HUMAN REPRODUCTION:

Safety and efficacy have not been established. Avoid using if pregnant or lactating.

DOSAGE AND DIRECTIONS FOR USE:

Take one tablet with water, in the morning before breakfast and 1 tablet with water, at night before dinner or as recommended by your Healthcare Professional.

SIDE EFFECTS:

Rejuvenesse[®] Cartiflex[™] Extra tablets may cause gastrointestinal disturbances, headache, fatigue, drowsiness, insomnia, difficulty concentrating, flushing, pruritus and increased allergy symptoms.

KNOWN SYMPTOMS OF OVERDOSAGE AND THE PARTICULARS OF ITS TREATMENT:

Refer to side-effects. Treatment is symptomatic and supportive.

IDENTIFICATION:

A capsule shaped beige film-coated tablet with a breakline.

PRESENTATION:

A white plastic bottle with a screw on cap that contains a white sponge, a white silica gel sachet and 60 tablets, packed in a unit carton together with a white paper printed Patient Information Leaflet (PIL).

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light. Store out of reach of children.

REGISTRATION NUMBER:

To be allocated by Council upon registration.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Manufactured and packed under pharmaceutical control for Rejuvenesse[®] by:
Hersol Manufacturing Laboratories (Pty) Ltd
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