Public Summary

Summary for ARTG Entry: 143703 Condrosulf 400

ARTG entry for	Medicine Listed
Sponsor	CS Ethical Pty Ltd
Postal Address	37 Ludgate Hill Road, ALDGATE, SA, 5154 Australia
ARTG Start Date	23/08/2007
Product category	Medicine
Status	Active
Approval area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Condrosulf 400

Product Type Single Medicine Product **Effective date** 28/08/2015

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Symptomatic relief of osteoarthritis. [Warning S required]

May help reduce joint swelling associated with arthritis.

Temporary relief of the pain of arthritis. (or) Temporary relief of arthritic pain. [Warning S required]

May help reduce joint inflammation associated with arthritis.

May assist in the management of osteoarthritis. [Warning S required]

Temporary relief of the pain of osteoarthritis (or) Temporary relief of osteoarthritic pain. [Warning S required]

May help increase joint mobility associated with arthritis.

Specific Indications

The therapeutic effects of chondroitin sulphate in patients suffering from osteoarthritis are due to an anti-inflammatory activity at the level of cellular components of the inflammation (in vivo), to the stimulation of the synthesis of endogen proteoglycans (in vitro) and hyaluronic acid (in vivo), and to a decrease in the catabolic activity of chondrocytes (in vivo) inhibiting some proteolytic enzymes (collagenase, elastase, proteoglycanase, phospholipase A2, N-acetylglucosaminidase, etc.) (in vitro, in vivo) and the formation of other substances that damage the cartilage (in vitro).

Condrosulf acts as a building block for cartilage regeneration.

After oral administration, chondroitin sulphate is also distributed in synovial fluid and cartilages, where the molecule can exert anti-inflammatory and chondro-protective activities.

Chondroitin sulphate inhibits human leukocyte elastase activity.

Condrosulf may assist in arresting the progression of osteoarthritis.

Condrosulf may assist in the management of arthritic pain.

Condrosulf facilitates the integration of proteoglycans, collagen and hyaluronan in large molecules.

Condrosulf has a safety profile that permits it to be sold without prescription.

Condrosulf has an anti-inflammatory activity at the level of the articular joints.

Condrosulf stimulates the production of proteoglycans, collagen and hyaluronan.

The complex pharmacokinetic profile of chondroitin sulphate orally administered represents a valid rationale for the clinical efficacy of chondroitin sulphate as a SySADOA drug.

The molecular structure of chondroitin sulphate, detected in human plasma, posesses sulphate groups, which are necessary for inducing anti-inflammatory response.

Condrosulf inhibits metalloprotease enzymatic activity.

Condrosulf is a SySADOA (Symptomatic Slow Acting Drug for Osteoarthritis).

Condrosulf is as well tolerated as placebo.

Condrosulf may assist in the management of osteoarthritis.

After oral absorption, chondroitin sulphate reaches the blood with a molecular mass even higher than 2 kDaltons.

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	Not recorded	Not recorded	Child resistant closure	Not recorded

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

shark sodium chondroitin sulfate **400 mg**