SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG

STRUCTUM 500 mg, Capsule.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Sodium chondroïtin sulphate.....500 mg

For the excipients, see section 6.1

3. PHARMACEUTICAL DOSAGE FORM

Capsule

4. CLINICAL DATA

4.1 Therapeutic Indications

Adjunctive therapy, with delayed action, to help relieve the pain resulting from the progressive destruction of joint cartilage.

4.2 Dosage and administration

For use by adults only (over 15 years of age).
Oral administration.
The capsules are to be swallowed whole with a large glass of water.

1 capsule of 500 mg twice a day (1 g daily).

Use in children: there is no evidence to support the use of chondroitin sulphate in children 0 to 18 years. Use of chondroitin sulphate in children is therefore not recommended.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

.
Not applicable

4.5 Interactions with other drugs and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy- Nursing mothers – Fertility

Pregnancy
There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of Chondroitin sulphate in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity
As a precautionary measure**,** it is preferable to avoid the use of STRUCTUM during pregnancy.

Breastfeeding
It is unknown whether Chondroitin sulphate / metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. Structum should not be used during breastfeeding.

Fertility
Animal studies do not indicate any effect on fertility.

4.7 Effects on the ability to drive vehicles and operate machinery

No corresponding clinical studies have been conducted.

4.8 Adverse reactions

The following table gives the ADRs observed in seven clinical studies, comprising a total of 2244 patients including 1154 on STRUCTUM® treatment.
Adverse reactions are listed according to the MedDRA system organ classification and listed below as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data). No adverse drug reactions were “very rare” or “very common” in frequency and therefore theses columns were not presented in the table.

Common >=1% to 10%	Uncommon >=0.1% to 1%	Rare < 0.1%
08-Nervous system disorders		
Dizziness*		
14-Gastrointestinal disorders		
Diarrhoea Abdominal pain* Nausea		Vomiting
16-Skin and subcutaneous tissue disorders		
	Urticaria Pruritus* - Rash*	Angioedema Erythema
22-General disorders and administration site conditions		
	Face oedema*	
**Sponsor's group*		

"Preferred Terms are ordered and grouped by HLGT; Terms in the same HLGT are separated by symbol "-"

4.9 Overdosage

Administer symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

(M: Muscle and Skeletal System)

Chondroitin sulphuric acid is the essential component of the ground substance of bone and cartilage.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL DATA

6.1 List of excipients

Talc
Composition of capsule shell: gelatin, titanium dioxide, indigotin.

6.2 Incompatibility

Not applicable.

6.3 Shelf life

3 years.

6.4 Special storage precautions

Do not store above 25°C

6.5 Nature and content of outer packaging

60 capsules in thermoformed blister packages (PVC-PVDC / Alu-lacquer)

6.6 Directions for use and handling

No particular requirement.

7. MARKETING AUTHORIZATION HOLDER

PIERRE FABRE MEDICAMENT
45, Place Abel Gance
92100, Boulogne
France

8. MANUFACTURER

PIERRE FABRE MEDICAMENT PRODUCTION
Site Progipharm
Rue du Lycée
45500 Gien
France

9. ADMINISTRATIVE IDENTIFICATION NUMBER

10. DATE OF ORIGINAL AUTHORIZATION / AUTHORIZATION RENEWAL

11. DATE ON WHICH TEXT WAS LAST REVISED

24/03/2014