

## Summary of Product Characteristics



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### المكتب العلمي:

مدخل ٥ - المبنى التجارى الثانى

المنطقة الخامسة، مساكن

الشيراتون رقم بريدى ١١٣٦١

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### 1. Name Of The Medicinal Product:

Chondrogen film coated tablets.

### 2. Qualitative And Quantitative Composition

Each tablet 1300 mg contains::			
<b>Active ingredients :</b>			
Chondroitin sulphate sodium	400 mg	USP 41	active
Glucosamine sulphate sodium chloride	500 mg	USP 41	active
<b>Inactive ingredients:</b>			
Calcium phosphate dibasic	100 mg	USP 41	filler
Talc	50 mg	B.P 2018	glidant
Magnesium stearate	20 mg	B.P 2018	lubricant
Starch	50 mg	B.P 2018	filler
Croscarmellose sodium (Acdisol)	50 mg	B.P 2018	disintegrant
Microcrystalline cellulose (Avicel pH 101)	75 mg	B.P 2018	filler
<b>Coat:</b>			
Hypromellose (HPMC 15 cps)	30 mg	B.P 2018	film former
Titanium dioxide	5 mg	B.P 2018	opacifier
Macrogols (PEG 6000)	10 mg	B.P 2018	plasticizer
Talc	10 mg	B.P 2018	glidant

### 3. Pharmaceutical Form:

Tablet for oral administration

### 4. Clinical Particulars:

#### 4.1 Therapeutic Indications:

Chondrogen is recommended for the following cases:

- Osteoarthritis.
- Generalized bone aches.

#### 4.2 Posology And Method Of Administration:

One tablet 2 times daily.

#### 4.3 Contraindications:

- During pregnancy and lactation.
- 30 days after major surgery.
- Hyper sensitivity to glucosamine or chondroitin sulphate.

• **4.4 Special Warnings And Precautions For Use:**

Chondrogen should be taken with meals to avoid gastric problems, nausea and diarrhea.

• **4.5 Interaction With Other Medicinal Products And Other Forms Of Interaction:**

There is no drug-drug interaction recorded with Chondrogen tablets.

**4.6 Pregnancy and Lactation:**

It is contraindicated to use Chondrogen tablets during pregnancy.

• **4.7 Effects On Ability To Drive And Use Machines:**

Not applicable.

• **4.8 Undesirable Effects:**

- High dosage of Chondrogen tablets may cause gastric problems, nausea, diarrhea, indigestion and heartburn. Chondrogen should be taken with meals to help avoid these problems.

• **4.9 Overdose:**

Not applicable.

**5. Pharmacological Properties:**

Chondrogen is an ideal comprehensive formula for the treatment of osteoarthritis. Chondrogen contains glucosamine sodium and sodium chondroitin sulphate, two elements that are highly effective and safe in the management of osteoarthritis.

Glucosamine sulphate (GS) functions as the primary building block for proteoglycans, large molecules in cartilage, also GS has been shown to have unique anti-inflammatory effects. Additionally, GS demonstrated a protective effect on cartilage as GS may inhibit the breakdown of cartilage and may have the potential to help build-up cartilage.

Chondroitin sulphate (CS) is a large molecule found in cartilage, it seems to work as anti-inflammatory and reduce pain. CS may slow cartilage breakdown and even spur cartilage growth, CS reduces inflammation and assists the glucosamine in protecting against future cartilage degeneration.

Chondrogen through its components has a dual mechanism of actions, firstly as anti-inflammatory and secondary as a cartilage protector, and so slows the progression of osteoarthritis, and ease pain without the side effects of COX-2 inhibitors or NSAIDS.



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## 6. Pharmaceutical Particulars:

### • 6.1 List Of Excipients :

#### Inactive ingredients:

Calcium phosphate dibasic	100 mg
Talc	50 mg
Magnesium stearate	20 mg
Starch	50 mg
Croscarmellose sodium (Acdisol)	50 mg
Microcrystalline cellulose (Avicel pH 101)	75 mg
<b>Coat:</b>	
HPMC 15 cps	30 mg
Titanium dioxide	5 mg
PEG 6000	10 mg
Talc	10 mg

### • 6.2 Incompatibilities:

- All excipients comply with their BP Pharmacopoeia monograph.
- None of the excipients contains materials of animal or human origin.
- No genetically modified organisms (GMO) have been used in the preparation of these products.
- No incompatibilities with the excipients or packaging materials have been shown during research of pre-formulation and formulation studies and nor during manufacturing processing and stability.

### • 6.3 Shelf Life

3 years

### • 6.4 Special Precautions For Storage:

No special precaution for storage

Store in a dry place at temperature not exceeding 30° C.

### • 6.5 Nature And Contents Of Container:

Carton box containing 2 (Aluminum /transparent PVC) strips, each of 10 tablets and inner leaflet.

### • 6.6 Special Precautions For Disposal And Other Handling:

Keep out of reach of children.



• **7. Marketing Authorization Holder:**

Arab Company for Pharmaceuticals & Medicinal Plants (Mepaco – Medi food) Egypt

• **8. Marketing Authorization Number(S)**

Reg. No: 25809/2008

• **9. Date Of First Authorization/Renewal Of The Authorization:**

Reg. No: 25809/2008

Authorization date: 25/12/2008



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