MODULE 1
ADMINISTRATIVE INFORMATION & PRODUCT INFORMATION

1.6 PRODUCT INFORMATION

1.6.1 PRESCRIBING INFORMATION (SUMMARY OF PRODUCT CHARACTERISTICS)

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

1.1 Proprietary Name

OSTEOMIN TABLETS

1.2 Strength

Each film coated tablet contains: Glucosamine Sulphate 2KCl 667mg Equivalent to Glucosamine Sulphate 500mg and Chondroitin Sulphate 400mg

1.3 Description

White film coated oval shaped tablet.

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

2.2 Quantitative Declaration

Name of ingredient	Label claim per tablet (mg)	Quantity per tablet (mg)
Glucosamine Sulphate 2 KCl	667.00	500.00
Equivalent to Glucosamine Sulphate	*500.00*	
Chondroitin Sulphate	400.00	400.00

'For full list of excipients, see section 6.1

3. Pharmaceutical Form

Film coated tablets.

4. Clinical Particulars

4.1 Therapeutic Indications

Provide relief to sufferers of arthritis by reducing joint inflammation and relieving associated pain. It may help increase joint mobility by restoring cartilage tissue.

MODULE 1
ADMINISTRATIVE INFORMATION & PRODUCT INFORMATION

4.2 Posology and method of administration

One tablet three times per day with meals.

Method of Administration: Oral

4.3 Contraindications

Individuals with known hypersensitivity to any ingredients.

4.4 Special Warnings and Precautions for Use

Not applicable.

4.5 Interaction with other medicinal products and other forms of interaction

Should not take Osteomin concomitant with warfarin.

4.6 Fertility, pregnancy and lactation

Not recommended taking Osteomin in pregnant women or breast-feeding women without consulting with the physician.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable Effects

Adverse effects of glucosamine are minimal. There are reports of gastrointestinal symptoms, drowsiness, headache, and some skin rashes.

4.9 Overdose

Not applicable.

MODULE 1
ADMINISTRATIVE INFORMATION & PRODUCT INFORMATION

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Not applicable.

5.2 Pharmacokinetic Properties

Not applicable.

5.3 Preclinical Safety Data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Composition	Content/tablet
Microcrystalline cellulose	202.890 mg
Crospovidone	50.000 mg
Croscarmellose sodium	50.000 mg
Hydroxypropylcellulose	30.000 mg
Magnesium stearate	20.000 mg
Silica-colloidal anhydrous	6.000 mg
Opadry-II White 85G58923	30.000 mg

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 25°C in a dry place, away from direct sunlight.

6.5 Nature and Contents of Container

Unit carton containing 3x10 tablets blister packed.

Aluminium foil: Printed Aluminium foil

Blister film: PVC/PVDC film

Outer Carton: Printed cardboard carton

MODULE 1
ADMINISTRATIVE INFORMATION & PRODUCT INFORMATION

6.6 Special precaution for disposal and other handling

No special requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

Marketing Authorization Holder

(Company) Name: Mega Lifesciences Public Company Limited

Address:384 Moo 4, Pattana 3 Road, Soi 6, Bangpoo Industrial Estate,
Preaksa, Muang Samutprakarn,10280, Thailand.

Country: Thailand

Tel: + 66 (0) 2 401 8686

Fax: +66 (0) 2 324 0451

Email: snehal@megawecare.com

Manufacturing Site Addresses

(Company) Name:	MEGA LIFESCIENCES (Australia) Pty. Ltd.
Address:	60 National Avenue, SouthEast Business Park, Pakenham, Victoria, Australia 3810
Country:	Australia
Telephone:	(613) 5941 8599
Telefax:	(613) 5940 3089
E-Mail:	info.au@megawecare.com

8. Marketing Authorization Number: AUSTRALIA: AUST L 132647

9. Date of first Registration/ Renewal of the Registration: 30/10/2006

10. Date of revision of the text: October 2023