Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glusamin 750mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 942mg glucosamine sulfate sodium chloride equivalent to 750 mg glucosamine sulfate or 589 mg glucosamine.

Excipients with known effect:
Each tablet contains 75.9 mg (3.3mmol) of sodium, 3.0 mg lactose monohydrate and soya lecithin (E322).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Off-white oblong shaped film-coated tablet,8x19mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Glusamin tablets are indicated for relief of symptoms in mild to moderate osteoarthritis of the knee.

4.2 Posology and method of administration

Administration:
Glusamin tablets should be swallowed whole.
Tablets can be taken with or without food.

Adults and the elderly:
One Glusamin tablet should be taken twice daily.

Or

Two Glusamin tablets to be taken once daily.
Glucosamine is not indicated for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after several weeks of treatment and in some cases even longer. If no relief of symptoms is experienced after 2-3 months, continued treatment with glucosamine should be reevaluated.

Additional information on special populations:
Children/ adolescents:
Safety and efficacy has not been established in children and adolescents, therefore, Glusamin tablets should not be used in persons under the age of 18 years.

Elderly
No specific studies have been performed in the elderly, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, elderly patients.

Impaired renal and/or liver function
In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been

performed.

4.3 Contraindications

Known sensitivity to glucosamine (or any of its derivatives), sulfates or any of the other ingredients in Glusamin tablets (listed in section 6.1).

Glusamin tablets must not be used in patients who are allergic to shellfish as the active ingredient is obtained from shellfish.

Glusamin tablets contains soya lecithin. Persons allergic to soya or peanut should therefore not use this medicinal product.

4.4 Special warnings and precautions for use

Warnings
Glusamin tablets contain lactose monohydrate, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicinal product contains 75.9 mg sodium per dose. The daily sodium intake is 151.7 mg (equivalent to 6.6 mmol). To be taken into consideration by patients on a controlled sodium diet.

The presence of other joint disease, which would require alternative treatment, should be excluded.
In patients with impaired glucose tolerance, monitoring of the blood glucose levels and, where relevant, insulin requirements is recommended before start of treatment and periodically during treatment.
In patients with a known risk factor for cardiovascular disease, monitoring of the blood lipid levels is recommended since hypercholesterolemia has been observed in a few patients treated with glucosamine.

A report on exacerbated asthma symptoms triggered after initiation of glucosamine therapy has been described (symptoms resolved after withdrawal of glucosamine). Asthmatic patients starting on glucosamine should therefore be aware of potential worsening of asthma symptoms.

4.5 Interaction with other medicinal products and other forms of interaction

Increased effect of coumarin anticoagulants (e.g. warfarin) during concomitant treatment with glucosamine has been reported. Patients treated with coumarin anticoagulants should therefore be monitored closely when initiating or ending glucosamine therapy.

Close monitoring of blood sugar levels is recommended for diabetics on hypoglycaemic agents.

Concurrent treatment with glucosamine may increase the absorption and serum concentrations of tetracyclines, but the clinical relevance of this interaction is probably limited.

Due to limited documentation on potential drug interactions with glucosamine, one should generally be aware of altered response or concentration of concurrently used medical products.

4.6 Fertility, pregnancy and lactation

Pregnancy:
There are inadequate data concerning the use of glucosamine in pregnant women. From animal studies only insufficient data are available. Glucosamine should not be used during pregnancy.

Breast feeding:
There is no data available on the excretion of glucosamine in breastmilk. The use of glucosamine during breast feeding is therefore not recommended as there is no data on the safety of the child.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machines have been performed. If dizziness or drowsiness is experienced, car driving and the operating of machinery is not recommended.

4.8 Undesirable effects

The most common adverse reactions associated with treatment with glucosamine are nausea, abdominal pain, indigestion, constipation and diarrhoea. In addition, headache, tiredness, rash itching, and flushing have been reported. The reported adverse reactions are usually mild and transitory.

Medra System Organ Class	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1,000 to <1/100)**	**Rare (≥1/10,000 to <1/1000)**	**Not known (cannot be estimated from the available data)**
Nervous system disorders	Headache Tiredness			Dizziness
Respiratory, thoracic and mediastinal disorders				Asthma / Asthma aggravated
Gastrointestinal disorders	Nausea Abdominal pain Indigestion Diarrhoea Constipation			Vomiting
Skin and subcutaneous tissue disorders		Rash Itching Flushing		Angiodema Urticaria
Metabolism and nutrition disorders				Diabetes mellitus inadequate control Hypercholesterolaemia
General disorders and administration site conditions				Oedema/peripheral oedema

Cases of Hypercholesterolemia, Asthma, aggravated and Diabetes mellitus inadequate control have been reported, but causality has not been established.

Glusamin tablets may cause Hepatic enzyme elevation and rarely jaundice.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the online reporting option (preferred method) accessible from the IMB homepage (www.imb.ie). A downloadable report form is also accessible from the IMB website, which may be completed

manually and submitted to the IMB via ‘freepost’ (see details below). Alternatively, the traditional post-paid ‘yellow card’ option may also be used.

FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O’Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

Signs and symptoms of accidental or intentional overdose with glucosamine might include headache, dizziness, disorientation, arthralgia, nausea, vomiting, diarrhoea or constipation.

In cases of overdose, treatment with glucosamine should be discontinued and standard supportive measures should be adopted as required.

In clinical trials one of five healthy young subjects experienced headache following infusion of glucosamin up to 30 g. In addition, one case of overdose has been reported in a 12-year old female who took orally 28 g of glucosamine hydrochloride. She developed arthralgia, vomiting and disorientation. The patient fully recovered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other anti-inflammatory and anti-rheumatic agents, non-steroidal anti-inflammatory drugs.
ATC code: M01AX05

Glucosamine is an endogenous substance, a normal constituent of the polysaccharide chains of cartilage matrix and synovial fluid glucosaminoglycans. In vitro and in vivo studies have shown glucosamine stimulates the synthesis of physiological glycosaminoglycans and proteoglycans by chondrocytes and of hyaluronic acid by synoviocytes. The mechanism of action of glucosamine in humans is unknown. The period to onset of response cannot be assessed.

5.2 Pharmacokinetic properties

Glucosamine is a relatively small molecule (molecular mass 179), which is easily dissolved in water and soluble in hydrophilic organic solvents. The available information on the pharmacokinetics of glucosamine is limited. The absolute bioavailability is unknown. The distribution volume is approximately 5 litres and the half-life after intravenous administration is approximately 2 hours. Approximately 38% of an intravenous dose is excreted in the urine as unchanged substance.

5.3 Preclinical safety data

D-glucosamine has low acute toxicity. Animal experimental data relating to toxicity during repeated administration, reproduction toxicity, mutagenicity and carcinogenicity is lacking for glucosamine.

Results from in vitro studies and in vivo studies in animals have shown that glucosamine reduces insulin secretion and induces insulin resistance, probably via glucokinase inhibition in the beta cells. The clinical relevance is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet:
Microcrystalline cellulose 101
Microcrystalline cellulose 102
Lactose monohydrate
Pregelatinised maize starch
Crospovidone
Stearic acid

Coating:
Poly(vinyl) alcohol
Titanium dioxide (E171)
Talc (E553b)
Lecithin soya (E322)
Macrogol 3350

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
After first opening of the tablet container the medicinal product should be used within 6 months.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Cartons containing PVdC coated PVC/Al blisters: Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.

OR

Cartons containing HDPE containers fitted with a tamper-evident HDPE screw cap.
Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 MARKETING AUTHORISATION HOLDER

FMC Pharma Ltd.

Unit 622
Northern Extension
Co. Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1521/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th August 2011

10 DATE OF REVISION OF THE TEXT

August 2015