

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glusartel 1500 mg powder for oral solution ▼

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains: 1884 mg glucosamine sulphate sodium chloride, corresponding to 1500 mg glucosamine sulphate or 1178 mg glucosamine.

Excipients with known effect:

Each sachet contains 2.5 mg aspartame, 151 mg sodium and 2,028.5 mg sorbitol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution. White, crystalline, odourless powder contained in single-dose sachets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief of symptoms in mild to moderate osteoarthritis of the knee.

4.2 Posology and method of administration

1500 mg glucosamine sulphate (one sachet) to be taken once a day. The entire contents of one sachet should be fully dissolved in at least 250 ml of water (one glass) before drinking.

Glucosamine is not indicated for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after some weeks of treatment or sometimes even longer. If no relief of symptoms is experienced after 2-3 months, continued treatment with glucosamine should be re-evaluated.

Additional information on special populations

Children and Adolescents

Glucosamine should not be used in children and adolescents below the age of 18 years (see 4.4).

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

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

Glusartel must not be given to patients who are allergic to shellfish, as the active ingredient is obtained from shellfish.

4.4 Special warnings and precautions for use

A doctor must be consulted to rule out the presence of joint diseases for which other treatment should be considered.

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.

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 symptoms.

This medicine contains 2,028.5 mg sorbitol. Patients with hereditary fructose intolerance (HFI) should not take this medicine.

This medicine contains 2.5 mg aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicinal product contains 151 mg sodium per sachet, equivalent to 7.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Glucosamine should not be used in children and adolescents under the age of 18 years since safety and efficacy have not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Data on possible drug interactions with glucosamine is limited, but increased INR with coumarin anticoagulants (warfarin and acenocoumarol) has been reported. Patients treated with coumarin anticoagulants should therefore be monitored closely when initiating or ending glucosamine therapy.

Concurrent treatment with glucosamine may increase the absorption and serum concentration 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 medicinal products.

4.6 Pregnancy and lactation

Pregnancy

There are no adequate data from the use of glucosamine in pregnant women. From animal studies only insufficient data are available. Glusartel should not be used during pregnancy.

Breast Feeding

There are no data available on the excretion of glucosamine into human milk. The use of glucosamine during breastfeeding is therefore not recommended as there is no data on the safety for the newborn.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects such as headache, somnolence tiredness, dizziness or visual disturbances are possible after taking this medicine. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very rare ($< 1/10,000$)

Not known (cannot be estimated from the available data)

The most common adverse reactions associated with treatment with glucosamine are nausea, abdominal pain, dyspepsia, flatulence, diarrhoea and constipation. The reported adverse reactions are usually mild and transitory.

In the following table, adverse reactions have been grouped on the basis of “Internationally agreed Order of Importance” System Organ Class (SOC) MedDRA Classification. In each SOC, undesirable effects were classified according to their occurrence frequency. In each frequency class the undesirable effects are reported according to a decreasing order of severity.

System Organ Class	Common from $\geq 1/100$ to $< 1/10$	Uncommon from $\geq 1/1,000$ to $< 1/100$	Rare from $\geq 1/10,000$ to $< 1/1,000$	Very rare $< 1/10,000$	Not Known*
Immune system disorders					Allergic reaction (Hypersensitivity)
Metabolism and nutrition disorders					Diabetes inadequate control
Psychiatric disorders					Insomnia
Nervous system disorders	Headache Somnolence				Dizziness
Eye disorders					Visual disturbances
Cardiac disorders					Cardiac arrhythmias e.g. Tachycardia
Vascular disorders		Flushing			
Respiratory, thoracic and mediastinal					Asthma / Asthma aggravated
Gastrointestinal disorders	Diarrhoea Constipation Nausea Flatulence Abdominal pain Dyspepsia				Vomiting
Hepatobiliary disorders					Jaundice
Skin and subcutaneous tissue disorders		Erythema Pruritus Rash			Angioedema Urticaria
General disorders and	Tiredness				Oedema/peripheral oedema

administration site conditions					
Investigations					Hepatic enzyme elevation Blood glucose increased Blood pressure increased International normalized ratio fluctuation

* frequency cannot be estimated by the available data

Sporadic, spontaneous cases of hypercholesterolemia have been reported, but causality has not been established.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No case of accidental or intentional overdose has been reported. There is little information on overdose with glucosamine, but it is likely to be of low acute toxicity. Symptoms are unlikely to arise after acute ingestion of this product. It is possible that nausea and vomiting or diarrhoea may occur.

Management:

If overdose occurs treatment should be discontinued, symptomatic and standard supportive measures should be adopted as required e.g. act to restore the hydroelectrolytic balance. Patients should be advised on discharge to seek medical attention if symptoms subsequently develop.

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

Aspartame

Sorbitol

Citric acid anhydrous

Macrogol 4000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30 °C.

Store in the original package.

6.5 Nature and contents of container

One sachet made of a three-layered material comprising paper, aluminium and polyethylene.

Pack-sizes of 4 (sample pack), 30 and 90 sachets. Not all pack-sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Mylan Products Ltd.,
Station Close,
Potters Bar,
Hertfordshire,
EN6 1TL,
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 46302/0107

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/10/2009

10 DATE OF REVISION OF THE TEXT

08/11/2021