

I. NAME OF THE MEDICINAL PRODUCT

ALATERIS™ 625 mg tablets▼

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 625mg of glucosamine (as glucosamine hydrochloride).
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

White to light beige, oval tablet marked with “G” and a score line. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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

Two tablets (1250 mg glucosamine) once daily for relief of symptoms.

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 re-evaluated.

Tablets can be taken with or without food.

Additional information on special populations.

Children and Adolescents

ALATERIS™ is not recommended for use in children and adolescents below the age of 18, due to lack of data on safety and efficacy.

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 hypersensitivity to glucosamine or to any of the excipients.

ALATERIS™ must not be given to patients who are allergic to shellfish as the active substance 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.

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 cases in 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 symptoms.

4.5. Interactions 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 is no adequate data from 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 human milk. The use of glucosamine during breastfeeding is therefore not recommended as there is no data on the safety of 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. 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.

System Organ Class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to < 1/1000)
Nervous system disorders	Headache Tiredness	-	-
Gastrointestinal disorders	Nausea Abdominal pain Indigestion Diarrhoea Constipation	-	-
Skin and subcutaneous tissue disorders	-	Rash Itching Flushing	-

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

4.9. Overdose

No case of overdose has been reported.

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

Microcrystalline cellulose

Hydroxypropyl cellulose

Low substituted hydroxypropyl cellulose (L-HPC)

Magnesium stearate

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years

6.4. Special precautions for storage

Do not store above 30°C.

Keep the bottle or blister package tightly closed. Store in the original package in order to protect from moisture.

6.5. Nature and contents of container

PVC/PVDC-aluminium blisters packed in paper cartons.

Pack-sizes of 40, 60 or 180 tablets.

HDPE tablet container with a silica gel desiccant in paper bags.

Pack-sizes of 60 or 180 tablets.

Not all pack-sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Navamedic ASA
Fornebuveien
1366 Lysaker
Norway

8. MARKETING AUTHORISATION NUMBER

PL 25081/0001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

15/06/2007

10. DATE OF (PARTIAL) REVISION OF THE TEXT

15/06/2007

LEGAL CATEGORY

POM

Medical information enquiries and adverse event reports should be directed to William Ransom on 0845 6189590. Information about adverse events reporting can be found at www.yellowcard.gov.uk

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