SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Glucosamine Navamedic 625 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 750 mg of glucosamine hydrochloride equivalent to 625 mg of glucosamine.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

White to light beige, oval tablet of 10x18.75 mm marked with “G” on one side and a score line on the other side. 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

Posology
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.

Additional information on special populations.

Paediatric population
Glucosamine Navamedic should not be used in children and adolescents below the age of 18 (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.

Method of administration
Tablets can be taken with or without food.

4.3 Contraindications

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

Glucosamine Navamedic 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

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

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 Interaction with other medicinal products and other forms of interaction

There are limited data on possible drug interactions with glucosamine but increments in the INR parameter have been reported with oral vitamin K antagonists. Patients treated with oral vitamin K antagonists should therefore be closely monitored at the time of initiation or termination of 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)	Not known (cannot be estimated from the available data)
Nervous system disorders	Headache Tiredness	-	-	Dizziness
Gastrointestinal disorders	Nausea Abdominal pain Indigestion Diarrhoea Constipation	-	-	Vomiting
Hepatobiliary disorders				Hepatic enzyme elevation and jaundice
Skin and subcutaneous tissue disorders	-	Rash Itching Flushing	-	Angioedema Urticaria
General disorders and administration site conditions	-	-	-	Oedema/peripheral oedema

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

Patients with diabetes mellitus
Blood glucose control worsened in patients with diabetes mellitus. Frequency not known.

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 national reporting system listed in Appendix V*.

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.

Paediatric population
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.

Mechanism of action
The mechanism of action of glucosamine in humans is unknown.
The period to onset of response cannot be assessed.

5.2 Pharmacokinetic properties
Absorption
Glucosamine is a relatively small molecule (molecular mass 179), which is easily dissolved in water and soluble in hydrophilic organic solvents.

Distribution
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.

Elimination
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

3 years.

6.4 Special precautions for storage

Do not store above 30^{o}C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container and special equipment for use, administration or implantation

PVC/PVDC-aluminium blisters packed in paper cartons.
Pack-sizes of 20, 40, 60 or 180 tablets.

Not all pack-sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratoires Expanscience
1 place des Saisons
92048 Paris La Défense Cedex,
France

8. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: To be completed nationally

Date of latest renewal: To be completed nationally

10. DATE OF REVISION OF THE TEXT

2021-05-20

Detailed information on this medicinal product is available on the website of the {MS/Agency}: