SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

YOINTY 625 mg, hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 625 mg of glucosamine (equivalent to 750 mg of glucosamine hydrochloride).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.
Brown coloured hard gelatine capsules of size nº0EL.

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
Adults (including the elderly):
The recommended dose is 2 capsules to be taken once a day (1,250 mg/day glucosamine).
Glucosamine is not indicated for the treatment of acute pain. The relief of the pain may occur after several weeks of treatment, and sometimes after a longer time. If no relief of pain occurs after 2-3 months, the continuation of the treatment should be re-evaluated.
Paediatric population:
YOINTY is not recommended for use in children below 18 years of age, due to a lack of data on safety and efficacy.
Hepatic and/or renal impairment:
In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed.
Method of administration:
The capsules can be taken with or without food.
The capsules should be swallowed whole without chewing, and with a sufficient amount of water.

4.3 Contraindications

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

YOINTY 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

YOINTY should not be used in children and adolescents below the age of 18, due to lack of data on safety and efficacy.

A doctor should be consulted to rule out the presence of joint disease 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 known risk factor for cardiovascular disease, monitoring of the blood lipid levels is recommended, since hypercholesterolemia has been reported 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 asthma symptoms.

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 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 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 breast-feeding is therefore not recommended as there are 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 are not recommended.

4.8 Undesirable effects

The most common adverse reactions associated with treatment with glucosamine are described below. 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)	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	Angioedema Urticaria
Metabolism and nutrition disorders			Diabetes mellitus inadequate control Hypercholesterolaemia
General disorders and administration site conditions			Oedema Peripheral oedema

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 Yellow Card Scheme at: www.yellowcard.mhra.gov.uk

4.9 Overdose

No case of overdose has been reported.

The signs and symptoms caused by an accidental or intentional overdose with glucosamine may include headache, vertigo, disorientation, arthralgia, nausea, vomiting and diarrhoea.

In clinical studies, one in five young healthy subjects experienced headache after infusion of up to 30 g of glucosamine. One case of overdose was 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 antiinflammatory and antirheumatic agents, non-steroids. 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 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

Magnesium stearate.

Capsule composition:

Gelatin

Red iron oxide (E172)

Titanium dioxide (E171)

Black iron oxide (E172)

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 in order to protect from moisture.

6.5 Nature and contents of container

PVC/PVDC/aluminium-blister packed in cardboard carton.
Pack-sizes of 10 hard capsules (1 blister of ten capsules). 60 hard capsules (6 blisters of ten capsules each) and 180 hard capsules (3 packs of 60 hard capsules).
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

25174/0035

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 February 2012
Date of renewal: 18/01/2017

10 DATE OF REVISION OF THE TEXT

25/11/2021