

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Arthriex 1500 mg Film-coated Tablets

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each film-coated tablet contains 1884mg glucosamine sulfate sodium chloride equivalent to 1500 mg glucosamine sulfate or 1178mg glucosamine.

Excipient(s) with known effect:

Each tablet contains 151.8 mg (6.6mmol) of sodium.

Lactose monohydrate 6.0 mg

Lecithin soya (E322)

For a full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

Film-coated tablet.

Off-white oblong shaped film-coated tablet, 9.5x21mm.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Arthriex tablets are indicated for relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor.  
Glucosamine is not indicated for the treatment of acute painful symptoms.

## **4.2 Posology and method of administration**

### *Administration:*

This medicinal product should be swallowed whole.

Tablets can be taken with or without food.

### *Adults and the elderly:*

One Arthriex tablet should 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 re-evaluated.

Additional information on special populations:

### *Children/adolescents:*

Safety and efficacy has not been established in children and adolescents, therefore, Arthriex 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*

No studies have been performed in patients with impaired renal and/or liver function.

## **4.3 Contraindications**

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

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

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

Arthriex tablets should not be used in patients taking warfarin (or other coumarin anticoagulants) as increased effect during concomitant treatment with glucosamine has been reported (see section 4.5).

Arthriex tablets should not be used in patients with impaired renal and/or liver function, as no dose recommendations can be given since no studies have been performed.

Patients taking oral tetracycline should not take glucosamine at the same time, as concurrent treatment with glucosamine may increase the absorption and serum concentrations of tetracyclines (see section 4.5).

Glucosamine should not be used during pregnancy or breast-feeding as there are inadequate data concerning the use of glucosamine in pregnant or breast-feeding women (see section 4.6).

#### **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.

A doctor must be consulted if this medicine is intended for long term use. Continuous treatment beyond 3 years cannot currently be recommended as safety has not been established beyond this period.

As the risk of diabetogenic effects is unknown and until further evidence becomes available, caution should be exercised in patients with Diabetes or a predisposition for Diabetes. Therefore in patients with impaired glucose tolerance, pre-diabetics and diagnosed diabetics (Type I and II), monitoring of the blood glucose levels should be increased, as deemed necessary, before start of treatment, periodically during treatment and at the end of the treatment, as determined by the primary Healthcare Professional.

Where relevant, monitoring of insulin requirements is also recommended before start of treatment, periodically during treatment and at the end of the treatment under medical supervision.

In patients with a known risk factor for cardiovascular disease, monitoring of the blood lipid levels is recommended during treatment with Arthriex tablets since hypercholesterolemia has been observed in a few patients treated with glucosamine. The results should be a factor in determining whether treatment is continued after 2-3 months.

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.

Arthriex 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 151.8 mg sodium per dose equivalent to 6.6 mmol. To be taken into consideration by patients on a controlled sodium diet.

**The label will state:**

Read the package leaflet before use.

**Information for the Patient:**

Arthriex tablets are to be used only for the relief of symptoms of mild to moderate osteoarthritis of the knee that has previously been diagnosed by your doctor. Please make sure that you have been diagnosed with osteoarthritis of the knee before taking this product.

**Do not take this product if you:**

- are allergic to shellfish, soya, peanut, glucosamine, sulfates, or any other ingredient of this medicine
- are pregnant or breast-feeding
- have liver or kidney problems
- are under the age of 18 years
- are taking warfarin (or other coumarin anticoagulants)
- are taking oral tetracycline (an antibiotic effective against a wide range of bacterial infections), do not take glucosamine at the same time

**Speak to a doctor or pharmacist before taking this product if you:**

- have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke or heart problems as your doctor may need to monitor you more regularly
- are on a controlled sodium diet

Do not exceed the stated dose.

## **4.5 Interaction with other medicinal products and other forms of interaction**

**Arthriex should be used with caution in combination with:**

### **Hypoglycaemic agents:**

Close monitoring of blood sugar levels is recommended for diabetics on hypoglycaemic agents (see section 4.4).

### **Tetracyclines:**

Concurrent treatment with glucosamine may increase the absorption and serum concentrations of tetracyclines, but the clinical relevance of this interaction is probably limited. If the patient is taking oral tetracycline they should not take glucosamine at the same time.

### **Wafarin:**

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.

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. Glucosamine should not be used during breast feeding 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.

MedDRA 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)
Metabolism and nutrition disorders				Diabetes mellitus inadequate control Hypercholesterolaemia
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
General disorders and administration site conditions				Oedema/peripheral oedema

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

Arthriex 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 Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## **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 glucosamine 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: 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90 film-coated tablets

OR

Cartons containing HDPE containers fitted with a tamper-evident HDPE screw cap.

Pack Size: 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90 film-coated tablets

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)**

PL 51038/0002

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

30/10/2014

**10     DATE OF REVISION OF THE TEXT**

12/04/2023