Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Arthriex 750mg and 1500mg Film-coated tablets (glucosamine sulfate)

Public Consultation

Proposal to make available from Pharmacies

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side-effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (http://www.mhra.gov.uk/yellowcard)

Ref: ARM96

Arthriex 750mg and 1500mg Film-coated tablets (glucosamine sulfate)

Proposal to make available from Pharmacies without prescription

We want to know what you think

- Arthriex tablets are used for relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor
- Arthriex tablets are only at the moment available on prescription.
- We propose to make it available in pharmacies.
- We consider that this product can be available as a Pharmacy medicine.
- We want to know what you think about this change.

Please tell us your views – please use the form at the end of this document.

The deadline for comments is **04 August 2017**.

In this document there is:

- A summary of the proposed change and the background
- A copy of the patient information leaflet and label proposed if the change goes ahead
- A form for your response

The full names of the medicines are Arthriex 750mg Film-coated Tablets and Arthriex 1500mg Film-coated Tablets - in this document we will call them 'Arthriex.'

Contents:

Product details:

Product name: Arthriex 750mg and 1500mg Film-coated tablets

Active substances: Glucosamine sulfate

Licence holder: CF Pharma Ltd

Route of sale/supply: Current – on prescription (POM); Proposed – Pharmacy (P)

Indication: For relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor.

Marketing Authorisation Number: PL 36549/0001 and PL 36549/0002

Consultation is open from: 14 July 2017 – 04 August 2017

Reference: ARM96

Contact: reclassification@mhra.gsi.gov.uk

1. Background on deciding where medicines are available

The role of MHRA
MHRA regulates medicines and medical devices in the UK, on behalf of the UK Licensing Authority. This means that MHRA decides whether medicines are available:

- on prescription only - 'prescription only medicine' (POM)
- bought from pharmacies - 'pharmacy medicine' (P)
- bought from other shops - 'general sales list medicine' (GSL)

What is re-classification of a medicine?
Making a change on where a medicine is available is called 'reclassification'. This is sometimes referred to as 'switching'. To decide on this change, MHRA may:

- take advice from its committees of external experts
- take advice from a group ('stakeholder group') of health professionals and representatives of people affected by the classification change
- run a public consultation

To be reclassified from POM to P, a medicine must:

- be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used correctly
- be generally used correctly (i.e. not frequently or to a wide extent used incorrectly)
- not contain substances or preparations of substances where the activity of the product or its side effects require further investigation
- not normally be prescribed by a doctor for injection (parenteral administration)

What evidence is needed?
A company or organisation can ask MHRA for a medicine to be available as a pharmacy medicine or a general sale medicine. To do this, they need to get together evidence to show that the medicine

a) is likely to be used appropriately, and
b) with relatively little danger to the public.

This evidence needs to focus on the risk to the public. This includes evidence on the possible abuse or misuse of the medicine. The evidence may include:

- clinical studies
- evidence showing acceptable level of side effects
- advice of experts
- views of relevant health professionals and their professional bodies
- views of relevant public associations and individuals with an interest in the medicine under consideration.

Who makes the final decision?
The final decision on whether to approve a change is made by the MHRA, on behalf of the UK Licensing Authority.

2. About Arthriex 750mg and 1500mg Film-coated Tablets

Arthriex tablets are used for relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor.

The main symptoms of osteoarthritis are joint pain and stiffness. Some people also experience swelling, tenderness and a grating or crackling sound when moving the affected joints.

Glucosamine sulfate, the active ingredient in Arthriex, belongs to a group of medicines called other anti-inflammatory and anti-rheumatic agents as it has a different mode of action compared to painkillers such as paracetamol or non-steroidal anti-inflammatory drugs such as ibuprofen. It is found in the body, in the protective cartilage on the ends of the bones and the fluid of the joints. Clinical studies have shown that glucosamine sulfate can be effective in relieving the symptoms of osteoarthritis in the knee joint. The mechanism of action of glucosamine in humans is unknown.

The MHRA considers that this product is safe enough to be made available as a Pharmacy medicine in certain circumstances. This report outlines the background to this decision. Please tell us your views by using the response form at the end of this document (Annex 1). The deadline for comments is **04 August 2017**.

The patient information leaflet, label and summary of product characteristics are provided in Annex 2, 3 and 4.

This is the first application for a glucosamine sulfate product to be available as a Pharmacy medicine.

This report relates specifically to the proposal to reclassify Arthriex from a prescription to pharmacy medicine. If you want more information on glucosamine sulfate as a prescription medicine then please refer to the Public Assessment Reports that are available here: http://www.mhra.gov.uk/public-assessment-reports/

NHS Choices provides health advice about osteoarthritis: http://www.nhs.uk/Conditions/Osteoarthritis/Pages/Introduction.aspx

3. Proposal to make Arthriex available as a Pharmacy medicine

Who has made the proposal?
The licence-holder for Arthriex tablets (CF Pharma Ltd) has applied to make this product available from Pharmacies, by or under the supervision of a pharmacist.

CF Pharma Ltd is referred to as 'the applicant' throughout this document.

What are the details of this change?
The application proposes to make Arthriex 750mg and 1500mg tablets available through Pharmacy outlets in the following circumstances:

- For oral use
- For the relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor in adults aged 18 years and above
- Dose: 1500mg glucosamine sulfate daily, taken as a single dose, or in the case of the 750mg tablets, one tablet twice daily
- Maximum dose: 1500mg
- Maximum daily dose: 1500mg
- Maximum pack size: 4.5g (3 months' supply: 90 tablets of 1500mg or 180 tablets of 1500mg).

4. How was the proposal assessed for Arthriex being available on as a Pharmacy medicine?

A medicine will be non-prescription unless it fulfills the criteria for prescription control as set out below. Prescription only status will apply where:

- a direct or indirect danger exists to human health, even when used correctly, if used without medical supervision
- there is frequently incorrect use which could lead to direct or indirect danger to human health
- further investigation of activity and/or side-effects is required
- the product is normally prescribed for parenteral administration (by injection)

In the UK these criteria are laid down in the Human Medicines Regulations 2012, regulation 62(3).

Assessment of suitability for Pharmacy availability
The MHRA assessed the application against the above criteria to assess the suitability for Pharmacy availability.

Direct danger
A direct danger may be present if the product causes adverse reactions that are important or where danger may arise from drug interactions with commonly used medicines.

The safety of glucosamine sulfate is well known and it is generally well tolerated. The side effects are usually mild and short-lived, with few having been reported. The most common side effects are nausea, abdominal pain, indigestion, constipation and diarrhoea. Occasionally headache, tiredness, rash, itching, and flushing have been reported.

Individuals who are considered to be at risk of serious adverse reactions to glucosamine sulfate will not receive Arthriex. These individuals include people who are allergic to shellfish (a source for glucosamine), soya (an ingredient of the product), and peanut (as those who have a soya allergy also may be allergic to this peanut); also people who have liver or kidney problems. Arthriex will also not be available for women who are pregnant, planning to become pregnant or breastfeeding as there is no evidence of safe use in these women. Children will also not receive this product as there is no information on efficacy in this age group.

Certain individuals may only receive Arthriex if they have been advised by a doctor or other qualified prescriber. This includes people who:
- suffer from impaired glucose tolerance or diabetes (Type I or Type II) as more blood glucose monitoring may be necessary when starting treatment
- have cardiovascular disease or hypercholesterolaemia (high cholersterol), as cholesterol levels may increase and monitoring of cholesterol is recommended during treatment with Arthriex
- suffer from asthma, as asthma symptoms may worsen.

There have been reports of interactions between glucosamine and some other drugs. Individuals should not use Arthriex if they are taking coumarin anticoagulants (medicines to stop the blood clotting, as an increase in the anticoagulant (anti-blood clotting) effect can occur; similarly with tetracycline, higher blood levels of oral tetracycline can occur leading to a greater risk of side effects from the medicine.

Indirect Danger
Indirect danger to health, even when the product is used correctly, could occur where treatment might mask or hide an underlying condition requiring medical attention and supervision. Use of the medicine might delay diagnosis and definitive treatment and jeopardise the chance of more successful therapy. Therefore it is important that the condition or symptoms for which a medicinal product not subject to a medical prescription is indicated, can be correctly assessed or identified by the patient and that the product can be used without medical supervision.

Arthriex may only be used specifically for the treatment of osteoarthritis of the knee as efficacy has only been demonstrated in this condition. In addition, as osteoarthritis of the knee cannot be diagnosed by an individual or a pharmacist the proposal is for the product only to be authoirsed for the treatment of osteoarthritis of the knee that has already been diagnosed by a doctor.
It is important to ensure that the product is not used by people who have not been diagnosed with osteoarthritis of the knee as they may have more serious conditions, such as rheumatoid arthritis, systemic lupus, gout and tumours where the symptoms include painful, swollen joints, warmth and redness, persistent stiffness and pain in one or more joints, even at rest, and an increase in body temperature. Use of Athriex by these people could delay them getting medical treatment for their more serious condition.

Whilst taking Arthriex, it can take several weeks for the relief of symptoms to be fully seen, especially pain relief. However, users will be advised that If no relief of symptoms has occurred after 2-3 months continuous use, advice should be sought from a doctor.

Arthriex is considered to be safe in long term use provided there are no serious side effects; however if an individual wishes to continue treatment beyond 3 years, they should consult their doctor.

Incorrect use - frequently and to a very wide extent
Addiction, dependence, recreational use, and misuse can be considered to be incorrect use.

There is no indication from the reported data that patients develop dependence or addiction to glucosamine; similarly, there have been no reports of drug abuse or drug dependence with glucosamine.

Arthriex is not considered to pose a risk of frequent and widespread incorrect use.

Activity and/or the side effects require, further investigation"
Glucosamine sulfate has been available in the UK as a prescription only medicine for 10 years and more widely throughout the world. The activity and side effects are well established therefore this criterion does not apply.

Is normally prescribed as an injection
This product is a tablet for oral use, so this criterion does not apply.

5. Further details on the application

Risk Management Plan
As is required for all new marketing authorisations applications, the application contains a risk management plan (RMP) which documents the following:

- the known safety profile of the medicine including any important identified and potential risks
- what is not known about the safety profile ('missing information')
- how the safety profile will be monitored after the medicine is licensed, including any plans for further studies to actively gain more knowledge about the safety of the medicine ('additional pharmacovigilance activities')
- how any important risks will be prevented or minimised in patients ('risk minimisation measures') and how effectiveness of the risk minimisation measures will be measured.

The RMP for Arthriex has detailed the important identified and potential risks based on the known safety profile of glucosamine sulfate, which is well established. It proposes how these will be managed in the product information (Summary of Product Characteristics, labelling and

patient information leaflet) and by the provision of training material for pharmacists and their staff.

Label and leaflet
The patient information leaflet and label that individuals will have when they buy this product are provided in Annex 2 and 3.

Summary of Product Characteristics
The Summary of Product Characteristics is provided in Annex 4. This document is a description of the properties and the conditions attached to the use of Arthriex as a Pharmacy medicine. It is used as a reference by healthcare professionals.

6. Advice from the Commission on Human Medicines

The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. CHM is an advisory non-departmental public body, sponsored by the Department of Health.

The CHM advised in favour of Pharmacy availability of Arthriex 750mg and 1500mg Film coated Tablets under the circumstances outlined above i.e. for the relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor with a maximum dose and maximum daily dose of 1500mg glucosamine sulfate.

7. What do you think?

- Arthriex are used for the relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor
- Arthriex tablets are only at the moment available on prescription.
- We propose to make it available in pharmacies.
- MHRA considers that this product can be available as a Pharmacy medicine.
- We want to know what you think about this change.

Please tell us your views – please use the form on the next page in Annex 1. Please respond by 04 August 2017.

Your details

Name:

Position (if applicable):

Organisation (if applicable):

Email:

a. Do you consider that Arthriex 750mg and 1500mg Film-coated Tablets should be available as a Pharmacy medicine?

Yes ☐ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

b. Do you have any specific comments on the leaflet or the label provided in the public reclassification report? In particular:

- **If you are a potential patient, do you find the patient information leaflet (Annex 2) and the label (Annex 3) understandable?**
- **If you are a pharmacist or healthcare professional would you be confident to supply this product if suitable pharmacy training was provided?**

c. Do you have any other comments on the reclassification?

d. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐ Partially* ☐ No ☐

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gsi.gov.uk) to arrive by **04 August 2017.** Contributions received after that date cannot be included in the exercise.

Package Leaflet: Information for the User

Arthriex 750 mg Film Coated Tablets

Glucosamine Sulfate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2-3 months.

What is in this leaflet

1. What Arthriex 750 mg Film Coated Tablets are and what they are used for

This medicine belongs to a group of medicines called other anti-inflammatory and anti-rheumatic agents, non steroids.

This medicine should only be used for the relief of symptoms (signs of illness) 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.

Mild to moderate osteoarthritis of the knee is a type of joint disease with signs of illness such as stiffness (after sleep or long rest) and pain when you move (e.g. when climbing the stairs, kneeling, bending, walking or running).

This medicine is **not** to be used for the treatment of any other areas of your body affected by osteoarthritis.

This medicine is **not** to be used for treating rheumatoid arthritis.
You must talk to a doctor if you do not feel better or if you feel worse after 2-3 months.

2. What you need to know before you take Arthriex 750 mg Film Coated Tablets

Do not take Arthriex 750 mg Film Coated Tablets

- If you are allergic to Glucosamine or to any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to Shellfish, since Glucosamine sulfate tablets are manufactured from shellfish.
- If you are allergic to peanut or soya.
- If you are taking Warfarin (a medicine used to thin the blood) or similar type of products (anticoagulants used to prevent blood-clotting) as Glucosamine may increase the effect of Warfarin making blood clotting even slower. This could cause bruising and bleeding that can be serious.
- If you are taking oral tetracycline (an antibiotic effective against a wide range of bacterial infections) do not take Glucosamine at the same time.
- If you are pregnant or breast-feeding.
- If you have kidney or liver problems (discuss with your doctor if you are not sure).

Warnings and precautions

Talk to your doctor or pharmacist before taking this product if you:

- Suffer from impaired glucose tolerance or diabetes (type I or II). More frequent monitoring of your blood glucose levels may be necessary when starting treatment with Glucosamine tablets, regularly during treatment and when discontinuing from Glucosamine.
- Have a known risk factor for heart (cardiovascular) disease, since high cholesterol (hypercholesterolemia) has been observed in a few cases in patients treated with Glucosamine tablets. Monitoring of cholesterol levels is therefore recommended during treatment with Glucosamine.
- Suffer with asthma. When starting on Glucosamine tablets, you should be aware of potential worsening of symptoms (your signs of illness).
- If you have joint swelling, warmth and redness, joint painfulness, persistent joint stiffness, pain at rest, pain in more than one joint, increased body temperature and decrease in body weight because they can be symptoms (signs of illness) of more serious diseases such as rheumatoid arthritis, systemic lupus, gout, tumours.
- You must talk to a doctor if you intend to use this medicine for a very long time because

  there is not enough information available on the use of Glucosamine beyond 3 years.

Talk to your doctor before using Arthriex 750 mg Film Coated Tablets if any of the above mentioned applies to you.

Other medicines and Arthriex 750 mg Film Coated Tablets

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Caution should be exercised if Arthriex 750 mg Film Coated Tablets have to be combined with other medicines, especially with:

- Medicines for diabetes, as your doctor or pharmacist or nurse may wish to monitor your blood sugar levels more closely while you are taking this medicine.

Please contact your doctor or pharmacist for medical advice before using this medicine if you use any of the above mentioned medicines.

Arthriex 750 mg Film Coated Tablets with food and drink

You can take this medicine with or without food.

Pregnancy and breast-feeding

This medicine should not be used during pregnancy because there is not enough information available on the use of Glucosamine in pregnant women.

This medicine should not be used during breast-feeding because there is no information available on the risk to your child.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. If you experience dizziness or drowsiness from this medicine, you should not drive or operate machinery.

Arthriex 750 mg Film Coated Tablets contain

This medicinal product contains 76 mg sodium per tablet. This should be taken into consideration by patients on a controlled sodium diet. This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product because your blood sugar levels will need to be checked regularly when you are taking it. This medicine contains soya lecithin. Do not use this product if you are allergic to soya or peanuts.

3. How to take Arthriex 750 mg Film Coated Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

One tablet should be taken twice daily or two tablets to be taken once daily. The tablets should be swallowed whole with water.

You may notice that the relief of your symptoms (signs of illness) might not happen for several weeks of treatment and in some cases may take even longer. If you do not feel any better after 2-3 months, you should speak to your doctor, pharmacist or nurse to find out if you should stop taking this medicine.

Use in children and adolescents

This medicine is not recommended for use in children and adolescents below the age of 18, because safety and efficacy has not been established.

Use in elderly

No dosage adjustment is required when treating otherwise healthy elderly patients. Please speak to your doctor if you are not sure of the dose you should be taking.

If you take more Arthriex 750 mg Film Coated Tablets than you should

If you have taken large quantities you must consult your doctor or a hospital.

In case of an overdose you may experience symptoms (signs of illness) such as:

- headache

- dizziness
- disorientation
- joint pain
- feeling sick (nausea) or being sick (vomiting)
- diarrhoea or constipation.

If you forget to take Arthriex 750 mg Film Coated Tablets
Do not take a double dose to make up for a forgotten dose.

If you stop using Arthriex 750 mg Film Coated Tablets
Your symptoms (signs of illness) may reoccur. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

You should stop taking Arthriex 750 mg Film Coated Tablets and see your doctor immediately if you experience signs of illness such as: swollen face, tongue and/or pharynx and/or difficulty to swallow or hives together with difficulties to breathe (angioedema).

The following side effects have been reported:
Common side-effects (in less than 1 in 10 patients but in more than 1 out of 100 patients treated)
- Headache
- Tiredness
- Nausea
- Abdominal pain
- Indigestion
- Diarrhoea
- Constipation
- Wind (flatulence)

Uncommon side-effects (in less than 1 in 100 patients but more than 1 in 1000 patients treated)
- Rash
- Itching
- Flushing

Unknown frequency
- Allergic reaction
- Visual disturbance
- Hair loss (alopecia)
- Dizziness
- Swelling of the feet or ankles
- Vomiting
- Diabetes mellitus inadequate control
- Asthma or aggravation of pre-existing asthma

- Increased liver enzymes (hepatic enzyme elevation)
- Yellow discoloration of the skin (jaundice)

Elevated cholesterol levels have been also reported. It is not possible to determine whether these events were directly related to Glucosamine tablets

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arthriex 750 mg Film Coated Tablets

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date stated on the label and carton after EXP:.
The expiry date refers to the last day of that month.
After first opening of the tablet container the product should be used within 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Arthriex 750 mg Film Coated Tablets contain
- The active substance is Glucosamine sulfate. Each tablet contains 942 mg of Glucosamine sulfate sodium chloride (equivalent to 750 mg of Glucosamine sulfate) or 589 mg Glucosamine.
- The other ingredients are; **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.

What Arthriex 750 mg Film Coated Tablets look like and contents of the pack
Glucosamine sulfate 750 mg tablets are off-white, oblong, film-coated tablets.

The tablets are available in two types of packaging:

Cartons containing PVdC coated PVC/Al blisters.
Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180 film-coated tablets.
or

Cartons containing HDPE containers fitted with a tamper-evident HDPE screw cap.
Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180 film-coated tablets.
Not all pack sizes may be marketed.

Marketing authorisation holder
CF Pharma Ltd., The Racecourse, Danesfort, Kilkenny, Ireland

Manufacturers

Walmark a.s, Oldrichovice 44, 739 61 Trinec, Czech Republic.
Millmount Healthcare Ltd. Block 7, City North Business Campus, Stamullen, County Meath Ireland

This leaflet was last revised in: 08/2016

Arthriex
750 mg

EU Standardised BRAILLE grid

1.6mm dot base
2.5mm between next dot
6mm between two letters of one word
10mm line space (return)
12mm hyphenation
Number sign before first number and space after last number.

43.50

260

30

140

30

Arthriex 750 mg
Film Coated Tablets
Glucosamine Sulfate

Relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor

BN.:
Exp.:

Arthriex 750 mg
Film Coated Tablets
Glucosamine Sulfate

Arthriex 750 mg
Film Coated Tablets
Glucosamine Sulfate

Arthriex 750 mg
Film Coated Tablets
Glucosamine Sulfate

Relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor

Arthriex 750 mg
Film Coated Tablets
Glucosamine Sulfate

Relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor

INSTRUCTIONS ON 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, pharmacist or nurse may need to monitor you more regularly
- are on a controlled sodium diet

Do not exceed the stated dose.

P

MARKETING AUTHORISATION NUMBER: PL 36549/0001
PK1190-00

SPECIAL WARNING AND PRECAUTIONS

Keep out of the sight and reach of children.
Return to your doctor for advice if no relief of symptoms is experienced after 2-3 months.

EXCIPIENTS: contains sodium, soya lecithin and lactose monohydrate. See leaflet for further information.

METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use. Read the package leaflet before use.

SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture. Once opened the tablets should be used within 6 months.

60 Tablets

60 Tablets

750 mg

000000000

750 mg

750 mg

60 Tablets

Each tablet contains 942 mg glucosamine sulfate sodium chloride equivalent to 750 mg glucosamine sulfate or 589 mg glucosamine.

MARKETING AUTHORISATION HOLDER:
CF Pharma Ltd.,
The Racecourse,
Danesfort,
Kilkenny,
Ireland.

Arthriex 750 mg
Film Coated Tablets
Glucosamine Sulfate

Relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor

11

75.00

45.00

75.00

44.50

250.50

Client: CF Pharma
Ref: Arthriex Carton
Job. 4129 | Variant: 750 mg
Date: 12/06/17 | Colours: 4

Artefact.ie
The brands you trust, trust...
Design & Brand Consultants
57 Clontarf Road
Dublin 3
Tel: 01 853 7308/833 0081/
Fax: 01 832 5683
Email: info@artefact.ie

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YELLOW | BLACK
Varnish Free | Braille Plate

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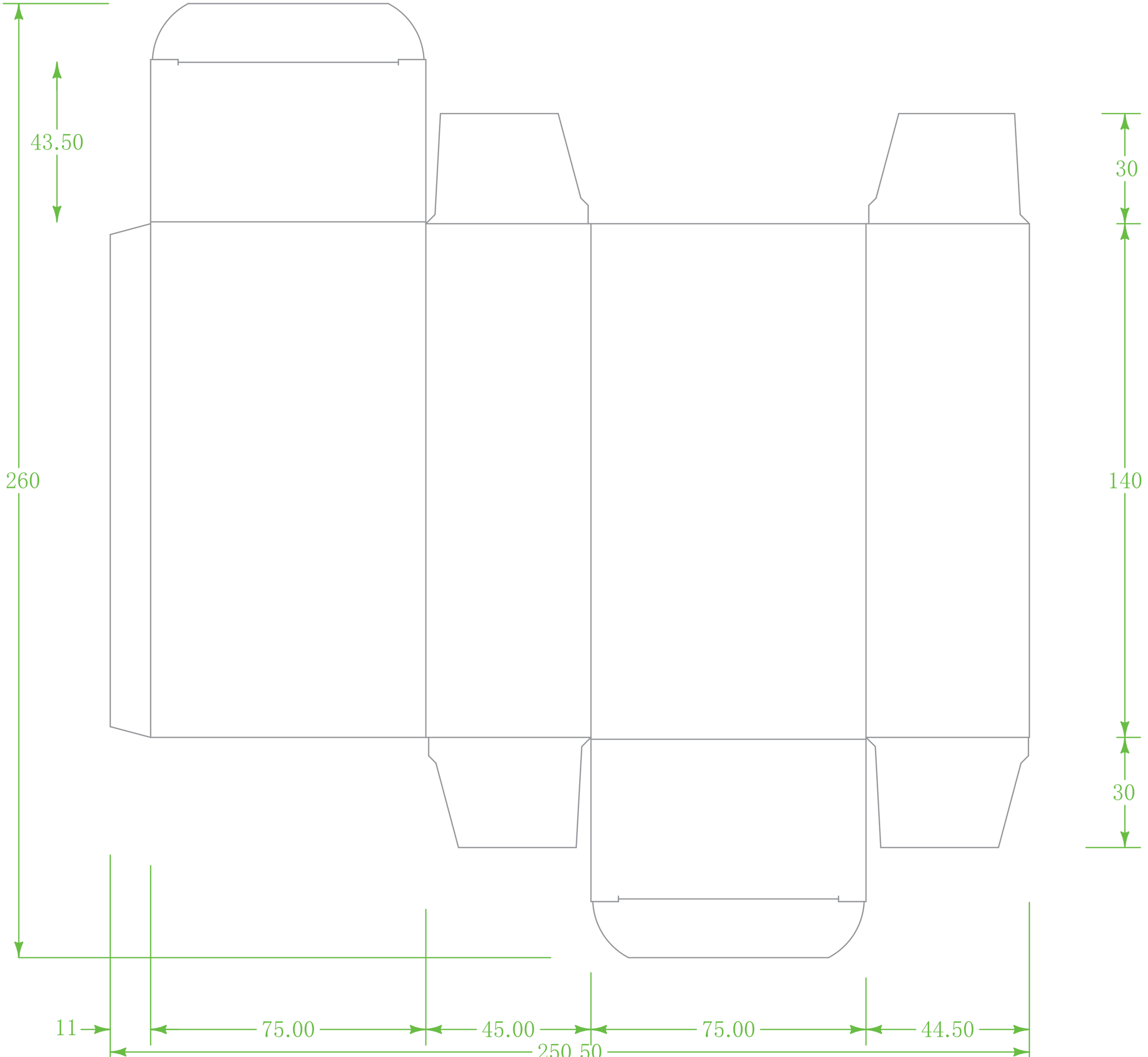

Client: PHOENIX LABS

Ref: Arthrimel Carton

Job. 3188 | Variant: 750 mg

Date: 19/11/14 | Colours: 4

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Do NOT print Grid Keylines

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Package Leaflet: Information for the User

Arthriex 1500 mg Film Coated Tablets

Glucosamine Sulfate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to a doctor if you do not feel better or if you feel worse after 2-3 months

What is in this leaflet

1. What Arthriex 1500 mg Film Coated Tablets are and what they are used for

This medicine belongs to a group of medicines called other anti-inflammatory and anti-rheumatic agents, non steroids.

This medicine should only be used for the relief of symptoms (signs of illness) 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.

Mild to moderate osteoarthritis of the knee is a type of joint disease with signs of illness such as stiffness (after sleep or long rest) and pain when you move (e.g. when climbing the stairs, kneeling, bending, walking or running).

This medicine is **not** to be used for the treatment of any other areas of your body affected by osteoarthritis.

This medicine is **not** to be used for treating rheumatoid arthritis.
You must talk to a doctor if you do not feel better or if you feel worse after 2-3 months.

2. What you need to know before you take Arthriex 1500 mg Film Coated Tablets

Do not take Arthriex 1500 mg Film Coated Tablets

- If you are allergic to Glucosamine or to any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to Shellfish, since Glucosamine sulfate tablets are manufactured from shellfish. If you are allergic to peanut or soya.
- If you are taking Warfarin (a medicine used to thin the blood) or similar type of products (anticoagulants used to prevent blood-clotting) as Glucosamine may increase the effect of Warfarin making blood clotting even slower. This could cause bruising and bleeding that can be serious.
- If you are taking oral tetracycline (an antibiotic effective against a wide range of bacterial infections) do not take Glucosamine at the same time.
- If you are pregnant or breast-feeding.
- If you have kidney or liver problems (discuss with your doctor if you are not sure).

Warnings and precautions

Talk to your doctor or pharmacist before taking this product if you:

- Suffer from impaired glucose tolerance or diabetes (type I or II). More frequent monitoring of your blood glucose levels may be necessary when starting treatment with Glucosamine tablets, regularly during treatment and when discontinuing from Glucosamine.
- Have a known risk factor for heart (cardiovascular) disease, since high cholesterol (hypercholesterolemia) has been observed in a few cases in patients treated with Glucosamine tablets. Monitoring of cholesterol levels is therefore recommended during treatment with Glucosamine.
- Suffer with asthma. When starting on Glucosamine tablets, you should be aware of potential worsening of symptoms (your signs of illness).
- If you have joint swelling, warmth and redness, joint painfulness, persistent joint stiffness, pain at rest, pain in more than one joint, increased body temperature and decrease in body weight because they can be symptoms (signs of illness) of more serious diseases such as rheumatoid arthritis, systemic lupus, gout, tumours.
- You must talk to a doctor if you intend to use this medicine for a very long time because there is not enough information available on the use of Glucosamine beyond 3 years.

Talk to your doctor before using Arthriex 1500 mg Film Coated Tablets if any of the above mentioned applies to you.

Other medicines and Arthriex 1500 mg Film Coated Tablets

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Caution should be exercised if Arthriex 1500 mg Film Coated Tablets have to be combined with other medicines, especially with:

- Medicines for diabetes, as your doctor or pharmacist or nurse may wish to monitor your blood sugar levels more closely while you are taking this medicine.

Please contact your doctor or pharmacist for medical advice before using this medicine if you use any of the above mentioned medicines.

Arthriex 1500 mg Film Coated Tablets with food and drink
You can take this medicine with or without food.

Pregnancy and breast-feeding
This medicine should not be used during pregnancy because there is not enough information available on the use of Glucosamine in pregnant women.
This medicine should not be used during breast-feeding because there is no information available on the risk to your child.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. If you experience dizziness or drowsiness from this medicine, you should not drive or operate machinery.

Arthriex 1500 mg Film Coated Tablets contain
This medicinal product contains 152 mg sodium per tablet. This should be taken into consideration by patients on a controlled sodium diet. This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product because your blood sugar levels will need to be checked regularly when you are taking it. This medicine contains soya lecithin. Do not use this product if you are allergic to soya or peanuts.

3. How to take Arthriex 1500 mg Film Coated Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.
One tablet should be taken once daily. The tablets should be swallowed whole with water.

You may notice that the relief of your symptoms (signs of illness) might not happen for several weeks of treatment and in some cases may take even longer. If you do not feel any better after 2-3 months, you should speak to your doctor, pharmacist or nurse to find out if you should stop taking this medicine.

Use in children and adolescents
This medicine is not recommended for use in children and adolescents below the age of 18, because safety and efficacy has not been established.

Use in elderly
No dosage adjustment is required when treating otherwise healthy elderly patients. Please speak to your doctor if you are not sure of the dose you should be taking.

If you take more Arthriex 1500 mg Film Coated Tablets than you should
If you have taken large quantities you must consult your doctor or a hospital.
In case of an overdose you may experience symptoms (signs of illness) such as:
- headache
- dizziness
- disorientation
- joint pain

- feeling sick (nausea) or being sick (vomiting)
- diarrhoea or constipation.

If you forget to take Arthriex 1500 mg Film Coated Tablets
Do not take a double dose to make up for a forgotten dose.

If you stop using Arthriex 1500 mg Film Coated Tablets
Your symptoms (signs of illness) may reoccur. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

You should stop taking Arthriex 1500 mg Film Coated Tablets and see your doctor immediately if you experience signs of illness such as: swollen face, tongue and/or pharynx and/or difficulty to swallow or hives together with difficulties to breathe (angioedema).

The following side effects have been reported:
Common side-effects (in less than 1 in 10 patients but in more than 1 out of 100 patients treated)
- Headache
- Tiredness
- Nausea
- Abdominal pain
- Indigestion
- Diarrhoea
- Constipation
- Wind (flatulence)

Uncommon side-effects (in less than 1 in 100 patients but more than 1 in 1000 patients treated)
- Rash
- Itching
- Flushing

Unknown frequency
- Allergic reaction
- Visual disturbance
- Hair loss (alopecia)
- Dizziness
- Swelling of the feet or ankles
- Vomiting
- Diabetes mellitus inadequate control
- Asthma or aggravation of pre-existing asthma
- Increased liver enzymes (hepatic enzyme elevation)
- Yellow discoloration of the skin (jaundice)

Elevated cholesterol levels have been also reported. It is not possible to determine whether these events were directly related to Glucosamine tablets

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arthriex 1500 mg Film Coated Tablets

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date stated on the label and carton after EXP:.
The expiry date refers to the last day of that month.
After first opening of the tablet container the product should be used within 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Arthriex 1500 mg Film Coated Tablets contain

- The active substance is Glucosamine sulfate. Each tablet contains 1884 mg of Glucosamine sulfate sodium chloride (equivalent to 1500 mg of Glucosamine sulfate) or 1178mg Glucosamine.
- The other ingredients are; **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.

What Arthriex 1500 mg Film Coated Tablets look like and contents of the pack
Glucosamine sulfate 1500 mg tablets are off-white, oblong, film-coated tablets.

The tablets are available in two types of packaging.

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.

Marketing authorisation holder
CF Pharma Ltd., The Racecourse, Danesfort, Kilkenny, Ireland

Manufacturers

Walmark a.s, Oldrichovice 44, 739 61 Trinec, Czech Republic.
Millmount Healthcare Ltd. Block 7, City North Business Campus, Stamullen, County Meath Ireland

This leaflet was last revised in: 08/2016

Arthriex
1500 mg

EU Standardised BRAILLE grid

1.6mm dot base
2.5mm between next dot
6mm between two letters of one word
10mm line space (return)
12mm hyphenation
Number sign before first number and space after last number.

43.50

260

30

140

30

Arthriex 1500 mg Film Coated Tablets
Glucosamine Sulfate

Relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor

BN.:
Exp.:

Arthriex 1500 mg Film Coated Tablets
Glucosamine Sulfate

Relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor

INSTRUCTIONS ON 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, pharmacist or nurse may need to monitor you more regularly
- are on a controlled sodium diet

Do not exceed the stated dose.

P

MARKETING AUTHORISATION NUMBER: PL 36549/0002
PK1193-00

SPECIAL WARNING AND PRECAUTIONS

Keep out of the sight and reach of children.
Return to your doctor for advice if no relief of symptoms is experienced after 2-3 months.

EXCIPIENTS: contains sodium, soya lecithin and lactose monohydrate. See leaflet for further information.

METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use. Read the package leaflet before use.

SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture. Once opened the tablets should be used within 6 months.

30 Tablets
1500 mg

30 Tablets
1500 mg

000000000

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

MARKETING AUTHORISATION HOLDER:
CF Pharma Ltd.,
The Racecourse,
Danesfort,
Kilkenny,
Ireland.

30 Tablets
1500 mg

Arthriex 1500 mg Film Coated Tablets
Glucosamine Sulfate

Relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor

11
75.00
45.00
75.00
44.50
250.50

Client: CF Pharma
Ref: Arthriex Carton
Job. 4129 | Variant:1500 mg
Date: 12/06/17 | Colours: 4

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COLOURS ☐ PICS/ILLUST. ☐

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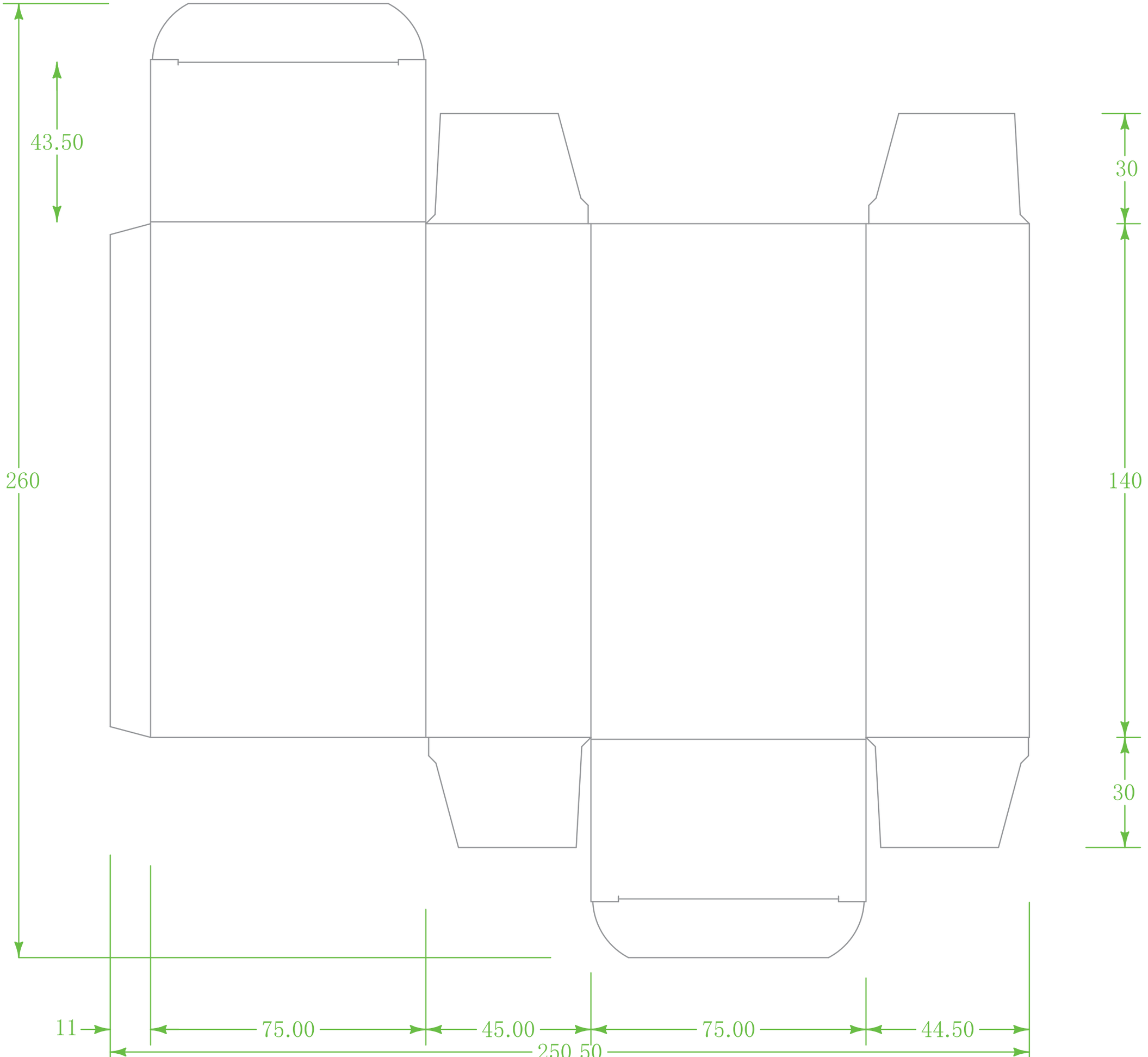
43.50
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30
140
30
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75.00
45.00
75.00
44.50
250.50

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glucosamine sulfate 750mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 942mg glucosamine sulfate sodium chloride equivalent to 750 mg glucosamine sulfate or 589 mg glucosamine.

Excipient(s) with known effect:

Each tablet contains 75.9 mg (3.3mmol) of sodium.

Lactose monohydrate 3.0 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, 8x19mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Glucosamine sulfate tablets are indicated for relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor.

4.2 Posology and method of administration

Administration:
Glucosamine sulfate tablets should be swallowed whole.
Tablets can be taken with or without food.

Adults and the elderly:
One Glucosamine sulfate tablet should be taken twice daily.

Or

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

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

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

Patients taking warfarin (or other coumarin anticoagulants).

4.4 Special warnings and precautions for use

Patients should be sure to consult a doctor to rule out the presence of any other joint diseases for which alternative 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 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.

Glucosamine sulfate 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 75.9 mg sodium per dose. The daily sodium intake is 151.7 mg (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.

Do not take this product if you are:

- allergic to shellfish, soya, peanut, glucosamine, sulfates, or any other ingredient of this medicine
- pregnant
- under the age of 18 years
- taking warfarin (or other coumarin anticoagulants).

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, heart, liver or kidney problems
- are on a controlled sodium diet

Do not exceed the stated dose.
Keep out of the sight and reach of children.
Return to your doctor for advice if no relief of symptoms is experienced after 2-3 months.

4.5 Interaction with other medicinal products and other forms of interaction

Glucosamine sulfate should be avoided in combination with:

Coumarin anticoagulants: Increased effect of coumarin anticoagulants (e.g. warfarin) during concomitant treatment with glucosamine has been reported.

Glucosamine sulfate should be used with caution in combination with:

Hypoglycaemic agents: Close monitoring of blood sugar levels is recommended for diabetics on hypoglycaemic agents.

Tetracyclines: 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 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. The use of glucosamine during breast feeding is therefore not recommended 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, aggravated and Diabetes mellitus inadequate control have been reported, but causality has not been established.
Glucosamine sulfate 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.

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
Poly(vinyl) alcohol
Coating:
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: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.

OR

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

Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

CF Pharma Ltd,
The Racecourse,
Danesfort,
Kilkenny,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 36549/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/10/2014

10 DATE OF REVISION OF THE TEXT

30/10/2014