Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Response document for MHRA public consultation on the proposal to make Arthriex 750mg and 1500mg Film-coated Tablets available in Pharmacies **ANNEX 1**
Ref: ARM96

Your details

Name: [redacted]

Position (if applicable): Regulatory Affairs Consultant

Organisation (if applicable): Freelance

Email: [redacted]

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

Yes X No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

The product should only be made available as a Pharmacy medicine if the points detailed in section b are resolved adequately.

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?**

Leaflet

Section 1

1) The sentence about glucosamine not being indicated for the treatment of acute painful symptoms in section 4.2 of the SmPC of the product to be considered for addition to the leaflet as follows:

Suggestion:
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. Glucosamine is not indicated for the treatment of acute painful symptoms. Please make sure that you have been diagnosed with osteoarthritis of the knee before taking this product.

2) The message about not treating any other types of arthritis could be made more emphatic.

Suggestions:
This medicine is to be used only for the treatment mild to moderate osteoarthritis of the knee.
This medicine is **not** to be used for the treatment of any other areas of your body affected by Osteoarthritis or to treat other type of arthritis e.g. rheumatoid arthritis.

Delete the following sentence as it is covered by the changes suggested.
~~This medicine is **not** to be used for treating rheumatoid arthritis.~~

3) The following sentence could benefit from rewording as it has the potential to be misread by a patient.
You must talk to a doctor if you do not feel better or if you feel worse after 2-3 months.

Suggestion:

You must talk to a doctor if you do not feel better after 2-3 months, or if you feel worse.

Section 2

1) If a patient is on medication for high cholesterol, they should consult their GP prior to taking this medicine, so consider adding this to the warnings and precautions section. Also delete the text 'If you' as shown below to avoid duplication.

Suggestions:

Warnings and precautions
Talk to your doctor or pharmacist before taking this product if you:
- ~~If you~~ Have joint swelling ….etc.
- Are taking medication for the treatment of high cholesterol

2) Stating that there is not enough information available on the use of glucosamine beyond 3 years could potentially be considered as encouraging patients to use the medicine long-term even when it is unnecessary for them to do so. It would be more prudent to encourage patients to consult their doctor whether to continue using the medicine for a period beyond 3 months.

Suggestions:
~~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~~

If you experience a benefit from taking this medicine and intend to continue using it past 3 months, please discuss this with your doctor.

Section 3

1) Consider amending the following sentence as shown below as it seems more appropriate to use the word 'continue' rather than 'stop'. If the treatment has not worked for 3 months, then it seems reasonable that a patient would not continue taking the medicine. 'Using the word 'stop' implies that the patient might continue with the treatment.

Suggestion:
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~~ continue taking this medicine.

Section 4

The following information is included in this section:

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).

If a patient experiences a swollen face, tongue and or pharynx and or difficulty to swallow or to breathe, this is potentially an emergency situation, so the appropriate advice should be given (see suggestion below).

Suggestion:

You should stop taking Arthriex 750 mg Film Coated Tablets and see your doctor immediately or go to the casualty department at your nearest hospital 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).

Section 5

The following sentence appears in this section:
After first opening of the tablet container the product should be used within 6 months.

This sentence is somewhat unusual as it is not normal practice to state on the pack of a tablet product that it should be used within 6 months of opening the pack. Normally, tablets are considered to be stable until their expiry date. Is it possible that the product is unstable in HDPE containers and if so, is there the need to consider disallowing the HDPE container pack. Also, does the reduced 6 month shelf-life also apply to product in blisters once the pack has been opened (as the text suggests i.e. even with the tablets not yet removed from the blisters?

The above comments also apply to the same text on the carton.

SmPC
Section 4.4 of the SmPC includes the section which commences:

The label will state
Read the package leaflet before use.
etc….
.
Question
Is it correct (or even necessary) that this information should appear in the SmPC? As is normally the case, packaging text is based on the SmPC and there is normally no need for it to be repeated in the SmPC unless there is a compelling reason to do so

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 X

*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 **xxxxxx 2017.** Contributions received after that date cannot be included in the exercise.