#### INSTRUCTIONS FOR USE



FOR OSTEOARTHRITIS

FlexiSEQ Max Strength is a medical device for self-administration. Read the whole leaflet carefully before you start using this product. Keep this leaflet for future reference. If you have any further questions, contact us at enquiries@flexiseq.com

# WHAT IS THE INTENDED PURPOSE OF FLEXISEQ MAX STRENGTH & HOW DOES SEQ TECH™ WORK?



FlexiSEQ Max Strength lubricates the cartilage in joints to relieve pain and stiffness and improve impaired joint function associated with all stages of osteoarthritis.

FlexiSEQ Max Strength is a topically applied gel that is clinically proven to relieve joint pain and improve mobility.

FlexiSEQ Max Strength contains billions of plant-based, oily droplets called Sequessomes™. Activated when our gel dries on the skin, these tiny, flexible droplets pass through the skin and into target joints, where they localise on cartilage surfaces to form a lubricating layer that protects damaged cartilage. We call this unique, lubricating mode of action SEQ Tech™ and it's the revolutionary driving-force powering FlexiSEQ Max Strength.

FlexiSEQ Max Strength is our strongest formula that contains the maximum concentration of Sequessomes™, and helps to restore joint function, relieve pain and improve mobility in adult patients who have received a diagnosis of osteoarthritis and need maximum strength relief.

FlexiSEQ Max Strength is drug free and can be used long term and alongside medications without drug interactions or exacerbating pre-existing conditions. It is suitable for all synovial joints.

#### COMPOSITION

Aqua, Phosphatidylcholine, Alcohol, Glycerin, Carbomer, Polysorbate 80, Disodium Phosphate, Sodium Hydroxide, Benzyl Alcohol, Methylparaben, Ethylparaben, Linalool, Disodium EDTA, Sodium Phosphate, Sodium Metabisulfite, BHT.

# PRESENTATION AND PACK SIZE

FlexiSEQ Max Strength is a white to yellow gel with a citrus odour and comes in 30g, 50g and 100g tubes.

# LIMITATIONS, CONTRAINDICATIONS, PRECAUTIONS OR WARNINGS

- FlexiSEQ Max Strength is for use by adults only. It is not for use on children.
- FlexiSEQ Max Strength has not been tested on pregnant or breastfeeding women and they should seek the advice of a healthcare professional before using it.
- FlexiSEQ Max Strength contains benzyl alcohol and linalool. Do not use FlexiSEQ Max Strength if you are allergic (hypersensitive) to any of the ingredients.
- Do not use FlexiSEQ Max Strength on open wounds, broken or infected skin or mucous membranes (the lining of the openings of the body, such as the mouth, nose or eyes).
- $\bullet \ \mathsf{Do} \ \mathsf{not} \ \mathsf{use} \ \mathsf{if} \ \mathsf{the} \ \mathsf{tube} \ \mathsf{is} \ \mathsf{split}, \mathsf{or} \ \mathsf{the} \ \mathsf{product} \ \mathsf{does} \ \mathsf{not} \ \mathsf{look} \ \mathsf{or} \ \mathsf{smell} \ \mathsf{as} \ \mathsf{described}.$
- There are no known interactions with medicines or medical devices.
- · Keep out of the reach of children.
- $\bullet \text{Fabric (clothing, bedding etc.)} \text{ that has been in contact with this product may burn more easily. Washing clothing and bedding may reduce product build up but not totally remove it. } \\$
- Wash hands after using FlexiSEQ Max Strength. If your hands are the area being treated, wait 10–15 minutes, until the treated area is dry, before washing.
- Avoid using other moisturisers, creams, or massage oils on the treated area until FlexiSEQ Max Strength has fully dried.
- $\bullet \ \, \text{Do not apply the recommended amount of } \textbf{FlexiSEQ Max Strength} \ \text{more than 4 times in any 24-hour period.}$
- Dispose of used tube and packaging in line with local regulations.

## POTENTIAL SIDE EFFECTS

- Minor skin irritations such as dryness and redness at the site of application may affect about 6 in 100 people. If affected, reduce the frequency of application to once daily. If this does not improve the condition, you may discontinue application until the problem resolves, usually within a few days. You may then restart the application. If the problem persists, then discontinue use.
- If you have any concerns or notice any side effects not listed in this leaflet, please talk to your healthcare professional and/or contact us at enquiries@flexiseq.com
- In the event of a serious incident, please contact your authority having jurisdiction and inform us via enquiries@ flexiseq.com

# **KEY TO SYMBOLS**



Legal Manufacturer: PBB Devices Limited, 4th Floor Phoenix House, 1 Station Hill, Reading, Berkshire, RG1 1NB. UK.



Temperature limitation (store between 8°C and 25°C).



Caution.



EU Authorised Representative: NEXTEC medical GmbH, Zöllinplatz 4, 79410 Badenweiler, Germany.



Date of manufacture (see imprint on the carton).



Medical device.



Use by (see imprint on the tube and carton). Do not use the product after the expiry date.



Batch number (see imprint on the tube and carton).



Consult instructions for use.



European Conformity marking and Notified Body identity number.



Non Sterile.





## APPLYING FLEXISEQ MAX STRENGTH TO YOUR JOINTS

FlexiSEQ Max Strength is not like other gels. It is important to apply our gel correctly to joints to ensure it works effectively. It should **NOT** be rubbed into the skin. It should be allowed to dry completely before covering. It is most effective when applied to soft tissues around joints, rather than to bone.

#### Application



Apply to clean, dry skin. Spread a thin layer of gel evenly to the soft tissues around the joint. Do NOT rub in. Wash hands after use.

# Drying Time



Once applied, the correct amount should take roughly 10 minutes to air dry. Do NOT cover whilst drying. After 10 minutes, the treated area might feel slightly sticky to touch and can be washed if preferred.

#### Frequency



Apply FlexiSEQ Max Strength twice daily, every day, in the morning and evening.

#### Effect Time



FlexiSEQ Max Strength can take several days to start taking effect.

#### Storage



Replace cap after use. Store at room temperature between 8°C and 25°C and use within three months of opening.

#### Knees



Apply a line of gel as long as your index finger to the back and sides of your knee joint. It should not be applied to the kneecap.

#### Hands



Apply a pea-sized quantity of gel around each affected joint. Avoid washing treated hands for 10-15 minutes after application.

# Hips



Locate the edge of your hip bone and apply a line of gel as long as your index finger to the soft tissue below, where the bone can no longer be felt. Spread towards your groin, not buttocks.

**Shoulders** 

Apply a line of gel as long as your index finger making sure you evenly cover the area around your joint from the top of the arm, leading into your armpit. It should not be applied to the bone or shoulder blade.

Please visit www.flexiseq.com/help-and-advice to find out how to get the best from our product and www.flexiseq.com/how-to-apply-flexiseq to view videos that demonstrate the correct application of FlexiSEQ Max Strength to various joints.

# THE BENEFITS OF A DRUG FREE PRODUCT

 $As a drug free treatment, \textbf{FlexiSEQ} \, \textbf{Max} \, \textbf{Strength} \, has several \, added \, benefits for the following osteoarthritis patients: \, \textbf{As a drug free} \, \textbf{The following osteoarthritis} \, \textbf{As a drug free} \, \textbf{The following osteoarthritis} \, \textbf{As a drug free} \, \textbf{The following osteoarthritis} \, \textbf{As a drug free} \, \textbf{The following osteoarthritis} \, \textbf{As a drug free} \, \textbf{The following osteoarthritis} \, \textbf{As a drug free} \, \textbf{The following osteoarthritis} \, \textbf{As a drug free} \, \textbf{The following osteoarthritis} \, \textbf{As a drug free} \, \textbf{As a$ 



for a drug free formula.



Patients wanting reduced systemic side effects.



Patients who need treatment that can be used for longer than 14 days



NSAIDs are not suitable.



Patients taking medications that may interact with traditional painkillers.

## WELCOME TO THE FLEXISEQ MOVEMENT

We're delighted to welcome you to the FlexiSEQ family. Our products are designed to help you move without pain and to give you the freedom to say 'yes' to life.

Our help and support doesn't end with our range of products. Visit our website to sign up to our free FlexiSEQ newsletter and each month we'll send you updates from our amazing community and news of our latest promotions. If you have any questions, comments or feedback, you can also find us on social media or feel free to contact us at enquiries@flexiseq.com

Together we are stronger, that's what the #FlexiseqMovement is all about.

# www.flexiseq.com

# PATENTS AND TRADEMARKS

Europe: EP2437726 validated in AT, CH, DE, ES, FR, GB, IE, IT, LT, LV, NL, TR

EP2836203 validated in ES, GB, RO, SI
GB: See www.ascension.co.uk/patents Singapore: 176297

Malaysia: MY-170121-A

South Africa: 2012/00017

 $\label{eq:controlled} Flexiseq^{\emptyset}, Sequessome \ Technology^{\emptyset}, Sequessomes^{\texttt{tot}}, SEQ \ Tech^{\texttt{tot}}, the \ SEQ \ TeCh^{\texttt{tot}} \ roundel \ and \ the \ Ascension \ logo \ are \ trademarks \ of \ AH \ Development \ Healthcare \ Limited.$ 





