

# Patient Leaflet: Instructions for Use

# Flexiseq™

## (Gel incorporating Sequessome Technology™)

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- Read the whole leaflet carefully before you start using this product.
  - Keep this leaflet for future reference.
  - If you have any further questions, consult your doctor or pharmacist.

### 1. Composition

Soy Phosphatidylcholine, Polysorbate 80, Methylhydroxybenzoate, Ethylhydroxybenzoate, Butylated hydroxytoluene, Disodium hydrogenphosphate dodecahydrate, Sodium dihydrogenphosphate dihydrate, Sodium hydroxide, Sodium edetate, Sodium metabisulphite, Ethanol, Benzyl alcohol, Carbomer, Glycerol hydrate 85%, Linalool, Purified water.

### 2. Presentation and pack size

- Flexiseq is a white to yellow gel and comes in a 50 g tube.

### 3. Intended use

- Flexiseq is used for the treatment of pain associated with osteoarthritis.



## Precautions and Safety Measures

- Keep out of the reach of children.

### 4. Before you use Flexiseq

#### Do not use Flexiseq

- If you are allergic (hypersensitive) to any of the ingredients in Flexiseq.
- 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).

### 5. Pregnancy and breast-feeding

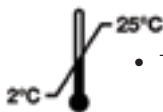
- Flexiseq has not been tested on pregnant women in clinical trials and therefore its use during pregnancy is not advised unless it has been deemed necessary by your doctor or physician.
- It is unknown whether Flexiseq may be harmful to your child if you are breast-feeding. Please ask your doctor or pharmacist for advice before using the product.

## 6. How to use Flexiseq

- Flexiseq is for external use only.
- Unless otherwise directed by your doctor, apply twice daily, in the morning and in the evening, a quantity appropriate to the size of the joint being treated. For example, when applying to the knee, a quantity of 2.2g, corresponding to a gel length of approximately half the length of the carton, should be evenly applied.
- It is important to allow the treated area to dry out before covering. Failure to do so will reduce the functionality of the product.

## 7. Possible side effects

- There have been no serious side effects reported, relating to Flexiseq.
- Flexiseq can cause minor skin irritations, although not everybody gets them.
- Side effects affecting the skin and subcutaneous tissue (the soft tissue beneath the skin) could occur after approximately two weeks of treatment, but should disappear within a further few weeks if you continue to use the product. In case of continuing side effects, you may first reduce the dose (e.g. from twice daily to once daily). If this does not improve the condition, you may discontinue treatment with the product until the event resolves, which could be within a few days. You may then be able to restart administration of the product after improvement of the skin condition, if there is no evidence of allergic reactions resulting from skin contact.
- In the event of serious side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- There are no known interactions with other medicines.



- This product must be stored at temperatures between 2°C and 25°C.



- For batch no. and expiry date of the product: see imprint on the tube and carton



- Do not use the product after the expiry date which is stated on the carton and tube after "EXP".
- After first opening of the container, use the product within three months.



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