Patient Leaflet: Instructions for Use

FLEXISEQ® ACTIVE

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

2. Presentation and pack size
- FLEXISEQ Active is a white to yellow gel and comes in 50g and 100g tubes.

3. Intended use
- FLEXISEQ Active lubricates the cartilage in joints to relieve pain and stiffness, and improve impaired joint function associated with all stages of osteoarthritis.

4. How to use FLEXISEQ Active
- FLEXISEQ Active is for external use only, avoid contact with the eyes. If product gets into eyes, rinse well with clean water immediately.
- Unless otherwise directed by your doctor, apply twice daily, in the morning and the evening, to the soft tissues around the affected joint. Apply a quantity appropriate to the size of the joint being treated:
  – For a knee, shoulder or hip, a line as long as your index finger.
  – For an ankle, wrist or the fingers on one hand, a line as long as half of your index finger.
- It is important that you personalise the dose for the particular joint you are treating.
- Wash hands after application.
- It is important to allow the treated area to dry out before covering. Failure to do so will reduce the functionality of the product.
- You must allow the FLEXISEQ Active gel to dry for at least 10 minutes, or until the skin is touch dry before covering the area.
- If the gel is taking longer than 10 minutes to dry, you have probably applied too much and you should try using a little less next time.
- If the gel is taking less than 10 minutes, you should apply a little more next time.
- You can reduce the time it takes for FLEXISEQ Active to dry by warming the skin before applying the gel.
- Twice-daily treatment with FLEXISEQ Active can provide pain relief after as little as 2 days. However, it may take up to several days of continuous use for the full effect to be seen.
- Once opened, continue to store between 8°C and 25°C and use the product within three months.

Apply the gel evenly around the joint.

Evenly spread over the soft tissue around the joint (avoiding the knee cap). Do not rub in.

Allow Flexiseq Active to dry for 10 minutes before covering.

5. Precautions and safety measures
- Keep out of the reach of children.

5.1 Do not use FLEXISEQ Active...
- If you are allergic (hypersensitive) to any of the ingredients in FLEXISEQ Active.
- 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).

5.2 Pregnancy and breastfeeding
- FLEXISEQ Active 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.
- It is unknown whether FLEXISEQ Active may be harmful to your child if you are breastfeeding. Please ask your doctor or pharmacist for advice before using the product.

5.3 Use in children
- FLEXISEQ Active has not yet been tested on children. Use in these patients should be discussed with your doctor.

6. Possible side effects
- There have been no serious side effects reported, relating to FLEXISEQ Active.
- Flexiseq Active may cause minor skin irritations, such as erythema, dry skin and rash at the site of application. These were usually of mild to moderate intensity, transient and fading away by itself. A treatment interruption was not necessary.
- Side effects affecting the skin and subcutaneous tissue (the soft tissue beneath the skin at the site of application) could occur after approximately two weeks of treatment, but should disappear within a 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 medicines.

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

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

• Caution

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

• Consult instructions for use

• Manufacturer
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