

## PATIENT INFORMATION LEAFLET

### SULJEL 3% gel

#### For external use.

- **Active substance:** Each 1 gram gel contains 30 mg nimesulide.
- **Excipients:** Ethanol, disodium edetate (EDTA disodium), liquid paraffin, methyl paraben (E218), propyl paraben (E216), ethyl paraben (E214), carbomer 980, triethanolamine and purified water.

**Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher or lower** dose other than the recommended to you.*

#### **What is in this leaflet:**

1. *What SULJEL is and what is it used for?*
2. *Before you use SULJEL*
3. *How to use SULJEL?*
4. *Possible side effects*
5. *How to store SULJEL?*

#### **1. What SULJEL is and what is it used for?**

- SULJEL is an externally used gel containing nimesulide and is marketed in 30 g aluminum tubes.
- SULJEL is used for the treatment of soft tissue rheumatic diseases, soft tissue trauma such as strain, contusion and musculoskeletal diseases characterized by pain, inflammation and muscle strain.

#### **2. Before you use SULJEL**

##### **Do NOT use SULJEL in the following cases**

- If you are allergic (hypersensitive) to nimesulide or any of the other ingredients of the SULJEL
- If you have previously shown a hypersensitivity reaction (such as narrowing of the respiratory tract (bronchospasm), nasal discharge (rhinitis), itching) to aspirin (acetylsalicylic acid) or other non-steroidal anti-inflammatory drugs
- If you have an injured or abraded skin in the presence of local infection
- If you are using another topical creams simultaneously
- In children under 12 years
- With occlusive dressings
- If you have gastrointestinal ulcer and hepatic failure

**Take special care with SULJEL in the following conditions**

Avoid getting SULJEL on the eyes or similar mucous membranes.

Do not take this medicine by mouth. Wash your hands after using it.

If skin irritation is observed, stop using it.

If you have gastro or intestinal bleeding, active or suspected peptic ulcer, severe renal or hepatic dysfunction, severe coagulation disorders or severe/non controlled heart failure, use it with caution.

Do not use without consulting your doctor in pregnancy.

Undesirable effects may be reduced if you use the smallest dose for the shortest time as possible.

Take special care if you have known hypersensitivity to other NSAIDs. Keep in mind the possibility of developing hypersensitivity in the course of therapy.

Be careful against exposure to direct and solarium sunlight to reduce the risk of photosensitivity.

If symptoms persist or the condition is aggravated, seek medical advice.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

**Using SULJEL with food and drink:**

No interaction with food and drink.

**Pregnancy**

*Ask your doctor or pharmacist for advice before using the medicine.*

Use it under medical supervision in pregnancy, if necessary. SULJEL should not be used during pregnancy unless clearly necessary.

*If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.*

**Breast-feeding**

*Ask your doctor or pharmacist for advice before using the medicine.*

Because SULJEL can pass into milk, do not use without consulting your doctor during breast-feeding.

**Driving and using machines**

There is no negative effect on driving and using machines.

**Important information about some of the excipients of SULJEL**

SULJEL contain methyl paraben (E218), propyl paraben (E216), and ethyl paraben (E214) which may rarely cause delayed allergic reactions and local skin reactions.

### **Using with other medicines**

No interactions of SULJEL with other medicinal products are known or to be expected via the topical route.

*Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.*

### **3. How to use SULJEL?**

- **Instructions for appropriate method and dose/frequency of administration:**

Unless advised otherwise by a physician, apply to the affected site 2 or 3 times per day. The duration of treatment is 7-15 days.

- **Route and method of administration:**

SULJEL is for external use only.

Apply in a thin layer to your skin and massage gently until it is completely absorbed.

- **Different age groups:**

**Use in children:**

It should not be used in children under 12 years.

**Use in elderly:**

The use of SULJEL in elderly patients is similar to that of adults.

- **Special populations:**

**Kidney/Liver failure:**

Do not use in severe kidney and liver failure.

*If you have the impression that the effect of SULJEL is too strong or too weak, talk to your doctor or pharmacist.*

**If you have used more SULJEL than you should:**

*If you may have taken more SULJEL than you should, talk to a doctor or pharmacist.*

Since SULJEL is used in a limited and superficial region, there is no side effect of overdose.

**If you forget to use SULJEL:**

*Do not take double dose to balance the missed doses.*

**If you stop using SULJEL:**

Not applicable.

### **4. Possible side effects**

Like all medicines, SULJEL may cause side effects in some patients who are sensitive to the substances contained in SULJEL.

Side effects were listed as shown in the following categories:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

**Stop using SULJEL and tell your doctor straight away or seek the nearest hospital emergency department if you experience any of the following**

- Swelling in the face, tongue, throat
- Difficulty in breathing, wheezing

These are very serious side effects. If you have them, you may have had a serious allergic reaction to SULJEL. There may be an urgent need for medical intervention or hospitalization.

These side effects are very rare.

**Tell your doctor if you notice any of the following:**

**Common**

- Itching
- Skin redness

These side effects disappear when the dosage is reduced or treatment is stopped.

*If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

## **5. How to store SULJEL?**

*Keep out of the sight and reach of children and store in the original package.*

Store at room temperature below 25°C.

**Use in accordance with the expiry date.**

*Do not use SULJEL after the expiry date on packaging or tube.*

Do not use SULJEL if you notice any damage on product and/or packaging.

***Marketing authorization holder:***

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul, Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

[info@berko.com.tr](mailto:info@berko.com.tr)

***Manufacturer:***

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/ İstanbul, Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

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