

# Ibrugan

## 50 mg/g gel

### 1. NAME OF THE MEDICINAL PRODUCT

Ibrugan 50 mg/g gel

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of gel contains 50 mg ibuprofen.

Excipients with known effects: This medicine contains 10 mg benzyl alcohol / gram (1% w/w). A single dose (1-2.5 grams gel) contains 10-25 mg benzyl alcohol (1-2.5% w/w).

For all excipients list, see section 6.1.

### 3. PHARMACEUTICAL FORM

Gel.

Transparent, homogenous, colourless gel, with characteristic smell of isopropyl alcohol.

### 4. CLINICAL DATA

#### 4.1 Therapeutic indications

This medication is indicated for adults and adolescents aged 12 years and older.

Local symptomatic relief of occasional mild muscle and joint pain such as those caused by: minor bruises, bumps, strains, torticollis or other contractures, lower back pain, and mild sprains resulting from twists.

#### 4.2 Posology and method of administration

##### Posology

*Adults and adolescents (12 years and older):* Apply a thin layer of gel to the painful area 3 to 4 times a day with a light massage to facilitate penetration.

The safety and efficacy of this medication has not been established in children (under 12 years of age) due to a lack of data.

##### Method of administration

Cutaneous use, exclusively external.  
Wash hands after each application.

If symptoms persist after 7 days of treatment, irritation occurs or worsens, the clinical situation should be evaluated.

#### 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the components of this medicine listed in section 6.1.
- Do not use on sunburn, open wounds, mucous membranes or eczematous skin.
- Do not administer to patients who have had allergic reactions (rhinitis, asthma, pruritus, angioedema, urticaria, shock or others) caused by acetylsalicylic acid or other NSAIDs due to the possibility of cross-hypersensitivity.
- Third trimester of pregnancy.

#### 4.4 Special warnings and precautions for use

- Use only on intact skin.
- Avoid contact with eyes.
- Do not expose the treated area to the sun, to reduce the risk of photosensitivity reactions (skin lesions such as eczema, vesiculobullous rash, etc., may appear).
- Do not use with occlusive dressings.

- Do not use on large areas or for prolonged periods.
- Do not apply simultaneously to the same area as other topical preparations.
- Do not use on children under 12 years of age.

#### Risk of GI Ulceration, Bleeding and Perforation with NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms. Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

#### Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) and acute generalised exanthematous pustulosis (AGEP), which may be life-threatening or fatal, have been reported in association with the use of ibuprofen (see section 4.8). The majority of these reactions occurred within the first month of treatment.

If signs and symptoms suggestive of these reactions appear, ibuprofen should be discontinued immediately and alternative treatment considered (as appropriate).

#### Excipients with known effect:

This medicine contains 10 mg benzyl alcohol / gram (1% w/w). A single dose (1-2.5 grams gel) contains 10-25 mg benzyl alcohol (1-2.5% w/w). Benzyl alcohol may cause allergic reactions and mild local irritation.

If symptoms persist after 7 days (5 days in adolescents) of treatment, irritation occurs or worsens, the clinical situation should be evaluated.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

They have not been described for cutaneous use, but the possibility of using other analgesics during treatment with this medicine will be assessed.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy:

Although systemic absorption is very low after cutaneous use, the preparation should not be used during pregnancy.

There are no clinical data on the use of topical forms of Ibrugan gel during pregnancy. Even if systemic exposure is lower compared to oral administration, it is unknown whether systemic exposure to Ibrugan gel achieved following topical administration may be harmful to an embryo/foetus. During the first and second trimester of pregnancy, Ibrugan gel should not be used unless clearly necessary. If used, the dose should be kept as low and the duration of treatment as short as possible.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors, including Ibrugan gel, may induce cardiopulmonary and renal toxicity in the foetus. In late pregnancy, prolonged bleeding may occur in both the mother and the foetus, and delivery may be delayed. Therefore, Ibrugan gel is contraindicated during the last trimester of pregnancy (see section 4.3).

### Lactation:

Although systemic absorption is very small when used cutaneously, the preparation should not be used during breastfeeding unless otherwise indicated by a doctor.

### **4.7 Effects on ability to drive and use machines**

This medicine has no or negligible influence on the ability to drive and use machines.

### **4.8 Side effects**

#### **Skin and subcutaneous tissue disorders:**

- Common (1/1,000 to <1/100): moderate local erythema, dermatitis, local irritation, itching at the application site, which disappears upon discontinuation of treatment.
- Rare (>1/10,000, <1/1,000): photodermatitis.
- Very rare (<1/10,000): severe cutaneous adverse reactions (SCARs) (including erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis).
- Not known: drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), acute generalized exanthematous pustulosis (AGEP), photosensitivity reactions.

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health professionals are asked to report any suspected side effect through the reporting system.

National Centre for Adverse Drug Reaction Monitoring

<https://www.npra.gov.my/index.php/en/health-professionals/reporting-adr>

### **4.9 Overdose**

Because this medicine is for cutaneous use, poisoning is not likely to occur.

In case of accidental ingestion, the symptoms of overdose will depend on the dose ingested and the time elapsed since ingestion. The most frequent symptoms are: nausea, vomiting, abdominal pain, lethargy, drowsiness, dizziness, spasms and hypotension.

Treatment: If less than 1 hour has elapsed, gastric lavage will be performed and activated charcoal administered to reduce drug absorption. If more than 1 hour has elapsed, it is recommended to correct blood electrolytes with the addition of alkalis, since there is no specific antidote for ibuprofen.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Topical products for joint and muscle pain. Non-steroidal anti-inflammatory preparations for topical use: ibuprofen. ATC code: M02AA13.

Ibuprofen is a non-steroidal anti-inflammatory and analgesic (NSAID) that acts by preventing the synthesis of prostaglandins through competitive and reversible inhibition of the various isoforms of cyclooxygenase (COX).

The analgesic effect of NSAIDs is related to the inhibition of excessive production of prostaglandins (PGs). These seem to have, at peripheral level, a significant sensitizing effect on nociceptive endings, enhancing the algogenic effect of bradykinin.

The anti-inflammatory action is also related to the local inhibition of prostaglandin synthesis, since the inflammatory response is always accompanied by the release of various prostanoids, with potent vasodilatory properties, which cause the precapillary arterioles to increase their calibre, leading to the typical red colour of the skin corresponding to the inflamed areas. In addition, they enhance the effect of bradykinin and histamine on vascular permeability, favouring the formation of the characteristic inflammatory oedema.

### **5.2 Pharmacokinetic properties**

After local application of the product, high concentrations are obtained in the subcutaneous tissues close to the application area. Ibuprofen penetrates the tissues directly and not via the bloodstream, resulting in low systemic absorption.

## **6. PHARMACEUTICAL PROPERTIES**

### **6.1 List of excipients**

#### *List of excipient(s)*

Hypromellose  
Sodium hydroxide  
Isopropyl alcohol  
Benzyl alcohol  
Purified water

### **6.2 Incompatibility**

Not applicable.

### **6.3 Shelf life**

As printed on the product box.

### **6.4 Special precautions for storage**

Store below 30°C. Keep container tightly closed.

### **6.5 Nature and contents of container**

The gel is packed into an aluminium tube with HDPE shoulder and orifice and a white polypropylene cap containing 40g of ibuprofen gel in a carton along with package insert.

### **6.6 Special precautions for disposal**

Any unused medications or waste materials should be disposed in accordance with local requirements.

## **7. PRODUCT REGISTRATION HOLDER**

### **ARMS PHARMA SDN. BHD.**

22-1, JALAN PJU5/20D,  
THE STRAND,  
47810  
KOTA DAMANSARA,  
SELANGOR, MALAYSIA

### **Name and Address of Manufacturer**

Laropharm S.R.L.  
Sos. Alexandriei, no. 145A,  
Loc. Bragadiru, Oras Bragadiru, Judet Ilfov, 077025, ROMANIA

## **8. DATE OF REVISION OF THE TEXT**

August 2025

The type size is 7 points, as measured in font "Times New Roman" with a space between lines of 3 mm."