

IBRUGAN 50MG/G GEL

Ibuprofen (50mg)

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What Ibrugan gel is used for

Ibrugan gel is available in gel form for cutaneous use. This medicine belongs to the group of topical anti-inflammatory drugs.

This medicine is indicated for adults and adolescents aged 12 years and older for the symptomatic relief of occasional mild muscle and joint pain such as that caused by: minor bruises, bumps, strains, torticollis or other contractures, lumbago and mild sprains caused by twists.

How Ibrugan gel works

Ibrugan is a gel for cutaneous use. This medicine belongs to the group of topical anti-inflammatory drugs.

It contains the active ingredient, ibuprofen, a non-steroidal anti-inflammatory drug that acts by preventing the synthesis of prostaglandins through competitive and reversible inhibition of the various isoforms of cyclooxygenase (COX). Because it is formulated in an aqueous/alcoholic gel, the preparation also has a soothing and cooling effect when applied to the affected area.

Before you use Ibrugan gel

- When you must not use it
Do not use Ibrugan gel:
 - If you are allergic to ibuprofen or any of the other ingredients of this medicine.
 - If you are allergic to aspirin or any other nonsteroidal anti-inflammatory or analgesic drugs.
 - On open wounds, mucous membranes or eczematous skin.

- If you have a sunburn in the affected area.
- In children (under 12 years old).
- If you are in the last 3 months of pregnancy.

Fertility, pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not use Ibrugan gel if you are in the last 3 months of pregnancy. You should not use Ibrugan gel during the first 6 months of pregnancy unless it is clearly necessary and your doctor has advised you to do so. If you need treatment during this time, the lowest dose should be used for the shortest possible time.

Oral forms (e.g. tablets) of Ibrugan gel may cause adverse reactions in the fetus. It is unknown whether the same risk applies to Ibrugan gel when used on the skin.

- Before you start to use it
Talk to your doctor or pharmacist before using Ibrugan gel.
 - This medicine is for cutaneous use only, do not ingest.
 - Apply only to intact, unbroken skin.
 - You should avoid contact with mucous membranes (nose, mouth) and eyes.
 - Do not apply the gel to large areas of skin or for long periods of time.
 - Do not use with tight bandages or apply heat to the area where it is used. If you cover the area where you have used this medicine, do so in such a way that the clothing covering the treated area is slightly loose.
 - The treated areas should not be exposed to the sun (even when cloudy) or to ultraviolet lamps (UVA rays).

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should not apply other preparations for skin use on the same area of skin as you are using this medicine.

How to use Ibrugan gel

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. If you are not sure, ask your doctor or pharmacist.

The recommended dose for adults and adolescents 12 years and older is 3 to 4 applications per day.

This medicine is for external cutaneous use, exclusively on intact skin.

Apply a thin layer of gel to the painful area using a gentle massage to facilitate penetration.

Wash your hands after each application.

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

You should consult a doctor if your condition gets worse or does not improve after 7 days (5 days for teenagers) of treatment.

- If you forget to use it

Do not use a double dose to make up for a forgotten one.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you use too much (overdose)

Due to external use, cases of poisoning are unlikely. In case of accidental ingestion, consult your doctor or pharmacist immediately.

While you are using Ibrugan gel

Things you must do

Wash your hands after each application.

Stop treatment with Ibrugan gel if skin rashes or itching develops and talk to your doctor.

Use your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while using this medication.

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Things you must not do

Avoid contact with mucous membranes (nose, mouth) and eyes.

Do not use with tight bandages or apply heat to the area where it is used.

Do not expose the treated areas to the sun (even when cloudy) or to ultraviolet lamps (UVA rays).

Do not apply other preparations for skin use on the same area of skin as you are using this medicine.

- Things to be careful of

Driving and using machines

No effects on the ability to drive and use machinery have been reported when used externally on the skin.

Take special care with Ibrugan gel:

Serious skin reactions such as exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop taking Ibrugan gel and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions.

Ibrugan gel contains benzyl alcohol. This medicine may cause skin irritation because it contains benzyl alcohol.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Ibrugan gel and seek medical attention immediately if you notice any of the following symptoms:

- Non-raised, target-shaped or circular red spots on the trunk, often with blisters in the center, peeling skin, ulcers in the mouth, throat, nose, genitals, and eyes. These severe rashes may be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- Generalized skin rash, elevated body temperature, and enlarged lymph nodes (DRESS syndrome).

- A widespread, red, scaly rash with raised bumps under the skin and blisters, accompanied by fever. Symptoms usually appear at the start of treatment (acute generalised exanthematous pustulosis).

Uncommon (may affect up to 1 in 100 people): redness, inflammation of the skin (dermatitis), local irritation and itching may occur at the application site, which disappear when treatment is stopped.

Rare (may affect up to 1 in 1,000 people): dermatitis (inflammation of the skin) caused by the sun.

Not known: Widespread red scaly rash with bumps under the skin and blisters located mainly in skin folds, trunk and upper limbs, accompanied by fever at the start of treatment (acute generalised exanthematous pustulosis). Stop taking Ibrugan gel if you experience these symptoms and seek medical attention immediately. The skin becomes sensitive to light.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <http://www.npra.gov.my>
Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)

By reporting side effects, you can help provide more information on the safety of this medicine.

Storage and Disposal of Ibrugan

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Keep container tightly closed.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Gel for topical application. Ibrugan gel is a Transparent, homogenous, colorless gel, with characteristic smell of isopropyl alcohol.

1 tube consists of an aluminium tube with HDPE shoulder and orifice and a white propylene cap containing 40g of ibuprofen gel in a carton along with package insert.

- Ingredients

- Active ingredient(s)

The active ingredient is ibuprofen. One gram of gel contains 50 mg ibuprofen.

- Inactive ingredients

The inactive ingredients are: hypromellose, sodium hydroxide, isopropyl alcohol, benzyl alcohol, purified water.

- 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).

Manufacturer

Laropharm SRL,
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Product Registration Holder

ARMS PHARMA SDN. BHD.

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