

### Description

Doloraz Get is the trade name of Ibuprofen, nonsteroidal anti-inflammatory

Doloraz Get tube contains Ibuprofen 5% (w/w)

#### Chemistry

Ibuprofen is: (2RS)-2-[4-(2-Methylpropyl) phenyl] propanoic acid. Clinical pharmacology

The active constituent of Ibuprofen is a phenyl propionic acid derivative. When administered as a topical preparation Ibuprofen has been shown to be an effective analgesic and anti-inflammatory by virtue of percutaneous

Ibuprofen diffuses through the skin as a function of time and after 24 hours an application to human skin shows that the dose administered is present in the epidermis and dermis. Percutaneous absorption amounts to about 5% of that which occurs after oral dosing with Ibuprofen. Therapeutic concentrations are reached locally but not systemically.

## Indications

- □ Topical analgesic and anti-inflammatory for backache, rheumatic and muscular pain, sprains, strains, lumbago and fibrositis, sports injuries. □ Symptomatic treatment in mild trauma: sprains, contusions.
- □ Symptomatic treatment of superficial tendonitis of the upper or lower limbs.

## Dosage

# Usual adult dose and children over 12 years:

The recommended dose is 50-125 mg 3-4 times daily.( equivalent to 4-10 cm expressed from tube). Apply the gel to affected area and rub gently onto the skin until absorbed

### Notes

- Do not give to children under 12 years of age except on the advice of a doctor.
- The dose should not be repeated more frequently than every 4 hours and no more than 4 times in any 24-hour period.
- Review treatment after 2 weeks, especially if the symptoms worsen or persist
- Wash hands after each application.

### Adverse effects

- Gastrointestinal: abdominal pain, dyspepsia.
- Hypersensitivity reactions have been reported following treatment with Ibuprofen. These may consist of: non-specific allergic reactions and anaphylaxis, respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

## Pregnancy

Whilst no teratogenic effects have been demonstrated in animal experiments. The onset of labour may be delayed and duration of labour increased.

Apart from extremely limited obstetric use which requires specialised supervision, prescription of NSAIDs should only be considered where necessary during the first 5 months of pregnancy. It is contra-indicated from the 6th month onwards.

## Lactation

Ibuprofen appears in breast milk in very low concentration and is unlikely to affect the breast fed infant adversely.

# Interference with laboratory tests

### Not Documented

#### Drug interaction

Concurrent use of aspirin or other non steroidal anti-inflammatory drugs (NSAIDs) may result in an increased incidence of adverse reactions.

#### Contraindication

- Injured skin, whatever the lesion: oozing dermatoses, eczema, infected lesion, burn or wound.
- Hypersensitivity to Ibuprofen or aspirin or other non-steroidal antiinflammatory drugs including patients predisposed to asthma, rhinitis
- □ last 4 months of pregnancy

### Warning

- □Avoid contact with eyes, mucous membranes and inflamed or broken
- Discontinue therapy if a rash develops.
- □Do not use under occlusive dressings. Do not exceed the stated dose.

# □ For external use only.

#### Overdose

Overdosage with topical Ibuprofen is unlikely to occur. Symptoms of Ibuprofen overdose include headache, vomiting, drowsiness and hypotension. When treating symptoms, correction of severe electrolyte abnormalities should be considered.

### Precaution

Hands should be washed immediately after use.

#### How supplied

- □Tubes of 50 gm DOLORAZ Gal
- Store according to conditions specified on the package.
- Do not use after the expiry date shown on the package.

# THIS IS A MEDICAMENT



- □ A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- □ The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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COUNCIL OF ARAB HEALTH MINISTERS UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request



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