

Patient Information Leaflet

Hisamitsu®

Salonpas® Diclofenac Gel 1%

Diclofenac sodium 1%

Indications:

For relief of aches, pains and inflammation associated with: ■ muscle pain ■ stiff shoulder ■ backache ■ bruises ■ sprains ■ strains ■ joint pain ■ tendons inflammation ■ elbow pain

Contraindications:

Do not use ■ on wounds or damaged skin. ■ on eyes, mucous membranes or rashes. ■ on suppurating area. This product may mask skin infection. ■ if you are allergic to any ingredients of this product. ■ if you are pregnant. ■ if you are with a history of asthma. ■ on children under 15 years of age.

Warnings:

For external use only. It should be noted that the treatment with anti-inflammatory analgesics is not a curative therapy but a symptomatic therapy. This product should be used only in the presence of symptoms.

Ask a doctor or pharmacist before use ■ if you are allergic to external application products. ■ if you are taking other medications. ■ if you are taking New quinolone antibiotics. ■ if you are breast-feeding. ■ If you are allergic to non-steroidal anti-inflammatory medicines.

When using this product ■ use only as directed. ■ do not use with, or at the same time as, other external analgesic products. ■ do not use with a heating pad. ■ be careful not to get this product in your eyes. If accidentally applied, rinse your eyes right away with water. ■ do not use with occlusive bandages. ■ wash your hands after using this product.

Stop use and ask a doctor if ■ conditions worsen. ■ symptoms persist for more than 6 days or clear up and occur again within a few days. ■ you notice any of the following signs.

1) Contact dermatitis or photosensitivity:

At the site of application, skin reactions such as rash, redness, itching, irritation, pain, pigmentation, roughness and desquamation may occur. These reactions can be exacerbated and result in swelling, blisters and erosions, which may extend to the whole body and become serious. In addition, at the site exposed to sun, symptoms can occur and be exacerbated.

2) Shock or anaphylaxis:

Itchy skin, urticaria, swelling of the face, lips, tongue or throat, hoarseness, sneeze, itchy throat, shortness of breath, palpitation or deteriorating consciousness may rarely occur immediately after using this product.

Keep out of reach of children. Package not child resistant. If swallowed, get medical help immediately.

Directions:

Adults and children 15 years of age and over: Clean and dry affected area. Apply to affected area not more than 3 to 4 times daily. Do not use more than 50g per week.

Children under 15 years of age: Do not use.

What you should do if you miss a dose: Do not worry, apply Salonpas® Diclofenac Gel 1% as soon as you remember and then continue with the normal dose. Do NOT use a double application to make up for forgotten individual application.

Other information: ■ Store below 30°C. ■ Keep away from fire. ■ Avoid direct sunlight. ■ Discard any unused gel remaining after 3 months of first opening the tube.

Description of product: Colorless to slightly yellow clear gel with a characteristic odor.

Active ingredient: Diclofenac sodium 1% (NSAID: nonsteroidal anti-inflammatory drug)

Excipients: Diisopropyl adipate, Lactic acid, Isopropanol, Sodium pyrosulfite, Hydroxyethylcellulose, Hydroxypropylcellulose, and Purified water.

Product of
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Manufactured by
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