PACKAGE LEAFLET

Package leaflet: Information for the user

Salonpas_®

Pain Relief Patch, 105 mg/31.5 mg, Medicated Plaster

Methyl Salicylate / Levomenthol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

- 1. What Salonpas is and what it is used for
- 2. What you need to know before you use Salonpas
- 3. How to use Salonpas
- 4. Possible side effects
- 5. How to store Salonpas
- 6. Contents of the pack and other information

1. What Salonpas is and what it is used for

The medicine is used for the symptomatic relief of pain of muscles & joints associated with strains and sprains.

2. What you need to know before you use Salonpas

Do not use Salonpas:

- if you are allergic (hypersensitive) to any of the ingredients of the medicine.
- if you suffer with allergic conditions, have a history of allergy or had attacks of asthma, especially when taking other pain killers, medicines to reduce fever and other non-steroidal anti-inflammatory drugs (NSAIDs).
- if you are taking similar pain relieving products as the combination can cause additional side effects, if in doubt ask your pharmacist.
- if you have had a severe heart condition.
- if you have severe problems with your kidneys or liver.
- if you have any bleeding ulcers or bleeding problem.
- if you are in the third trimester (last 3 months) of pregnancy.
- to children and adolescents under 18 years of age.

The plaster should not be used on open wounds, irritated skin, eyes or mucosa.

Warnings and precautions

- If you have or have had stomach ulcer/bleeding or a history of gastrointestinal (stomach) ulcer or chronic dyspepsia (discomfort after eating or heartburn).
- If you have a history of asthma.
- Exercise caution if elderly, as you are generally more prone to adverse side effects.

Prolonged or repeated use of the product can cause sensitisation (hypersensitivity). Treatment must be stopped if allergic (hypersensitivity) reactions occur.

Other medicines and Salonpas

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Consult your doctor before using Salonpas if you are taking anticoagulants such as warfarin (medicines that thin your blood).

Pregnancy and breast feeding

Salonpas should not be used if you are in the third trimester (last 3 months) of pregnancy. Use of Salonpas should be avoided during the first and second trimester (first 6 months) of pregnancy.

Speak to your doctor or pharmacist before use if you are breast-feeding.

If you are planning to become pregnant, speak to your doctor or pharmacist before use.

3. How to use Salonpas

Clean and dry the affected area before applying the plaster. Remove the plastic film and apply the adhesive side directly to the skin.

HOW TO APPLY



Apply 1 plaster to the affected area and leave in place for up to 8 to 12 hours. If pain recurs 8 to 12 hours after applying the first plaster, the second plaster can be applied. Only use 1 plaster at a time. Do not use more than 2 plasters per day. Do not use for more than 3 days in a row.

Use in children

Not recommended for use in children or adolescents under 18 years of age.

Do not chew or swallow the plaster.

Duration of treatment

Do not exceed 3 days. If symptoms persist, contact your doctor or pharmacist.

If you use more Salonpas than you should Talk to a doctor or a pharmacist immediately.

No case of overdose has been reported.

If you forget to use Salonpas

Apply the medicine as soon as you remember and then continue with the normal dose. Do not apply a double dose to make up for forgotten individual doses.

4. **Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Very common (may affect more than 1 in 10 people)

· Application site erythema

Common (may affect up to 1 in 10 people)

- Application site pruritus, pain and warmth
- · Headache

Uncommon (may affect up to 1 in 100 people)

- Application site rash and discolouration
- · Pruritus and rash
- · Tinnitus

Not known (frequency cannot be estimated from the available data)

· Burns at application site

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salonpas

Keep this medicine out of the sight and reach of children.

Store this medicine below 25°C, in the original package in order to protect from light.

Whenever a plaster is removed from the packaging, carefully fold the open side of the sachet twice to protect the remaining plasters from light.

Do not use Salonpas after the expiry date which is stated on the carton, or more than 3 months after the packaging is first opened.

6. Contents of the pack and other information

What Salonpas contains

The active substances are 105 mg of methyl salicylate and 31.5 mg of levomenthol in one plaster.

The other inactive ingredients are alicyclic saturated hydrocarbon resin, liquid paraffin, polyisobutylene, styrene-isoprene-styrene block copolymer, synthetic aluminium silicate, backing cloth and plastic film.

What Salonpas looks like and contents of the pack:

This medicine is a light brown 70 cm^2 medicated plaster, with a flexible backing layer. The adhesive side is protected by a plastic film. 1 pack contains a sachet with 3 or 5 plasters.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Hisamitsu UK Limited, 3 Shortlands, Hammersmith, London W6 8DA, UK

Manufactured by

Hisamitsu Pharmaceutical Co., Inc., 408 Tashirodaikan-machi, Tosu, Saga, 841-0017, Japan

Manufacturer responsible for batch release

Penn Pharmaceutical Services Limited, Tredegar, Gwent NP22 3AA, UK

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