

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Salonpas Pain Relief Patch
(Methyl Salicylate 10%w/w, *l*-menthol 3%w/w Transdermal Patch)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each patch (7cm ×10 cm) contains 10% w/w and Methyl salicylate and 3% w/w *l*-menthol.

For excipients, see section 6.1.

3. PHARMACEUTICAL FORMs

Patch for topical application.

70 cm² patch

Translucent adhesive mass with a characteristic odor on a light brown to brown cloth.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of stiff shoulder, backache, muscle pain, muscle fatigue, bruises, sprains, joint pain, frostbite.

4.2 Posology and method of administration

Adults 18 years of age and over:

Clean and dry affected area.

Remove patch from backing film and apply to skin.

Do not use more than a total of 4 patches per day.

Use only 1 patch at a time per affected area. (Do not apply the patch to skin that is injured or irritated (such as skin that is cut, scraped, sunburned, infected, or has a rash).

Apply 1 patch to the affected area and leave in place for up to 8 to 12 hours.

Do not use patches for more than 5 days in a row.

Children under 18 years of age: This product should not be used by children younger than 18 years without a doctor's advice.

4.3 Contraindications

Do not use this product on damaged skin, rash wounds, around the eyes and mucous membranes.

4.4 Special warnings and precautions for use

For external use only.

Do not use this product on damaged skin, rash wounds, around the eyes and mucous membranes. (See section 4.3)

Before using this medication, tell your healthcare provider your medical history, especially of:

- asthma
- growths in the nose (nasal polyps)

If the following symptoms appear after use, they may be side effects. Stop using this product immediately and notify your healthcare provider and bring this instruction manual when you consult a healthcare provider.

If the symptoms persist after 5-6 days of use, immediately stop using this product and bring this instruction manual when you consult a healthcare provider.

Before using this product, tell your healthcare provider if you are allergic to menthol or methyl salicylate; or to aspirin or other salicylates (such as salsalate); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

If you are going to have an MRI test, tell testing personnel if you are using this patch. Some patches may contain metals that can cause serious burns during an MRI. Ask your doctor whether you will need to remove your patch before the test and apply a new patch afterward, and how to do so properly.

This drug contains an aspirin-like product (salicylate). Children and teenagers younger than 18 years should not use this product if they have chickenpox, flu, or any undiagnosed illness or if they have recently received a vaccine. In these cases, using aspirin or aspirin-like products increases the risk of Reye's syndrome, a rare but serious illness.

Tell your doctor if you are pregnant or if you plan to become pregnant. This medication may harm an unborn baby and cause problems with normal labor/delivery. It is not recommended for use in pregnancy from 20 weeks until delivery. If your doctor decides that you need to use this medication between 20 and 30 weeks of pregnancy, you should use the lowest effective dose for the shortest possible time. You should not use this medication after 30 weeks of pregnancy. Discuss the risks and benefits with your doctor.

It is unknown if this product passes into breast milk. Consult your doctor before breastfeeding.

Heat can increase the risk of side effects. Do not apply this medication immediately before, during, or after activities that increase skin temperature (such as bathing in hot water, swimming, sun bathing, heavy exercise) or in hot/humid weather. Wait until your skin has cooled before applying the medication. Do not use a sunlamp/tanning bed, hot water bottle, or heating pad on the treated area.

Wash your hands well after handling the patch. Avoid getting this medication in your eyes, nose, or mouth. If you do get the medication in those areas, flush with plenty of water.

After removing each patch, fold the used patch with the sticky sides together, and throw away in the trash away from children and pets.

Tell your doctor if your condition lasts for more than 3 days, or if it gets worse, or if it keeps returning. If you think you may have a serious medical problem, get medical help right away. Do not apply to the same area continuously if you have sensitive skin.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Ask a health professional before use. There is no fertility data.

4.7 Effects on ability to drive and use machines

There is no data

4.8 Undesirable effects

Skin reactions such as redness, itching, rash, excessive irritation, burning sensation, swelling or blistering

Stop using this product and tell your doctor right away if you have any serious side effects, including:

- blistering/swelling at the application site
- increased/unusual pain at the application site
- nausea/vomiting
- ringing in the ears

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including:

- rash
- itching/swelling (especially of the face/tongue/throat)

- severe dizziness
- trouble breathing

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via the National Regulatory Authority: Pharmacovigilance Electronic Reporting System (PvERS)
<https://pv.pharmacyboardkenya.org>

4.9 Overdose

NA

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salonpas Pain Relief Patch is an Analgesic anti-inflammatory tape.
 ATC Code: M02AC

5.2 Pharmacokinetic properties

No data of relevance to the pharmacokinetic properties.

5.3 Preclinical safety data

No additional preclinical data of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alicyclic saturated hydrocarbon resin
 Mineral oil
 Polyisobutylene
 Styrene-isoprene-styrene block copolymer
 Synthetic aluminium silicate
 Backing cloth
 Plastic film

6.2 Incompatibilities

None reported.

6.3 Shelf life

3 (three) years

6.4 Special precautions for storage

Store this product below 30°C and avoid the sunlight

Avoid storing this product in other containers (it may result in a misuse or a change in quality)

6.5 Nature and contents of container

Aluminium based complex film

Each sachet contains 1 patch, 3 or 5 patches.

6.6 Special precautions for disposal <and other handling>

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

MARKETING AUTHORISATION HOLDER

Hisamitsu Pharmaceutical Co., Inc.

408, Tashirodaikan-machi, Tosu, Saga, Japan

MANUFACTURER

Hisamitsu Pharmaceutical Co., Inc.

408, Tashirodaikan-machi, Tosu, Saga, Japan

8. MARKETING AUTHORISATION NUMBER(S)

H2026/CTD12923/27368

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

July 2026

10. DATE OF REVISION OF THE TEXT

13th July 2026