

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Salonpas, Patch

Methyl Salicylate 6.29%w/w, *l*-menthol 5.71%w/w, Tocopherol acetate 2.00%w/w, *dl*-Camphor 1.24%w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each patch (4.2 cm×6.5 cm or 8.4cm×13cm) contains 6.29%w/w Methyl salicylate, 5.71% w/w *l*-menthol, 2.00% w/w Tocopherol acetate and 1.24% w/w.*dl*-Camphor

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Patch for topical application.

27.3 or 109.2 cm² patch.

Salonpas is a whitish aromatic patch. It can be easily adhered to the skin.

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

Apply the patch to the affected area several times a day. Children should use this product only under adult supervision. Clean the affected area before application.

Do not apply to the same area continuously if you have sensitive skin.

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).

Ask a doctor or pharmacist before use if you have a history of allergic symptoms due to drugs.

Ask a doctor or pharmacist before use if the following symptoms appear after use, they may be side effects. Stop using this product immediately and bring this instruction manual when you consult a doctor or pharmacist.

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

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

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>

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Salonpas Pain Relief Patch is an anti-inflammatory and analgesic product. It improves the circulation in peripheral blood vessels, thus reducing inflammation and relieving pain.

Methyl salicylate is an ester oil (wintergreen oil) and counterirritant ingredient in external analgesic drug products. Methyl salicylate is hydrolysed to salicylic acid. Its pharmacological actions are considered to be those of salicylic acid, and its mechanism of action is due to an inhibitory effect on prostaglandin biosynthesis. Methyl salicylate is also considered to have a counterirritant or rubefacient effect. Counterirritancy is believed to exert a benefit through a mechanism of irritation of sensory nerve endings that offsets firing of pain nerve endings in muscles and joints, masking the underlying discomfort.

Menthol is an alcohol (peppermint oil). It is commonly used on the skin, also as a counterirritant in external analgesic drug products. Topically, it acts to dilate blood vessels, causing a cooling sensation and an analgesic effect. Its counterirritancy effect is believed to be caused by stimulation of nerves that perceive cold while pain-sensing fibers are depressed. Skin hypersensitivity reactions may occur with topical or patch formulations.

5.2 Pharmacokinetic properties

No additional data of relevance to the pharmacokinetic properties.

Studies: FS-67 provided plasma/serum levels of the actives including menthol and methyl salicylate comparable to literature.

5.3 Preclinical safety data

No additional preclinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibutylhydroxytoluene
Hydrated Silicon Dioxide
Hydrogenated Rosin Glycerol Ester
Maleated Rosin Glycerin Ester

Perfume
Polybutene
Polyisobutylene
Raw Rubber
Starch Grafted Acrylate 1000
Titanium Oxide
Zinc Oxide
Backing cloth
Release liner

6.2 Incompatibilities

Not applicable.

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

Each sachet, which is made from aluminum based complex film, contains 2 or 10 or 20 patches as for regular size, and 2 or 4 patches as for large size.

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)

CTD12771

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

13th July 2026

10 DATE OF REVISION OF THE TEXT

13th July 2026