SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Salonpas Pain Relief Patch, 105 mg/31.5 mg
Medicated Plaster
Methyl Salicylate / Levomenthol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each medicated plaster contains 10% Methyl salicylate (105mg) and 3% Levomenthol (31.5mg).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster for topical application.

Light brown coloured 70 cm^2 medicated plaster, with a flexible backing layer. The adhesive side is covered by a plastic film

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of pain of muscles and joints associated with strains and sprains.

4.2 Posology and method of administration

Apply one 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, a second plaster can be applied. Only use one plaster at a time. Do not use more than 2 plasters per day. Do not use for more than 3 days in a row.

Salonpas Pain Relief Patch is not recommended for use in children and adolescents under 18 years of age due to insufficient data on safety and efficacy.

4.3 Contraindications

Hypersensitivity to the active substance, to non-steroidal anti-inflammatory drugs (NSAIDs) or to any of the excipients listed in section 6.1.

The medicated plaster should not be used in the following cases:

- Patients in whom substances with a similar mechanism of action (e.g. acetylsalicylic acid or NSAIDs cause attacks of asthma, bronchospasm or acute rhinitis, or cause nasal polyps, urticaria or angioedema)
- Severe heart failure
- Severe hepatic or renal dysfunction
- Gastrointestinal bleeding or other active bleeding or bleeding disorders
- Third trimester of pregnancy (see Section 4.6)

The plaster should not be used on open wounds or on skin with pathological changes such as eczema, acne, dermatitis, inflammation or infection of any nature or on mucous membrane of body orifices, or should not come into contact with the eyes.

4.4 Special warnings and precautions for use

Analgesics, antipyretics and non-steroidal anti-inflammatory drugs (NSAIDs) can cause potentially serious hypersensitivity reactions, including anaphylactic reactions, even in subjects with no previous exposure to this type of drug.

The systemic bioavailability of the active substances applied via the transdermal route is significantly lower than that following oral administration. However it is not possible to exclude completely the onset of systemic side effects.

Administer with caution to patients with allergic conditions or a history of allergy.

Patients currently suffering from or with a previous history of gastrointestinal disease should be carefully monitored for digestive disorders, in particular gastrointestinal bleeding. In the rare cases where gastrointestinal bleeding or ulceration occur in receiving treatment with methyl salicylate or levomenthol, treatment should be discontinued immediately.

Salonpas Pain Relief Patch is not recommended for use in patients with active or suspected gastrointestinal ulcer or a history of gastrointestinal ulcer or chronic dyspepsia.

Salonpas Pain Relief Patch is not recommended for use in patients with a history of bronchial asthma.

Salonpas Pain Relief Patch is not recommended for use in children and adolescents under 18 years of age due to insufficient data on safety and efficacy.

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

4.5 Interaction with other medicinal products and other forms of interaction

The low systemic bioavailability of the active substances from Salonpas Pain Relief Patch means that interaction with other medicines is unlikely.

Although no adequately controlled interaction studies have been undertaken, in reviewing the literature it is possible that excessive use of topical salicylates

may increase the effect of coumarin anticoagulants. It is therefore advisable that caution be exercised with patients who are taking coumarin anticoagulants such as warfarin.

Revulsives (anti-irritants) and analgesics act synergistically.

4.6 Fertility, pregnancy and lactation

Fertility

There have been no reports of effects of Salonpas Pain Relief Patch on fertility. However, as the use of methyl salicylate may impair female fertility, use of this product is not recommended in women attempting to conceive.

Pregnancy

During the first and second trimester:
The safety of Salonpas Pain Relief Patch in pregnant women has not been established. Therefore, the use of Salonpas Pain Relief Patch during the first and second trimester of pregnancy should be avoided.

During the third trimester:
During the third trimester of pregnancy, all prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the foetus. At the end of the pregnancy, prolonged bleeding time in both mother and child may occur. Therefore, Salonpas Pain Relief Patch is contraindicated during the last trimester of pregnancy (see section 4.3).

Lactation

It is not known whether cutaneous administration of methyl salicylate could result in sufficient systemic absorption to produce detectable quantities in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Salonpas Pain Relief Patch should be made taking into account the benefit of breast-feeding to the child and the benefit of Salonpas Pain Relief Patch therapy to the woman.

4.7 Effects on ability to drive and use machines

There are none described.

4.8 Undesirable effects

Localised skin reactions have been reported such as erythema, pain, pruritus, warmth, rash and discolouration.

Burns at application site have also been reported (frequency: not known).

The prolonged use of products for topical administration may cause hypersensitivity phenomena. In such case, the treatment should be discontinued and a suitable alternative therapy should be initiated.

Serious adverse reaction did not occur in clinical trials carried out with Salonpas Pain Relief Patch.

639 patients were treated with Salonpas Pain Relief Patch in clinical trials. The following adverse drug reactions were reported in the following table:

Tabulated list of adverse events

The following undesirable effects were assessed to be treatment-related and are classified according to the following convention: very common (≥1/10); common (≥1/100 to < 1/10); uncommon (≥1/1,000 to < 1/100); rare (≥1/10,000 to < 1/1,000); and very rare (≤ 1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

General disorders and administration site conditions	Very common: Application site erythema Common: Application site pruritus, pain and warmth Uncommon: Application site rash and discolouration
Nervous system disorders	Common: Headache
Skin and subcutaneous tissue disorders	Uncommon: Pruritus and rash
Ear and labyrinth	Uncommon: Tinnitus

The majority of the reactions that occurred in allergic/asthmatic patients and/or in patients with known hypersensitivity to NSAIDs have been serious.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: http://yellowcard.mhra.gov.uk

4.9 Overdose

No case of overdose has been reported.

In the event of overdose with obvious clinical manifestations, the treatment should be stopped immediately and symptomatic treatment should be initiated immediately and the usual appropriate emergency measures should be applied.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamic category: Topical products for joints and muscular pain

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 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 ruberfacient effect.

Levomenthol also acts as a counterirritant, and has been reported to have analgesic effects, including local anaesthetic actions, secondary to the activation of endogenous opioid receptors.

5.2 Pharmacokinetic properties

Methyl salicylate and levomenthol can be applied topically in effective concentrations, but with very low plasma concentrations of drug. Therapeutic levels in the affected tissues provide relief from pain and inflammation.

Studies have shown methyl salicylate is absorbed through the skin and is extensively metabolised to salicylic acid after topical application where it exerts its therapeutic action and small amounts are absorbed systemically where the salicylic acid is excreted renally, primarily as salicylic acid but also related metabolites. From a pharmacokinetic study in 18 healthy male volunteers who each received six Salonpas Pain Relief patches daily (2 patches applied for 8 hours three times daily) for five consecutive days, the baseline adjusted absorption kinetics for C_{max} for salicylic acid was 613 and 1426ng/ml on days 1 and 5 respectively. The T_{max} values were 3.24 to 3.80 hr. The mean adjusted half-life was 2.7 to 4.29 hr.

Studies with levomenthol have shown it is rapidly absorbed into the skin exerting its therapeutic action and small amounts are absorbed systemically where it is rapidly metabolised and excreted in the urine and bile as a glucuronide. From the pharmacokinetic study using a two plasters repeated application for five consecutive days, the baseline adjusted absorption kinetics for C_{max} for menthol was 5.06 and 19.8ng/ml on days 1 and 5 respectively. The T_{max} was 2.92 and 3.39 hr.

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
Liquid paraffin
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

After the sachet has been first opened: 3 months, when resealed after opening - see section 6.4.

6.4 Special precautions for storage

Store the medicinal product below 25ºC in the original package in order to protect from light.

Each time a plaster is take out of the package, carefully re-seal the open side of the sachet in order to protect the remainder of the plasters.

6.5 Nature and contents of container

Carton box contains a (one) sachet formed from cellophane/ PE/ aluminium/ PE laminate.

Each sachet contains 3 or 5 plasters.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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