

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-029

LABELING

b(4)

SALONPAS[®] PAIN/RELIEF PATCH PAIN RELIEVING PATCH

Press
Open

minty scent

Package not child resistant.
Keep out of reach of children.

Drug Facts

Active ingredients (in each patch)

Menthol 3%.....
Methyl salicylate 10%(NSAID)*.....
*nonsteroidal anti-inflammatory drug

Purpose

Topical analgesic
Topical analgesic

Uses

Temporarily relieves mild to moderate aches & pains of muscles & joints associated with:
▪ strains ▪ sprains ▪ simple backache ▪ arthritis ▪ bruises

Warnings

For external use only

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is small but higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- on the face or rashes
- on wounds or damaged skin
- if allergic to aspirin or other NSAIDs
- with a heating pad
- when sweating (such as from exercise or heat)
- any patch from a pouch that has been open for 14 or more days
- right before or after heart surgery

Ask a doctor before use if

- you are allergic to topical products
- the stomach bleeding warning applies to you
- you have high blood pressure, heart disease, or kidney disease
- you are taking a diuretic

When using this product

- wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
- rash, itching or skin irritation develops
- condition worsens
- symptoms last for more than 3 days
- symptoms clear up and occur again within a few days
- stomach pain or upset gets worse or lasts

If pregnant or breast-feeding, ask a doctor before use during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant.

Directions

Adults 18 years and older:

- clean and dry affected area
- remove patch from backing film and apply to skin (see illustration)
- apply one patch to the affected area and leave in place for up to 8 to 12 hours
- if pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours
- only use one patch at a time
- do not use more than 2 patches per day
- do not use for more than 3 days in a row

Children under 18 years of age:

- do not use

Drug Facts (Continued)

Other information

- some individuals may not experience pain relief until several hours after applying the patch
- avoid storing product in direct sunlight
- protect product from excessive moisture
- store at 20-25°C (68-77°F)

Inactive ingredients

alicyclic saturated hydrocarbon resin, backing cloth, film, mineral oil, polyisobutylene, polyisobutylene 1,200,000, styrene-isoprene-styrene block copolymer, synthetic aluminum silicate

SALONPAS[®] PAIN/RELIEF PATCH

Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

5 PATCHES

SALONPAS[®]

PAIN/RELIEF PATCH

Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

Effectiveness confirmed in clinical trial

NDC#46581-670-05



- STIFF NECK
- SORE SHOULDER
- BACKACHE
- JOINT PAIN

FDA Approved Non-Prescription
Pain Relieving Patch

***DO NOT USE MORE THAN ONE SALONPAS PATCH AT A TIME. SEE DIRECTIONS

Manufactured by

Hisamitsu Pharmaceutical Co., Inc. JAPAN SAGA TOSU

Questions or comments? Call 1-877-SALONPAS MON-FRI 9AM to 5PM (EST)

Made in Japan

Hisamitsu[®] www.salonpas.us

2 3/4" X 3 3/16" inch
(7cm X 10cm)

5 PATCHES

SALONPAS[®] PAIN/RELIEF PATCH

Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

5 PATCHES

LOT

EXP.



3 46581 67005 9

1M218T



h(4)

>& CUT OPEN HERE ----- FOLD TWICE AFTER OPENING

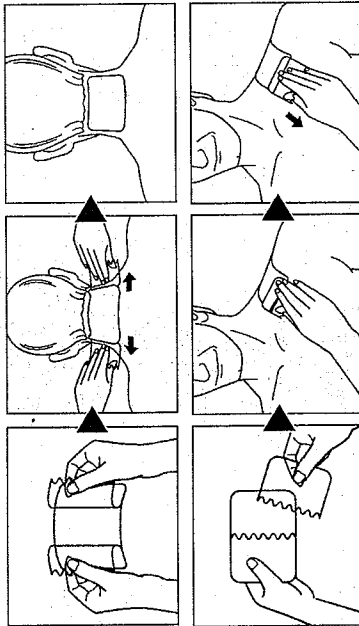
Discard unused patches 14 days after opening

FOLD TWICE AFTER OPENING

SALONPAS® PAIN RELIEF PATCH

Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

Effectiveness confirmed in clinical trial



Questions or comments?

Toll free 1-87-SALONPAS MON-FRI 9AM to 5PM (PST)

www.salonpas.us

※DO NOT USE MORE THAN ONE SALONPAS PATCH AT A TIME. SEE DIRECTIONS

Manufactured by
Hisamitsu Pharmaceutical Co., Inc.
JAPAN SAGA TOSU Made in Japan

2 1/4" X 3 1/8" (6cm X 10cm)
5 PATCHES

Hisamitsu®

>& CUT OPEN HERE ----- FOLD TWICE AFTER OPENING

Discard unused patches 14 days after opening

FOLD TWICE AFTER OPENING

SALONPAS® PAIN RELIEF PATCH PAIN RELIEVING PATCH minty scent

Drug Facts

Active ingredients (in each patch)

Menthol 3% Topical analgesic
Methyl salicylate 10%(NSAID) Topical analgesic
nonsteroidal anti-inflammatory drug

Uses

Temporarily relieves mild to moderate aches & pains of muscles & joints associated with:
■ strains ■ sprains ■ simple backache ■ arthritis ■ bruises

Warnings

For external use only

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is small but higher if you:
■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

Do not use

■ on the face or rashes ■ on wounds or damaged skin ■ if allergic to aspirin or other NSAIDs ■ with a healing pad ■ when sweating (such as from exercise or heat) ■ any patch from a pouch that has been open for 14 or more days ■ right before or after heart surgery

Ask a doctor before use if

■ you are allergic to topical products ■ the stomach bleeding warning applies to you ■ you have high blood pressure, heart disease, or kidney disease ■ you are taking a diuretic

When using this product

■ wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water. ■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

■ you feel faint, vomit, blood, or have bloody or black stools. These are signs of stomach bleeding. ■ rash, itching or skin irritation develops ■ condition worsens ■ symptoms last for more than 3 days ■ symptoms clear up and occur again within a few days ■ stomach pain or upset gets worse or lasts

If pregnant or breast-feeding, ask a doctor before use during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant.

Directions

Adults 18 years and older:

■ clean and dry affected area ■ remove patch from backing film and apply to skin (see illustration) ■ apply one patch to clean, dry skin ■ use one patch at a time ■ use one patch at a time ■ only use one patch at a time ■ do not use more than 2 patches per day ■ do not use for more than 3 days in a row

Children under 18 years of age:

■ do not use

Other information

■ some individuals may not experience pain relief until several hours after applying the patch. ■ avoid storing product in direct sunlight. ■ See product from excessive moisture ■ store at 20-25°C (68-77°F)

Inactive ingredients

alicyclic saturated hydrocarbon resin, backing cloth, film, mineral oil, polyisobutylene, polyisobutylene 1,200,000, styrene-isoprene-styrene block copolymer, synthetic aluminum silicate

Package not child resistant. Keep out of reach of children.

LOT

EXP.

1L296170

SALONPAS[®]
ARTHRITIS PAIN
PAIN RELIEVING PATCH

Press
Open

minty scent
Package not child resistant.
Keep out of reach of children.

Drug Facts

Active ingredients (in each patch)

Menthol 3%.....
Methyl salicylate 10%(NSAID)^{*}.....
^{*}nonsteroidal anti-inflammatory drug

Purpose
Topical analgesic
Topical analgesic

Uses

Temporarily relieves mild to moderate aches & pains of muscles & joints associated with:
• arthritis • sprains • strains • bruises • simple backache

Warnings

For external use only

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is small but higher if you:
• are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others) • have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed

Do not use

• on the face or rashes • on wounds or damaged skin • if allergic to aspirin or other NSAIDs • with a healing pad • when sweating (such as from exercise or heat) • any patch from a pouch that has been open for 14 or more days • right before or after heart surgery

Ask a doctor before use if

• you are allergic to topical products • the stomach bleeding warning applies to you • you have high blood pressure, heart disease, or kidney disease • you are taking a diuretic

When using this product

• wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water. • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

• you feel faint, vomit, blood, or have bloody or black stools. These are signs of stomach bleeding. • rash, itching or skin irritation develops • condition worsens • symptoms last for more than 3 days • symptoms clear up and occur again within a few days • stomach pain or upset gets worse or lasts

If pregnant or breast-feeding, ask a doctor before use during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant.

Directions

Adults 18 years and older:

• clean and dry affected area • remove patch from backing film and apply to skin (see illustration) • apply one patch to the affected area and leave in place for up to 12 hours • if pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours • only use one patch at a time • do not use more than 2 patches per day • do not use for more than 3 days in a row

Children under 18 years of age:

• do not use

Drug Facts (Continued)

Other information

• some individuals may not experience pain relief until several hours after applying the patch • avoid storing product in direct sunlight • protect product from excessive moisture • store at 20-25°C (68-77°F)

Inactive ingredients

alicyclic saturated hydrocarbon resin, backing cloth, film, mineral oil, polyisobutylene, polyisobutylene 1,200,000, styrene-isoprene-styrene block copolymer, synthetic aluminum silicate

SALONPAS[®] ARTHRITIS PAIN 5 PATCHES
Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

SALONPAS[®]
ARTHRITIS PAIN
Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

Effectiveness confirmed in clinical trial

NEW
SILVERADREN
COMFORT
STRETCH

FDA Approved Non-Prescription
Pain Relieving Patch

❖ DO NOT USE MORE THAN ONE SALONPAS PATCH AT A TIME. SEE DIRECTIONS

Manufactured by
Hisamitsu Pharmaceutical Co., Inc. (JAPAN SAKA TOSU)
Classical or comments? Call 1-877-SALONPAS (MORF) 911 to 5PM (PST)
Made in Japan
5 PATCHES
2 1/2" X 3 1/2" (6.4cm X 10cm)

SALONPAS[®] ARTHRITIS PAIN
Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

5 PATCHES

LOT

EXP.



12081-T

SALONPAS[®] ARTHRITIS PAIN
Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

15 PATCHES

SALONPAS[®] ARTHRITIS PAIN
Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

Effectiveness confirmed in clinical trial

NEW
COMFORT
STRETCH

FDA Approved Non-Prescription
Pain Relieving Patch

DO NOT USE MORE THAN ONE SALONPAS PATCH AT A TIME. SEE DIRECTIONS

Manufactured by
Hisamitsu Pharmaceutical Co., Inc. JAPAN (SAGA TOSHI)
Questions or comments? Toll free 1-877-SALONPAS MON-FRI 9AM to 5PM (PST)
Made in Japan
HisamitsuTM www.salonpas.us
15 PATCHES

SALONPAS[®] ARTHRITIS PAIN
Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

Drug Facts (Continued)

Other information

■ some individuals may not experience pain relief until several hours after applying the patch ■ avoid storing product in direct sunlight ■ protect product from excessive moisture ■ store at 20-25°C (68-77°F)

Inactive ingredients

alicyclic saturated hydrocarbon resin, backing cloth, film, mineral oil, polyisobutylene, polyisobutylene 1,200,000, styrene-isoprene-styrene block copolymer, synthetic aluminum silicate

SALONPAS[®] ARTHRITIS PAIN PAIN RELIEVING PATCH
minty scent
Package not child resistant.
Keep out of reach of children.

Press
Open

Drug Facts

Active ingredients (in each patch)

Menthol 3%..... Topical analgesic
Methyl salicylate 10%(NSAID)*..... Topical analgesic
*nonsteroidal anti-inflammatory drug

Uses

Temporarily relieves mild to moderate aches & pains of muscles & joints associated with:
■ arthritis ■ sprains ■ strains ■ bruises ■ simple backache

Warnings

For external use only

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is small but higher if you:
■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

Do not use

■ on the face or rashes ■ on wounds or damaged skin ■ if allergic to aspirin or other NSAIDs ■ with a heating pad ■ when sweating (such as from exercise or heat) ■ any patch from a pouch that has been open for 14 or more days ■ right before or after heart surgery

Ask a doctor before use if

■ you are allergic to topical products ■ the stomach bleeding warning applies to you ■ you have high blood pressure, heart disease, or kidney disease ■ you are taking a diuretic

When using this product

■ wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water. ■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

■ you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding. ■ rash, itching or skin irritation develops ■ condition worsens ■ symptoms last for more than 3 days ■ symptoms clear up and occur again within a few days ■ stomach pain or upset gets worse or lasts

If pregnant or breast-feeding, ask a doctor before use during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant.

Directions

Adults 18 years and older:

■ clean and dry affected area ■ remove patch from backing film and apply to skin (see illustration) ■ apply one patch to the affected area and leave in place for up to 8 to 12 hours ■ if pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours ■ only use one patch at a time ■ do not use more than 2 patches per day ■ do not use for more than 3 days in a row

Children under 18 years of age:

■ do not use



✂ CUT OPEN HERE ----- CUT OPEN HERE ✂

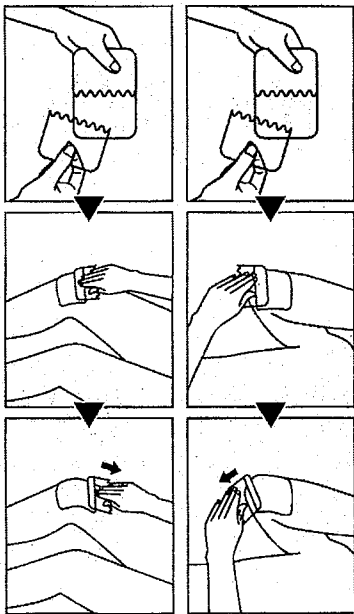
FOLD TWICE AFTER OPENING
Discard unused patches 14 days after opening
FOLD TWICE AFTER OPENING

SALONPAS[®]

ARTHRITIS PAIN

Menthol 3%, Methyl Salicylate 10% PAIN RELIEVING PATCH

Effectiveness confirmed in clinical trial



Questions or comments?
Toll free 1-87-SALONPAS MON-FRI 9AM to 5PM (PST)
www.salonpas.us

✂ DO NOT USE MORE THAN ONE SALONPAS PATCH AT A TIME. SEE DIRECTIONS

Manufactured by Hisamitsu Pharmaceutical Co., Inc. JAPAN SAGA-TOSU Made in Japan
5 PATCHES (2 3/4" X 3 3/8" each)

✂ CUT OPEN HERE ----- CUT OPEN HERE ✂

FOLD TWICE AFTER OPENING
Discard unused patches 14 days after opening
FOLD TWICE AFTER OPENING

SALONPAS ARTHRITIS PAIN PAIN RELIEVING PATCH minty scent

Drug Facts

Active ingredients (in each patch)
Menthol 3% Topical analgesic
Methyl salicylate 10%(NSAID) Topical analgesic
Nonsteroidal anti-inflammatory drug

Uses
Temporarily relieves mild to moderate aches & pains of muscles & joints associated with:
■ arthritis ■ sprains ■ strains ■ bruises ■ simple headache

Warnings

For external use only
Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is small but higher if you:
■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or rofecoxib) ■ are 5 or more seconds drinks every day while using this product ■ take more of it & longer than directed
Do not use or re-use ■ on wounds or damaged skin ■ if allergic to aspirin or other NSAIDs ■ with a healing pad ■ when sweating (such as from exercise or heat) ■ any patch from a pouch that has been open for 14 or more days ■ right before or after heart surgery

Ask a doctor before use if:
■ you are taking a diuretic
■ you have high blood pressure, heart disease, or kidney disease
With other medicines or products
■ Wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water. ■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if:
■ rash, itching or skin irritation develops ■ condition worsens ■ symptoms last for more than 2 days ■ symptoms clear up and occur again within a few days ■ stomach pain or upset gets worse or lasts
If pregnant or breast-feeding, ask a doctor before use during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant.

Directions
Adults 18 years and older:
■ clean and dry affected area ■ remove patch from backing (film and apply to skin (see illustration)) ■ apply one patch to the affected area and leave in place for 8 to 12 hours ■ use one patch at a time ■ do not use more than 2 patches per day ■ do not use for more than 3 days in a row
Children under 18 years of age:
■ do not use

Other information
■ some individuals may not experience pain relief until 15 minutes after applying the patch
■ protect product from excessive moisture ■ store at 20°-25°C (68°-77°F)

Inactive ingredients
aluminum silicate, calcium resin, backing cloth, film adhesive, oil polyisobutylene, polyisobutylene 1,200,000, styrene-isoprene-styrene block copolymer, synthetic aluminum silicate

LOT
EXP
Package not child resistant. Keep out of reach of children.
1208-1T