

Package leaflet: Information for the user

Elastoplast Back Pain 4.8 mg Medicated Plaster

Soft extract of cayenne pepper

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 pharmacist 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 of the 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 weeks.

What is in this leaflet:

1. What Elastoplast Back Pain 4.8 mg Medicated Plaster is and what it is used for
2. What you need to know before you use Elastoplast Back Pain 4.8 mg Medicated Plaster
3. How to use Elastoplast Back Pain 4.8 mg Medicated Plaster
4. Possible side effects
5. How to store Elastoplast Back Pain 4.8 mg Medicated Plaster
6. Contents of the pack and other information

1. What Elastoplast Back Pain 4.8 mg Medicated Plaster is and what it is used for

Elastoplast Back Pain 4.8 mg Medicated Plaster is used externally for the relief of muscle pain, eg. lower back pain of adults and adolescents over the age of 12 years.

2. What you need to know before you use Elastoplast Back Pain 4.8 mg Medicated Plaster

Do not use Elastoplast Back Pain 4.8 mg Medicated Plaster

- if you are allergic to cayenne pepper, to other capsaicinoid sources (e.g. paprika plants) or any of the other ingredients of this medicine (listed in section 6).
- on **broken skin and wounds**.

Warnings and precautions

Talk to your doctor or pharmacist before using Elastoplast Back Pain 4.8 mg Medicated Plaster

- in those more serious cases when your condition is accompanied by **reddening, swelling or a feeling of high temperature of the joints**,
- if you have **ongoing joint trouble**
- **if you have severe back pain** radiating into the legs and/or **associated with neurological syndromes** (e.g. numbness, tingling).

In addition please observe the following:

- The plaster should not be applied **near the eyes, mouth, tongue or lips**.
- It is recommended **not to scratch the application site** to avoid damage to the skin.
- **Avoid application of additional sources of heat** during treatment. Treatment should be discontinued if excessive warmth is experienced.

Children

Because there is no experience available, use of this medicinal product is not recommended in children below the age of 12 years.

Other medicines and Elastoplast Back Pain 4.8 mg Medicated Plaster

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- The plaster is not intended to be applied at the same time as other products [e.g. other rubefacient (agents that redden the skin due to increased blood flow) or pain relieving gels] at the same application site.
- Interactions with other products applied at the same application site may even occur several hours after the plaster has been removed.

Pregnancy and breast-feeding

Do not use the plaster if you are pregnant, planning to be pregnant or breastfeeding without first consulting your doctor.

The active substance of the plaster (soft extract of cayenne pepper) may pass into breast milk.

Driving and using machines

There is no reason to believe that the use of Elastoplast Back Pain 4.8 mg Medicated Plaster will impair the ability to drive or use machines.

Elastoplast Back Pain 4.8 mg Medicated Plaster contains wool fat

This medicinal product contains wool fat (lanoline). Wool fat may cause local skin reactions (e.g. contact dermatitis).

3. How to use Elastoplast Back Pain 4.8 mg Medicated Plaster

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage

A maximum of **1 plaster per day** should be used.

Method of administration

The plaster should only be used on **dry, intact skin**.

Peel off covering paper and apply the plaster over **the painful area**, with the adhesive side to the skin.

The plaster should be left in place for at least 4 and up to 8 hours.

To remove the plaster, raise one corner and carefully pull it off. Hands should be washed with soap and water after touching and handling the plaster.

Any remnants remaining on the skin after detachment of the plaster can be removed with vegetable oil, a moisturising cream or cold water.

There should be an interval of at least 12 hours before a new plaster is applied on the same application area.

Duration of treatment

New plasters should be applied until the pain subsides, if necessary, up to 3 weeks duration. Please consult your doctor if symptoms persist.

If you use more Elastoplast Back Pain 4.8 mg Medicated Plaster than you should

Overdose with this plaster is extremely unlikely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Elastoplast Back Pain 4.8 mg Medicated Plaster this medicine can cause side effects, although not everybody gets them.

The active ingredient of the plaster causes increased blood circulation with marked reddening of the skin and a sensation of warmth. This reaction is part of the normal effect of the preparation and subsides as a rule within a short time after removal of the plaster.

Rare side effects (may affect up to 1 in 1,000 people)

Skin hypersensitivity (allergic) reactions with reddening, itching and blistering may occur at the administration site. If this occurs, the plaster should be removed and treatment should be discontinued.

If during the first few days of treatment a burning sensation or any stinging or itching occurs which is excessive, the plaster should be removed and treatment discontinued.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Elastoplast Back Pain 4.8 mg Medicated Plaster

Keep out of the sight and reach of children.

After removal the plaster should be placed in a plastic bag, which should be sealed securely and be disposed of via household waste. Hands should be washed with soap and water after handling the plaster. Contact with the eyes or mouth/tongue/lips must be avoided.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

After first opening of the package use within 3 months.

6. Contents of the pack and other information

What Elastoplast Back Pain 4.8 mg Medicated Plaster contains

- The active substance is:
Soft extract of cayenne pepper.
Each medicated plaster contains 112 – 167 mg soft extract of cayenne pepper (4-7:1) corresponding to 4.8 mg capsaicinoids, calculated as capsaicin. Extract solvent is ethanol 80% (v/v).
- The other ingredients are:
Liquid glucose; purified water; 2,2'-methylene-bis-(6-tert-butyl-4-methylphenol); 2,2'-(propane-1,2-diyl-diiminodimethyl) diphenol; orris root powder/rice flour mixture; caoutchouc;

poly(butadiene-block-styrene) (76.5:23.5); cis-1,4-polyisoprene; talcum (E553b); beta-pinene homopolymer; poly (2-methylbut-2-ene-co-penta-1,3-diene); glycerol ester of hydrogenated colophony; light liquid paraffin; wool fat; viscose fabric (plaster carrier); paper siliconised on one side (covering paper).

What Elastoplast Back Pain 4.8 mg Medicated Plaster looks like and contents of the pack

Elastoplast Back Pain 4.8 mg Medicated Plaster is a rectangular perforated plaster (18 x 12 cm) with viscose fabric carrier. It is available in a pack with 1 or 2 medicated plasters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Beiersdorf AG
20245 Hamburg
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Hansamedic Wärmepflaster 4,8 mg wirkstoffhaltiges Pflaster Hansamedic Emplâtre Chauffant 4,8 mg emplâtre médicamenteux Hansamedic Warmtepleister 4,8 mg Pleister
Germany	Rheumaplast 4,8 mg wirkstoffhaltiges Pflaster
Greece	ΛΕΟΝΤΟΣ Έμπλαστρο 4,8 mg
Ireland	Elastoplast Back Pain 4.8 mg Medicated Plaster
Luxembourg	Hansamedic Wärmepflaster 4,8 mg wirkstoffhaltiges Pflaster
Portugal	Hansaplast 4,8 mg emplastro medicamentoso
Spain	Hansaterm 4,8 mg apósito adhesivo medicamentoso
United Kingdom	Elastoplast Back Pain 4.8 mg Medicated Plaster

This leaflet was last revised in 02/2014.