

Comfrey Cream

COMFREY ROOT EXTRACT



For the symptomatic treatment of joint pains, sprains, inflammation, and strains associated with restricted joint mobility

Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- This medicine is only for you. Do not give it to anyone else to take. It may harm them, even if their symptoms are the same as yours.
- If you have any further questions, please ask your doctor or pharmacist.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Nature's Best Comfrey Cream is and what it is used for

Nature's Best Comfrey Cream is used on the skin for the treatment of joint pains, sprains, inflammation and strains associated with restricted joint movement. The active ingredient is Comfrey Root Liquid Extract. It has anti-inflammatory (reduces inflammation and swelling) and analgesic (pain relieving) properties.

2. Before you use Nature's Best Comfrey Cream

Some people must not use this cream.

Do not use this cream:

- if you are allergic (hypersensitive) to comfrey root extract, rosemary oil or any of the other ingredients. See 'Other special warnings', and section 6. for the list of ingredients.
- if you are allergic to **peanut** or **soya** - Nature's Best Comfrey Cream contains peanut oil (arachis oil).
- to treat an open wound or on broken or irritated skin.
- if the child is under 12 years of age

You must be especially careful:

- If you often suffer from allergic reactions, you may be more likely to experience an allergic reaction when using this cream. You should discuss this with your doctor before starting to use the cream.
- The cream is for use on the skin only.
- The cream should not be applied to the eyes, mucous membranes (lips, nostrils, ears, anus (back passage)), genitals (private parts).
- Discontinue use of the cream if the skin becomes irritated, red or dry.

If you are not sure if the cream is suitable for you, consult your doctor or pharmacist before using the cream.

Taking other medicines

Always tell your doctor or pharmacist about all the medicines you are using. This includes medicines you have bought yourself as well as those you have been prescribed by your doctor.

Pregnancy and breastfeeding

If you are pregnant or breast feeding, do not use this medicine.

Other special warnings

- The fragrance contains benzyl benzoate which may cause mild irritation to the skin, eyes and mucous membranes which are the lips, nostrils, ears, anus (back passage) and genitals (private parts).
- Nature's Best Comfrey Cream contains parabens (ethyl (E214), propyl (E216), methyl (E218), isobutyl & butyl-4-hydroxybenzoate). These can cause allergic reactions, which may be delayed. It also contains cetostearyl alcohol, which may cause swelling (inflammation) of the skin (contact dermatitis) e.g. red, itchy, scaly skin, where the cream is applied.
- Nature's Best Comfrey Cream contains rosemary oil. This can cause allergic reactions, including difficulty in breathing in sensitized individuals.

Driving and using machinery

Nature's Best Comfrey Cream should not affect your ability to drive or operate machinery.

3. How to use Nature's Best Comfrey Cream

Always use Nature's Best Comfrey Cream exactly as indicated in this leaflet. You should check with your doctor or pharmacist if you are not sure.

If you are using this cream for the first time, you should test on a small area first e.g. your wrist, to make sure there is no reaction. The cream should only be used on skin that is intact and not broken.

For use on the skin only. Wash your hands before and after using the cream.

The usual dose is as follows:

Adults, the elderly and children age 12 years and over:

Apply a thread of cream, 2-6cm in length, to the part of the body to be treated, and massage in carefully. Adjust the amount of cream to be used depending on the size of the joint to be treated and how bad the symptoms are. Repeat this 4 times a day for up to 8 days.

This product is not recommended for use in children under the age of 12 years.

You should not use this cream for longer than 3 weeks.

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If symptoms worsen or persist, a doctor or pharmacist should be consulted.

If your symptoms are accompanied by swelling of the joint, redness or fever, consult your doctor.

If you apply more of the cream than you should:

Wash off any excess cream.

If this cream is accidentally swallowed you should contact a doctor straight away or go to the nearest casualty department as you may need urgent medical attention. Take this medicine and the leaflet with you.

If you forget to use Nature's Best Comfrey Cream:

If you miss applying your cream at the correct time do not worry. Simply carry on with the next application at your usual time. Do not apply the medicine twice to make up for a forgotten dose.

4. Possible side effects

Nature's Best Comfrey Cream is suitable for most people, but, like all medicines it may sometimes cause side effects. Most people find this medicine causes no problems when the right amount is used for the correct length of time (see section 3 above).

However the following side effects may occur:

Nature's Best Comfrey Cream can lead to allergic (hypersensitivity) reactions at the site of treatment. These reactions can cause reddening of the skin and the appearance of nodules and blisters (skin rash), usually with itching.

Skin reactions can occur at the site where the cream is applied because of reactions to some of the individual ingredients. This may cause skin inflammation (contact dermatitis), a painful and burning skin sensation, or dry, irritated skin (eczema).

There may also be generalised hypersensitivity reactions, which may affect:

- the skin (e.g. reddening, itching, hives, rashes not just at the application site, as well as a rapid swelling of the skin of the face, the eyelids and the area around the mouth (angioedema), skin inflammation (contact dermatitis), a painful and burning skin sensation, or dry, irritated skin (eczema)).
- the digestive tract (e.g. abdominal pain, nausea, diarrhoea).
- the eyes (e.g. red, watery, itchy eyes (allergic conjunctivitis)).
- the respiratory tract (e.g. inflammation of the nasal airways (allergic rhinitis), wheezing, difficulty breathing).

The frequency of these side effects occurring is not known.

If you experience any of these side effects, stop using this medicine and tell your doctor as soon as possible. If you notice any unwanted effects, even one not mentioned here, please go and see your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nature's Best Comfrey Cream **Keep out of the sight and reach of children.**

There are no special storage conditions. Store in the original package.

Do not use Nature's Best Comfrey Cream after the expiry date which is printed on the carton and on the tube. The expiry date refers to the last day of that month.

This medicine should be thrown away 1 year after first opening the tube.

Do not use Nature's Best Comfrey Cream if you notice any of the following:

- If the cream colour is different from the colour beige.
- If fluid comes out of the tube.
- If there is a change in the typical smell of the cream.

Medicines should not be thrown away in normal household waste. Return any unused cream to a pharmacist. This will help to protect the environment.

6. Further Information

Ingredients

Each 100 g of cream contains 35g of liquid extract (1:2) from Comfrey root (*Symphytum officinale* L.) Extraction solvent: Ethanol 60% v/v.

The other ingredients are arachis oil (peanut), cetostearyl alcohol, glycerol-1-stearate, sodium laurilsulfate, lavender oil, spruce needle oil, purified water, phenonip (phenoxethanol, parahydroxybenzoates - ethyl (E214), propyl (E216), methyl (E218), isobutyl & butyl-4-hydroxybenzoate), Eumulgin L and sodium hydroxide. Perfume oil R07338 Spezial PH: benzyl acetate, benzyl benzoate, eugenol, heliotropin, hydroxycitronellal, lavender oil, lemon oil, petitgrain oil, rosemary oil, phenylethyl alcohol, linalyl acetate, linalool.

What the medicine looks like

Nature's Best Comfrey Cream is a beige coloured cream. It is packed in 25g, 50g, 100g and 150g aluminium tubes. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer:

Seven Seas Limited, Bedford Cross, Stanwell Road, Feltham Middlesex, TW14 8NX, UK

Manufacturer: Merck KGaA & Co, Werk Spittal, Hoesslgasse 20, 9800 Spittal/Drau, Austria

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If you would like the leaflet in a different format, please contact the marketing authorisation holder at the above address.

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