

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flexagil cream

Comfrey root liquid extract

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Flexagil cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

In this leaflet you will find information about:

1. What Flexagil cream is and what it is used for
2. Before you use Flexagil cream
3. How to use Flexagil cream
4. Possible side effects
5. How to store Flexagil cream
6. Further information

1. WHAT FLEXAGIL CREAM IS AND WHAT IT IS USED FOR

Flexagil cream is a herbal medicinal product for symptomatic relief of local pain conditions of mild to moderate intensity in connection with minor joint injuries of small and middle-size joints.

2. BEFORE YOU USE FLEXAGIL CREAM

Do not use Flexagil cream

- if you are allergic (hypersensitive) to Comfrey, peanuts, soy bean or any of the other ingredients of Flexagil cream.

Take special care with Flexagil cream

- Do not apply Flexagil to or in the surroundings of eyes, mucous membranes or open wounds.

Using other medicines

There is no information available about possible influences of Flexagil on other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

No studies on safety during pregnancy and lactation have been performed, thus the use of Flexagil during pregnancy and lactation can not be recommended.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Important information about some of the ingredients of Flexagil cream

Flexagil cream contains arachis oil (peanut oil). Do not use this medical product if you are allergic to peanut or soya.

Flexagil cream contains butyl parahydroxybenzoate, ethyl parahydroxybenzoate, methyl parahydroxybenzoate and propyl parahydroxybenzoate (parabens) and allergic reactions may occur, even time-delayed.

Flexagil cream contain cetostearyl alcohol and local skin irritation may occur.

Flexagil contains bergamot oil which may increase your UV sensitivity (natural and artificial sunlight).

Flexagil cream contains benzyl benzoate which is mildly irritant to the skin, eyes and mucous membranes.

3. HOW TO USE FLEXAGIL CREAM

Flexagil cream is for topical application.

Adults and adolescents over 12 years of age:

Depending on the size of the part of the body to be treated and the severity of the symptoms; apply a thread of cream of 2 – 6 cm in length 2-4 times daily.

Apply Flexagil cream to the areas of the body to be treated and massage in thoroughly.

If the symptoms persist for more than 2 weeks during the use of Flexagil, a doctor should be consulted.

Flexagil cream is not recommended for use in children below 12 years of age.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flexagil cream can cause side effects, although not everybody gets them.

A few cases of hypersensitivity reactions such as pruritus, eczema, reddening and Quincke oedema (swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath) have been reported. The frequency is not known.

You should stop taking Flexagil and see your doctor immediately if you experience symptoms of angioedema (Quincke oedema), such as

- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

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.

5. HOW TO STORE FLEXAGIL CREAM

Keep out of the reach and sight of children.

Do not use Flexagil cream after the expiry date which is stated on the weld of the tube and on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Flexagil cream contains

The active substance is liquid extract of Comfrey root. Extraction solvent: Ethanol 60 %.

100 g Flexagil cream contains: 35 g of extract from Comfrey root (*Symphytum officinalis* L.), root, corresponding to 4 g dried comfrey root.

The other ingredients are

Water, purified, arachis oil, refined (peanut oil), cetostearyl alcohol, glycerol monostearate (E471), phenoxyethanol, methyl parahydroxybenzoate (E218), butyl parahydroxybenzoate, ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), sodium dodecyl sulphate, Perfume oil Spezial PH 032791 (including bergamot oil and benzyl benzoate), spruce needle oil lavender oil, emulgin L, sodium hydroxide.

What Flexagil cream looks like and contents of the pack

Beige soft cream with characteristic odour.

Available as 50 g and 100 g tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder;

Merck Selbstmedikation GmbH

Roesslerstrasse 96

DE-64293 Darmstadt

Germany

Manufacturer;

Merck KGaA & Co, Spittal/Drau, Austria

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

<{Name of the Member state}> <{Name of the medicinal product}>

This leaflet was last approved in 08/05/2012.