

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Flexagil, cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g Flexagil cream contains:

35 g of extract (as liquid extract) from *Symphytum officinalis* L., radix (Comfrey root), corresponding to 4 g dried comfrey root.

Extraction solvent: Ethanol 60 % v/v.

Excipients: Arachis oil, refined (peanut oil), benzyl benzoate, bergamot oil, butyl parahydroxybenzoate, cetostearyl alcohol, ethyl parahydroxybenzoate (E214), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

Beige soft cream with characteristic odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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.

4.2 Posology and method of administration

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 area of the body to be treated and massage in thoroughly.

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

4.3 Contraindications

Flexagil cream contains arachis oil (peanut oil) and should not be used by persons with allergy to peanut or soya.

Known hypersensitivity to comfrey root or any of the other excipients in Flexagil cream.

4.4 Special warnings and precautions for use

Flexagil, cream is intended for topical use only. The product should not be applied to eyes, mucous membranes or open wounds.

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

Flexagil, cream contains cetostearyl alcohol and local skin irritation may occur.

Flexagil, cream contains bergamot oil which may increase sensitivity to UV light (natural and artificial sunlight).

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

A few cases of hypersensitivity reactions (pruritus, dermatitis, erythema, Quincke oedema) have been reported. The frequency is not known.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: M02A

Pharmacotherapeutic group: Topical products for joint and muscular pain.

The mechanism of action is not known. In limited clinical trials, the active substance in Flexagil, cream has been found to reduce pain due to joint injuries.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

It is known that the herb *Symphytum officinale* contains toxic and carcinogenic pyrrolizidine alkaloids. However, during preparation of the product specific extract these alkaloids are removed. The amount of the

pyrrolizidine alkaloids in the finished product is less than 0.35 ppm, which is not considered to pose a safety concern at recommended dosage.

The product specific extract was non-mutagenic in the Ames test.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

After first opening: 1 year.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aluminium tubes with inner protective coating with a screwcap of polyethylene (HDPE).

50g and 100g

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Merck Selbstmedikation GmbH
Roesslerstrasse 96
DE-64293 Darmstadt
Germany

8. MARKETING AUTHORISATION NUMBER(S)

26601

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 November 2008

10. DATE OF REVISION OF THE TEXT

21 January 2010