

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

WINTOGENO CREAM

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 12.20% w/w Methyl Salicylate PhEur and 2.60% w/w Menthol PhEur

3 PHARMACEUTICAL FORM

A white to off-white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1) As a topical application for the symptomatic relief of muscular pains and stiffness, including backache, fibrositis, lumbago, muscular aches, neuralgia, painful bruises, sciatica, sprains and strains.

4.2. Posology and Method of Administration

Adults (including elderly): The affected area should be bathed in hot water prior to the application of Wintogeno. A small amount of the cream should be massaged into the skin with the palm of the hand until the area is almost dry, using further amounts as necessary. The area should then preferably be covered with a piece of warm dry flannel.

Wintogeno may be applied 2-3 times daily.

Children under 12 years: Not to be used for children under 12 years of age.

For topical application.

4.3. Contra-indications

Known hypersensitivity to salicylates or menthol; broken or inflamed skin; use under occlusive dressings or heating pads. Do not use for children under 12 years of age.

4.4 Special warnings and precautions for use

Use sparingly if aspirin or other salicylates are used concurrently.
The following warnings are also included on the product labelling:
For external use on unbroken skin only.
Do not use under occlusive dressings or heating pads.
Do not use during pregnancy or when breast feeding.
Do not use on the face.
Do not use if seal is broken.
Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6. Pregnancy and Lactation

Do not use during pregnancy or when breast feeding.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8. Undesirable Effects

Skin sensitivity reactions have rarely been reported.

4.9 Overdose

No special requirements are anticipated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Menthol is an essential oil which, when applied to the skin, dilates the blood vessels, causing a sensation of coldness followed by an analgesic effect. Methyl salicylate is a topical salicylate used for the relief of pain in rheumatic conditions.

5.2. Pharmacokinetic Properties

After absorption, menthol is excreted in the urine and bile as a glucuronide. Methyl salicylate is absorbed through the skin.

5.3. Preclinical Safety Data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Also contains cetomacrogol, cetostearyl alcohol, isopropyl myristate, paraffin, E216, E218

6.2. Incompatibilities

None known.

6.3. Shelf Life

Shelf-life

Three years from the date of manufacture.

Shelf-life after dilution/reconstitution

Not applicable.

Shelf-life after first opening

Not applicable.

6.4. Special Precautions for Storage

Store below 25°C.

6.5. Nature and Contents of Container

The product container is a carton containing an aluminium tube with screw cap.

Carton: White backed folding box board printed on white.

Tube: Manufactured from 99.5% pure aluminium; lacquered internally, printed externally on white.

Pack sizes: 45g

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Actavis UK Limited
(Trading style: Actavis)
Whiddon Valley
BARNSTAPLE
N Devon EX32 8NS

8 MARKETING AUTHORISATION NUMBER(S)

PL 0142/0324

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24.9.91

10 DATE OF REVISION OF THE TEXT

30/08/2007