

Package leaflet: information for the user

Calminemed (Flectormed) 140 mg medicated plaster Diclofenac epolamine

1. What Calminemed is and what it is used for

Indicated in adults, adolescents older than 16 years.

Calminemed belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Calminemed is used for the local symptomatic and short term treatment of minor painful conditions affecting joints, muscle, tendon and ligaments.

Children and adolescents below 16 years

Calminemed is not recommended for use in children and adolescents under 16 years

3. How to use Calminemed

Adults and adolescents older than 16 years

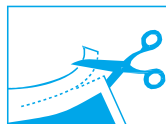
Use one plaster a day for a maximum period of 7 days. If there is no improvement, during the recommended duration of treatment or symptoms worsen, a doctor should be consulted.

This medicated plaster must not be used for children or adolescents aged below 16 years old as no sufficient data on efficacy and safety of this medicine are available.

Method of administration

Instructions for use in case of pack sizes of 2, 5 and 10 medicated plasters:

a) Cut the top of resealable envelope containing medicated plasters following the dotted line.



b) Take out a plaster and carefully close the seal by pressing on the zip closure.



c) Remove the plastic backing protecting the sticky side of medicated plaster.

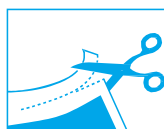


d) Apply the medicated plaster to the skin around the painful or swollen area.



Instructions for use in case of pack size of 7 medicated plasters only:

a) Cut the top of sealed envelope following the dotted line and take out the medicated plaster.



b) Remove the plastic backing protecting the sticky side of medicated plaster.



c) Apply the medicated plaster to the skin around the painful or swollen area.



If necessary, it may be held in place with an open weave gauze bandage, avoiding the use of air-tight dressings or using the elastic net contained in the box.

6. Contents of the pack and other information

What Calminemed contains

The active substance is diclofenac epolamine. Each medicated plaster contains a total of 180 mg of diclofenac epolamine, corresponding to 140 mg diclofenac sodium (1% w/w).

What Calminemed looks like and contents of the pack

Each medicated plaster consists of a white to pale yellow paste impregnated into a dressing with a removable clear plastic backing protecting the adhesive layer.

Box contains 2, 5, 10 medicated plasters in 1 or 2 resealable sachets, while the box of 7 medicated plasters contains 7 sealed sachets with 1 plaster each.

A tubular net is included.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2
26900 Lodi, Italy

Manufacturer

Altergon Italia srl
Zona Industriale ASI
83040 Morra De Sanctis (Av), Italy

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

Belgium	Flalgo/Weavor
Czech Republic	Flalgo
Hungary	Flectorin
Italy	Calminemed
Slovakia	Flectopar
Spain	Flectormed