ÆSCULAPIUS
FARMACEUTICI

BEFORE USE
CAREFULLY READ ALL THE INFORMATION ON THIS INFORMATION LEAFLET

This is an over-the-counter medication that can be used to treat mild and transient conditions that are easily resolved without the need for medical help.
Thus it can be purchased without a prescription but must be used properly to ensure its effectiveness and reduce side effects.

- For more information and advice, consult your pharmacist
- Consult your doctor if the problem is not resolved after a short period of treatment

CLEVIAN 1% GEL

PIROXICAM

COMPOSITION
100 g of 1% gel contains:
Active ingredient: Piroxicam 1 g
Excipients: Methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, polyethylene glycol, ethyl alcohol, Essence of Silverpine, Carboxypolymethylene, ethanolamine, Water.

PHARMACEUTICAL FORM
Clevian gel is supplied in the form of a gel for cutaneous use.
The contents of the package is 50 g.

PHARMACOTHERAPEUTIC CLASS
Non-steroidal anti-inflammatory for cutaneous use.

MARKETING AUTHORISATION HOLDER
AESCULAPIUS FARMACEUTICI S.r.l. - Via Cefalonia, 70 - 25124 Brescia, Italy

MANUFACTURER AND FINAL CONTROLLER
MITIM S.r.l. - Via Cacciamali, 34-36-38 - 25125 Brescia, Italy.

THERAPEUTIC INDICATIONS
Clevian gel is used for painful and inflammatory states of a rheumatic or traumatic nature of joints, muscles, tendons and ligaments.

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CONTRAINDICATIONS
Hypersensitivity to the active ingredient (Piroxicam) or any of the excipients.

Precautions during pregnancy and lactation
As a precautionary measure, unless a physician deems it absolutely necessary, the use of Clevian gel is not recommended during pregnancy and lactation.

INTERACTIONS
There are no known interactions with other drugs.
If you are using other medicines inform your doctor or pharmacist.

SPECIAL PRECAUTIONS
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see Adverse Reactions). In the early stages of therapy, patients appear to be at higher risk; the onset of the reaction occurs in most cases within the first month of treatment. Clevian gel should be discontinued at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity.
The application of topical products, especially if prolonged, may lead to sensitization. In the presence of hypersensitivity reactions treatment should be discontinued and appropriate therapy instituted.

DOSAGE AND ADMINISTRATION
Apply an appropriate amount of gel on the painful area, massaging gently until completely absorbed, repeating the application of two or three times a day.

Caution: Do not exceed recommended doses without medical advice.
Caution: Use only for short periods of treatment.

OVERDOSE
There have been no cases of overdose reported in the literature following the topical cutaneous use of Piroxicam. In the case of accidental ingestion, consult your doctor or go to the nearest hospital.

ADVERSE REACTIONS
Blistering reactions including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis are very rare.
The use of the product especially if prolonged, may lead to sensitization and local irritation. Immediate reactions with urticaria and/or bronchospasm may occur rarely. In this case stop treatment and consult your doctor to institute appropriate therapy.

Compliance with the instructions contained in the information leaflet reduces the risk of side effects.
These side effects are usually transient. In any case, when they develop it is advisable to consult your doctor or pharmacist.
It is important to tell your doctor or pharmacist if you notice any side effects not listed in this leaflet. Ask to fill in the Adverse Reactions report form available in the pharmacy (Form B)

EXPIRY DATE AND STORAGE

Do not use the medicine after the expiry date printed on the package.
Keep out of reach of children.
It is important to always have the information on the medicine available, so keep both the box and information leaflet.
No special precautions for storage are necessary.

REVISION OF THE INFORMATION LEAFLET BY THE *AGENZIA ITALIANA DEL FARMACO* (ITALIAN MEDICINES AGENCY): March 2017