ÆSCULAPIUS
FARMACEUTICI

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICINAL PRODUCT

CLOEL "708 mg/100 ml Oral suspension"

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of suspension contains:
Cloperastine fendizoate 708 mg
(equivalent to cloperastine hydrochloride 400 mg)

Excipients with known effects: methyl p-hydroxybenzoate, propyl p-hydroxybenzoate.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Sedative for coughs.

4.2. Posology and method of administration

Adults: 5 ml three times a day.
Children: Between 2 and 4 years old: 2 ml twice a day.
Between 4 and 7 years old: 3 ml twice a day.
Between 7 and 15 years old: 5 ml twice a day.
A 235 ml measuring cup is included in the package.

4.3. Contraindications

Hypersentivity to the active ingredient or to any of the excipients in this formulation.
It is usually contraindicated during pregnancy (see "Use during pregnancy and lactation)").

4.4. Special warnings and precautions for use

Cloel 708 mg/100 ml Oral suspension contains parabens such as methyl p-hydroxybenzoate and propyl p-hydroxybenzoate that may cause allergic reactions (possibly delayed).
Keep out of the reach and sight of children.
Precautions for use:
Shake well before use.

4.5. Interaction with other medicinal products and other forms of interaction

The simultaneous administration of sedatives or antihistamines, as well as the consumption of alcohol, may increase the undesirable effects of the drug.

4.6. Fertility, pregnancy and lactation

Even though toxicity studies conducted in animals during pregnancy have not shown any teratogenic activity and foetal toxicity, the risk of harmful effects on the foetus after taking cloperastine cannot be excluded. Therefore, as a precaution, do not take CLOEL in the first three months of pregnancy and, in the remaining time of pregnancy, take it only if strictly necessary and under direct medical supervision.

4.7. Effects on ability to drive and use machines

As the product may, even if rarely, cause drowsiness, this should be informed to those people who could drive vehicles or take care of operations that require alertness in good conditions.

4.8. Undesirable effects

Very high doses are evidenced by mouth dryness and light drowsiness that nevertheless quickly disappear by reducing the dose.

Reporting suspected adverse reactions

Reporting suspected adverse reactions seen after the authorisation of the medicinal product is important. It allows continued monitoring of benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reaction via the Italian national reporting system to this address: http://www.agenziafarmaco.gov.it/it/responsabili.

4.9. Overdose

In case of overdose, carry out gastric lavage immediately and keep the patient calm to minimise any sign of central excessive excitement; if necessary, use benzodiazepine.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

- Pharmacotherapeutic Group: sedative for coughs. ATC Code R05DB21.
- Pharmacodynamic effects:

  Cloperastine has a double activity: antitussive activity at central level and papaverine-like activity at peripheral level.
- Mechanism of action:

  At central level, the drug acts selectively by depressing the bulbar centre of cough, at peripheral level, thanks to its papaverine-like and antihistaminic activity, it solves the possible spasm responsible for the outbreak of excess cough.

  At experimental level, the drug activity has been found to be similar to the activity exerted by codeine.

  Cloperastine does not have any narcotic action or local anaesthetic action; it does not depress the breathing centre; and it does not cause significant effects on the cardiovascular system at doses considerably higher than the therapeutic doses.

5.2. Pharmacokinetic properties

Cloperastine is completely absorbed in the gastrointestinal tract, and excretion is mainly biliary within 24 hours after the administration.
The effect of CLOEL is already present 2030 minutes after the administration, and it persists for around 34 hours.

5.3. Preclinical safety data

Preclinical data show there are no risks for human beings on the basis of safety pharmacology conventional studies, toxicity with repeated doses, genotoxicity, carcinogenicity, reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Xantan gum, Polyoxyethylene stearate, Xylitol, Methyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Banana aroma, Deionised water.

6.2. **Incompatibilities**

Not applicable.

6.3. **Shelf life**

5 years.

6.4. **Special precautions for storage**

No special precautions for storage.

6.5. **Nature and contents of container**

Amber-coloured glass bottle containing 200 ml of suspension for oral use

6.6 **Special precautions for disposal and handling**

Medicines no longer used or medical waste should be disposed of in compliance with the local regulations in force.

7. **MARKETING AUTHORISATION HOLDER**

AESCULAPIUS FARMACEUTICI S.r.l. - Via Cefalonia, 70 - 25124 BRESCIA.

8. **MARKETING AUTHORISATION NUMBER**

MA No. 027764012

9. **DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION**

Date of renewal: August 2011

10. **DATE OF REVISION OF THE TEXT**

March 2017