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 and propyl p-hydroxybenzoate.
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Cough suppressant.

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.

Duration of treatment: 7 days. If you do not notice any significant improvement, consult your doctor.

A 2-3-5 ml measuring cup is included in the package.

4.3. Contraindications

Hypersensitivity to the active ingredient or to any of the excipients listed in section 6.1.
Since there are not any studies in the earliest infancy, this medicinal product is contraindicated in children under 2 years of age.
It is usually contraindicated during pregnancy (see the Pregnancy and Lactation section).

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 which may cause allergic reactions (possibly delayed).
Caution is advised when using this product in patients with intraocular hypertension, prostatic hypertrophy or bladder obstruction.
Keep out of the sight and reach of children.
Precautions for use:
Shake well before use.

Relevant information on some excipients
Cloel 708 mg/100 ml Oral suspension contains parabens such as methyl p-hydroxybenzoate and propyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed).
This medicinal product contains less than 1 mmol (23 mg) sodium per 5ml-dose, so it is essentially sodium-free.

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

Although the main side effects of cloperastine are significantly reduced, the drug may interact with both depressants and stimulants of the central nervous system.
Simultaneous intake of sedatives or antihistaminic drugs, as well as consuming alcohol, may increase the side effects of the drug.

4.6. Fertility, pregnancy and lactation

Pregnancy
Although toxicity studies conducted during pregnancy on animals have not shown teratogenic activity and foetal toxicity, the risk of harmful effects on the foetus after the administration of cloperastine cannot be excluded. As a precaution, it is preferable not to use Cloel during pregnancy.

4.7. Effects on ability to drive and use machines

Since the product may, even if rarely, cause drowsiness, people who may drive vehicles or attend operations requiring full alertness should be warned of this effect.

4.8. Undesirable effects

Undesirable effects are tabulated by system-organ class and frequency.
Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥ 1/10,000, <1/1,000); very rare (<1/10,000), and not known (frequency cannot be estimated from the available data).
Unknown frequency:
- Urticaria
- Erythema
- Very high doses are evidenced by mouth dryness and light drowsiness that nevertheless quickly disappear by reducing the dose.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after 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.aifa.gov.it/content/segnalazioni-reazioni-avverse.

4.9. Overdose

In case of overdose, gastric lavage should be performed within a short time; keep patient calm by minimising any signs of central over-excitement; if necessary, use benzodiazepine.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

- Pharmacotherapeutic group: cough suppressant. ATC Code: R05DB21.
- Pharmacodynamic effects:

  Cloperastine has dual antitussive activity at the central and peripheral papaverine-like levels.
- Mechanism of action:

  Centrally, the drug acts electively by depressing the bulbar cough centre; peripherally, due to its papaverine-like and antihistaminic activity, it solves any spasm responsible for the onset of excessive coughing.

  The activity of the drug has been found experimentally to be similar to that of codeine.

  Cloperastine has no narcotic activity, no local anaesthetic activity, does not depress the respiratory centre, and does not cause appreciable effects on the cardiovascular system at doses far in excess of the therapeutic dose in use.

5.2. Pharmacokinetic properties

Absorption

Cloperastine is completely absorbed in the gastrointestinal tract and is mainly excreted in urine within 24 hours after administration.

The effect of CLOEL is present as early as 20-30 minutes after administration and persists for approximately 3-4 hours.

5.3. Preclinical safety data

Preclinical safety data reveal no hazard for humans based on conventional studies of pharmacology safety, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Xanthan gum, macrogol stearate, xylitol, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, banana flavouring, sodium hydroxide, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

5 years.

6.4. Special precautions for storage

No special precautions for storage are required.

6.5. Nature and contents of container

Amber glass bottle containing 200-ml suspension for oral administration

6.6. Special precautions for disposal and other handling

Medicines no longer used or its 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: November 2019

10. DATE OF REVISION OF THE TEXT

October 2022