SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICINAL PRODUCT

PRIVITUSS
708 mg/100 ml Oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of suspension contains:
Active ingredient:
- Levocloperastine fendizoate: 708 mg
  (equivalent to cloperastine hydrochloride: 400 mg)

Excipients with known effects: methyl para-hydroxybenzoate and propyl para-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 2-3-5 ml measuring cup is included in the package.

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

4.3. Contraindications

Hypersensitivity to one of the components of the product or to any of the excipients listed in section 6.1.
Due to the absence of studies in the age group 0 to 2 years of age, the use of the drug in early childhood is not recommended.
It is usually contraindicated during pregnancy.

4.4. Special warnings and precautions for use

Caution is advised when using this product in patients with intraocular hypertension, prostatic hypertrophy or bladder obstruction.

Special precautions for use:
Shake well before use

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

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

Interaction studies have not been conducted.
Although the main side effects of levocloperastine are significantly reduced, the drug may interact with both depressants and stimulants of the central nervous system.
Be aware of the possibility of enhancing the effect of antihistaminic/antiserotonin substances and, to a lesser extent, of papaverine-type myorelaxants.
Consuming alcohol may increase the undesired effects of the medicinal product.

4.6. Fertility, pregnancy and lactation

Pregnancy

Although toxicity studies conducted during pregnancy in animals have not shown teratogenic activity and foetal toxicity, it is prudent not to take the drug during the first months of pregnancy, and in the subsequent period, only it is really and under the direct supervision of your doctor.

Lactation

The drug and/or its metabolites are not known to be excreted in breast milk; since the risk to the infant cannot be excluded, it is preferable to avoid cloperastine during lactation.

4.7. Effects on ability to drive and use machines

At therapeutic doses, Privituss does not induce sedation and does not impair the ability to drive vehicles or operate machinery.

4.8. Undesirable effects

Summary of the safety profile

Gastrointestinal disturbances of a mild, transient nature may occur with Privituss 708 mg/100 ml Oral Suspension.

The list shows the adverse reactions that have been identified for the active ingredient. Frequency: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, < 1/100); rare (≥ 1/10000, < 1/1000); very rare (<1/10000), and not known (frequency cannot be estimated from the available data).
Within each frequency group, undesirable effects are presented in descending order of severity.

System-organ class	**Adverse reactions**			
	Uncommon (≥ 1/1000, < 1/100)	**Rare (≥ 1/10000, < 1/1000)**	**Very rare (< 1/10000)**	**Not known**
Immune system disorders				Hypersensitivity and anaphylactic/anaphylactoid reactions
Skin and subcutaneous tissue disorders				Urticaria, Erythema
Gastrointestinal disorders	Dry mouth			

Clinical trial results showed only rare cases of gastrointestinal disturbances, which were mild, transient and their reasons were not clear.
At therapeutic doses, no signs or symptoms directly associated to a central sedative or excitatory effect have been detected.

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
Drowsiness episodes have occurred in the licensed studies, generally with doses of levocloperastine above the authorised doses.

In case of overdose, normal procedures (gastric lavage, activated charcoal, etc.) should be implemented and signs of over-excitement should be checked.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
ATC Code: R05DB21
- Pharmacotherapeutic Group:
  Sedative for coughs.

Mechanism of action:
Selective inhibitory action on the bulbar cough centre.
Sedative action on peripheral stimuli that induce cough reflex, through inhibiting mediators of the inflammatory process and an antibronchospastic effect.

5.2. Pharmacokinetic properties
The product is absorbed via the intestine and excreted mainly in a degraded form via the urine.
The maximum plasma peak is reached in 90-120 minutes, with subsequent wide distribution in tissue niches, especially in the lungs.

5.3. Preclinical safety data
Preclinical safety data reveal no risk to humans based on conventional pharmacology studies of safety: toxicity after repeated administration, genotoxicity, carcinogenic potential, reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
100 ml of suspension contains:
Xanthan gum, macrogol stearate, xylitol, **methyl p-hydroxybenzoate**, **propyl p-hydroxybenzoate**, banana flavouring, **sodium hydroxide**, deionised water.

6.2. Incompatibilities
None.

6.3. Shelf life
5 years.
Shelf life after first opening the bottle: 6 weeks

6.4. Special precautions for storage
No special precautions for storage are required.

6.5. Nature and contents of container

Yellow glass bottles with child-proof cap, with seal, containing a suspension with a fruity odour and sweet, pleasant taste.

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 - Italy

8. MARKETING AUTHORISATION NUMBER

PRIVITUSS 708mg/100ml Oral suspension– 100 ml-bottle MA No. 029134020
PRIVITUSS 708mg/100ml Oral suspension– 200 ml-bottle MA No. 029134018

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Privituss 708mg/100ml Oral suspension– 100 ml-bottle
June 2013
Privituss 708mg/100ml Oral suspension– 200 ml-bottle
June 1998

10. DATE OF REVISION OF THE TEXT

December 2022