ÆSCULAPIUS FARMACEUTICI

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRIVITUSS 708 mg/100 ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of suspension contain
Active substance:
- L-Cloperastine fendizoate: 708 mg
(equal to cloperastine hydrochloride: 400 mg)

3. PHARMACEUTICAL FORM

Suspension for oral use

4. CLINICAL PARTICULARS

4.1 - Therapeutic indications

Sedative for coughs

4.2 - Posology and method of administration

Adults: 5 ml three times per day.
Children: from 2 to 4 years: 2 ml twice per day;
from 4 to 7 years: 3 ml twice per day;
from 7 to 15 years: 5 ml twice per day.
A measuring cup marked at 2-3-5 ml is provided in the packaging.

4.3 - Contraindications

Hypersensitivity to one of the product components.
Due to a lack of studies from 0 to 2 years age, we recommend against using the medicine on very young infants.
It is generally not recommended during pregnancy.

4.4 - Special warnings and precautions for use

Special warnings:
None.
Special precautions for use:
Shake well before use.

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

Even if the secondary central effects of the levocloperastine are significantly reduced, the medicine may interact with both depressant and stimulant substances of the central nervous system.
The possibility of strengthening the effect of substances with an antihistamine/antiserotoninic action and to a lesser extent of myo-relaxants such as papaverine should be considered.

4.6 - Pregnancy and lactation
Whilst toxicity studies performed during pregnancy on animals have not highlighted any teratogen activity and foetal toxicity, it is prudentially good practice not to take the medicine during the initial months of pregnancy and in the later period only in the case of effective necessity under the direct control of a doctor.

4.7 - Effects on ability to drive and use machines
At the therapeutic doses, the medicine does not induce sedation and does not interfere with the ability to drive vehicles or to use machinery.

4.8 - Undesirable effects
The results of clinical experimentation have only rarely reported cases of mild, transitory cases of gastro-intestinal disturbances, of doubtful attribution.
No signs or symptoms that can be connected to a central effect of the sedative or stimulating types have been found at therapeutic doses.

4.9 - Overdose
In the case of overdose, we recommend performing the normal procedures (gastro lavage, activated carbon, etc.) and to check for any signs of over excitement.

5. PHARMACOLOGICAL PROPERTIES

5.1 - Pharmacodynamic properties
R05DB21
- Pharmaco-therapeutic group:
cough sedative
- Action mechanism:
Selective inhibiting action on the cough bulbar centre.
Sedative action on the peripheral stimuli that induce the cough reflex, by inhibiting the inflammatory process mediators and an anti-bronchospasm effect.

5.2 - Pharmacokinetic properties
The product is absorbed through the intestine and is principally excreted in urine, in a mainly degraded form.
The maximum plasmic peak is reached in 90-120 minutes, with a successive broad distribution in the histic regions and above all in the lungs.

5.3 - Preclinical safety data

The preclinical information demonstrate the absence of risks of toxicity from repeated administration, geno-toxicity, cancerogenic potential and reproductive toxicity in man, on the basis of conventional pharmacological studies.

6. PHARMACEUTICAL PARTICULARS

6.1 - List of excipients

100 ml of suspension contain:
Xanthan gum, polyoxyethylene stearate, Xylitol, Methyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Banana flavour, deionized water.

- **Additional notes:**

  May cause allergic reactions, even delayed ones.

6.2 - Incompatibilities

None.

6.3 - Shelf-life

5 years

6.4 - Special precautions for storage

This medicine does not require any special precaution for storage.

6.5 - Nature and content of the container

Amber-coloured glass bottle with a child-proof stopper and seal, containing a suspension with a fruit flavour and a sweet, pleasant taste.

6.6 - Special precautions for disposal and handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PRIVITUSS 708 mg/100ml oral suspension – 100 ml bottle
M.A. no. 029134020

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

Decree issued by Italian Drug Agency dated June 11th 2013

10. DATE OF REVISION OF THE TEXT

March 2017