

PRIVITUSS

Oral Suspension

COMPOSITION

100 mL of suspension contain:

Active ingredient

L-Cloperastine fenzidoate: 708 mg (equal to 400 mg of Cloperastine hydrochloride).

Excipients

xanthan gum, polyoxyethylene stearate, xylitol, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, banana flavor, sodium hydroxide, deionized water.

PHARMACEUTICAL FORM

Oral suspension, 100 ml bottle.

PHARMACOTHERAPEUTIC GROUP

Cough sedative.

INDICATIONS

Cough sedative.

DOSAGE AND ADMINISTRATION

Adults:

5mL 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.

Duration of treatment: 7 days.

Shake well before use.

A measuring spoon marked at 2-3-5 mL is provided in the pack.

CONTRAINDICATIONS

Hypersensitivity to one of the product components.

Due to the lack of studies in the age group from 0 to 2 years old, it is not recommended to use the drug in early childhood.

It is generally not recommended during pregnancy.

INTERACTIONS

This 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 / anti-serotonin action and to a lesser extent of muscle relaxants such as papaverine should be considered. Consuming alcohol may increase the undesired effects of the medicinal product.

PREGNANCY AND LACTATION

Whilst toxicity studies performed during pregnancy on animals have not highlighted any teratogenic activity and fetal toxicity, it is wise not to take the medicine during the initial months of pregnancy and in the later period except in case of necessity under the direct control of a doctor.

The drug and/or 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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

At therapeutic doses, this medicine does not induce sedation and does not interfere with the ability to drive vehicles or to use machines.

SIDE EFFECTS

The results of clinical experimentation have only rarely reported cases of mild, transient gastrointestinal disturbances. This medicine may cause allergic reactions, even delayed ones.

No signs or symptoms that can be connected to a central effect of the sedative or stimulating types have been found at therapeutic doses.

Observance of the instructions contained in the leaflet can reduce the risk of side effects.

All the side effects are generally transitory. It is important to inform the doctor or the pharmacist of the appearance of any undesirable effect even if not described in the leaflet.

OVERDOSAGE

In the case of overdose, it is recommended to perform the normal procedures (gastric lavage, activated carbon, etc.) and to check for any signs of over excitement.

PHARMACOLOGICAL ACTION

Selective inhibiting action on the bulbar cough center.

Sedative action on the peripheral stimuli that induce the cough reflex, by inhibiting the inflammatory process mediators and an anti-bronchospasm effect.

PHARMACOKINETICS

The product is absorbed through the intestine and is principally excreted in the urine, in a mainly degraded form.

Peak plasma concentrations are reached approximately 90 to 120 minutes after administration, with a wide distribution throughout the body and particularly in the lungs.

CONSERVATION

Store below 30°C.

Protect from light.

Keep out of the reach and sight of children.

Do not use after the expiry date indicated on the packaging.

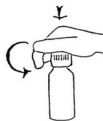
Instructions for opening and closing the bottle

-Opening:

Press the stopper downwards, unscrew to the left.

-Closing:

Screw the stopper deeply to the right.



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Manufactured by
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