

# FLUIBRON®

The active constituent of FLUIBRON® is trans-4[(2-amino-3,5-dibromobenzyl)-amino]cyclohexanol hydrochloride or Ambroxol, a substance identified as the metabolite VIII of bromhexine, the intense mucolytic and mucus-regulating activity of which is well-known and documented.

FLUIBRON®, due to its secretomotor and secretolytic properties, makes easier the excretion of the viscous mucus obstructing the airways, increasing the expectoration and, consequently, improving the respiratory function. Treatment with FLUIBRON® normalizes, both quantitatively and qualitatively, the bronchial mucous secretion, reducing the tussive stimulations permitting the reablement of the natural protective function of the mucous layer covering the surface of the bronchial mucosa.

FLUIBRON® presents a high degree of tolerance and, therefore, it is especially advisable also for prolonged treatments.

## INDICATIONS

Acute and chronic airways affections presenting increased or altered mucus production, particularly acute and chronic bronchitis, asthmatic bronchitis, bronchiectasis. Catarrhal rhinopharyngeal, laryngeal and tracheal affections. Sinusitis, otitis, tubal catarrh.

The employment of the ampuls is advisable also for pre- and postoperative treatment, especially in geriatric surgery and for the prophylaxis of respiratory complications during intensive therapies.

## DOSAGE

### Tablets:

**Adults:** at the start, 1 tablet 3 times a day; in maintenance therapy 1 tablet twice a day.

The tablets intake is advisable after meals and with some liquid.

### Syrup:

**Adults:** at the start 10 ml 3 times a day, then 5 ml 3 times a day.

**Children up to 2 years old:** 2.5 ml twice a day; **from 2 to 5 years:** 2.5 ml 3 times a day; **older than 5:** 5 ml 3 times a day.

At the start of treatment the dosage can be increased or even doubled according to the medical prescription.

10 ml = 30 mg. The enclosed measure bears graduated cuts at 10 ml, 5 ml and 2.5 ml.

### 0.75% Solution:

By inhalation:

**Adults and children older than 5:** 2-3 ml once or twice a day.

**Children younger than 5:** 2 ml, once-twice a day.

The solution can be administered through the normal apparatus for aerosol therapy. It can also be diluted in distilled water (ratio = 1:1).

By oral route:

**Adults:** 2-4 ml (15-30 mg) 3 times a day.

**Children older than 5:** 1-2 ml (7.5-15 mg) twice - 3 times a day.

**Infants and early childhood:** 1/2-1 ml (3.75-7.5 mg) twice - 3 times a day.

1 ml = 7.5 mg.

Dilute the drops in some water, tea, milk or fruit juices.

### Ampuls:

1-2 ampuls, twice - 3 times a day according to the seriousness of the case by intramuscular or intravenous route.

The administration can be carried out also by slow venous infusion, in physiological saline or glucose solution.

On the contrary, it is advisable to avoid the mixture of FLUIBRON® with alkaline solutions. For intensive treatments, the contemporary administration of FLUIBRON® both by parenteral and inhalatory route is particularly advisable.

## CONTRA-INDICATIONS

FLUIBRON® should not be administered to subjects manifesting hypersensitivity to the drug and in those affected with serious hepatic and/or renal alterations.

## WARNINGS

The studies of teratogenesis and of fetal toxicity on animals, did not point out any damaging effect of FLUIBRON® even at high doses. Anyway, it is not advisable, as for all the drugs of recent institution, the employment during the first 3 months of pregnancy, in the further period the drug will be administered only in case of real need under direct medical control.

As in the too deep inspiration of aerosols, a possible irritative cough may appear, during inhalation you should try to inspire and expire normally.

In particularly sensitive patients a pre-heating of the inhaled, at body-temperature, is advisable.

For patients suffering from bronchial asthma it is advisable the use of a bronchial spasmolytic before inhalation.

## PRECAUTION

FLUIBRON® should be carefully administered to patients affected with peptic ulcer.

**Keep out of the reach of children.**

## PACKAGING

Box of 30 tablets, 30 mg.

200 ml bottle of 0.3% syrup.

**The expiration date here reported refers to the product being in integral packaging, correctly stored.**

## DRUG INTERACTIONS

No drug interactions have been reported so far.



CHIESI FARMACEUTICI S.p.A.  
Via Palermo, 26/A - PARMA - ITALY

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