SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MUXOL, oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ambroxol hydrochloride ..... **0.300 g**
Corresponding amount of ambroxol base ..... **0.273 g**
For 100 ml of oral solution.

Excipient(s) with known effect: **Sorbitol**, **methyl parahydroxybenzoate**, **propyl parahydroxybenzoate**.

For the full list of excipients, see section **6.1**.

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of **bronchial secretion disorders** in adults, particularly in acute bronchial conditions and acute episodes of chronic bronchopulmonary diseases.

4.2 Posology and method of administration

Posology

FOR ADULT USE ONLY.

One tablespoon (15 ml) contains **45 mg of ambroxol hydrochloride**.

The usual dose is **90 mg per day**, divided into **2 doses**, i.e. **1 tablespoon twice daily**.

Method of administration

Oral use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- This medicinal product must not be taken by patients with **rare hereditary fructose intolerance**.
- The combination of a bronchial mucoregulator with an antitussive and/or substances that dry bronchial secretions (atropinic agents) is **irrational**.
- Due to the presence of **sorbitol**, this medicinal product may cause **a mild laxative effect**.
- Severe cutaneous adverse reactions (SCARs) such as **erythema multiforme, Stevens–Johnson syndrome (SJS), toxic epidermal necrolysis (TEN / Lyell's syndrome)** and **acute generalized exanthematous pustulosis (AGEP)** have been reported with ambroxol hydrochloride.
  → If signs or symptoms of a **progressive skin rash** (sometimes associated with blisters or

mucosal lesions) occur, ambroxol treatment **must be discontinued immediately**, and medical advice sought.
- This medicinal product contains **parahydroxybenzoates**, which may cause **allergic reactions** (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction
Not applicable.

4.6 Fertility, pregnancy and lactation
Pregnancy

- Animal studies have shown **no teratogenic effects**.
- In the absence of teratogenicity in animals, no malformative effect is expected in humans.
- However, currently there are **insufficient clinical data** to assess potential malformative or fetotoxic risks when ambroxol is used during pregnancy.

→ **As a precaution, ambroxol hydrochloride should preferably not be used during pregnancy.**

Breastfeeding

Use of this product is **not recommended** during breastfeeding.

4.7 Effects on ability to drive and use machines
Not applicable.

4.8 Undesirable effects
Gastrointestinal disorders

Frequency unknown: gastrointestinal symptoms such as **nausea**, **vomiting**, **gastric discomfort**, which usually resolve quickly after dose reduction.

Immune system disorders

Rare: hypersensitivity reactions.
Frequency unknown: anaphylactic reactions, including **anaphylactic shock**, **angioedema**, **pruritus**.

Skin and subcutaneous tissue disorders

Rare: rash, urticaria.
Frequency unknown: severe cutaneous reactions (including **erythema multiforme**, **Stevens–Johnson syndrome**, **toxic epidermal necrolysis**, **acute generalized exanthematous pustulosis**).

→ Treatment must be **discontinued immediately** if such reactions occur.

Nervous system disorders

Frequency unknown: headache, dizziness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after marketing authorisation is important. It enables continuous monitoring of the benefit–risk balance of the medicinal product.

Healthcare professionals should report any suspected adverse event via the national reporting system:

Agence nationale de sécurité du médicament et des produits de santé (ANSM) and the network of Regional Pharmacovigilance Centres — Website: https://signalement.social-sante.gouv.fr/

4.9 Overdose
Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic class: **MUCOLYTICS**
ATC code: **R05CB06**

Ambroxol exhibits **mucokinetic** and **expectorant** properties.
It stimulates bronchial secretion through its action on secretory cells and promotes the production of more fluid, more easily mobilised mucus.
It also **increases ciliary activity**.

5.2 Pharmacokinetic properties
- Ambroxol is **well absorbed orally**.
- Peak plasma concentration is reached in approximately **2 hours**.
- Bioavailability: **~70%**.
- A large volume of distribution indicates significant **extravasal diffusion**.
- Mean elimination half-life: **7.5 hours**.
- Elimination is mainly **urinary**, with two major metabolites excreted as **glucuronide conjugates**.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
- Glycerol
- Sorbitol 70% (crystallisable)
- Methyl parahydroxybenzoate
- Propyl parahydroxybenzoate
- Banana flavour (furfuryl acetate, isoamyl acetate, isobutyl acetate, methyl-3-butenyl acetate, acetoin, amyl butyrate, delta-decalactone, eugenol, piperonal, benzyl propionate, maltol, vanillin, propylene glycol)
- Citric acid monohydrate
- Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years

6.4 Special precautions for storage
No special storage conditions.

6.5 Nature and contents of container
180 ml in a brown glass bottle.

6.6 Special precautions for disposal and handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRES FRILAB
104 Boulevard Auguste Blanqui
75013 Paris
France

8. MARKETING AUTHORISATION NUMBER(S)

• **34009 330 243 4 5**: 180 ml in brown glass bottle.

9. DATE OF FIRST AUTHORISATION / RENEWAL

[To be completed later by the Marketing Authorisation Holder]

10. DATE OF REVISION OF THE TEXT

[To be completed later by the Marketing Authorisation Holder]

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

PRESCRIPTION AND DISPENSING CONDITIONS

Medicinal product not subject to medical prescription.