SEKROL®

SEKROL® syrup
15 mg / 5ml
Bottle of 100 ml

SEKROL® syrup
30 mg / 5ml
Bottle of 150 ml

SEKROL® INDICATIONS

The symptomatic treatment of acute and / or chronic respiratory tract infections where mucus viscosity is increased, secretion is decreased and mucociliary clearance is impaired.

(Secretolytic therapy in bronchopulmonor disease associated with abnormal mucus secretion)

SEKROL®
15 MG/5ML CHILDREN

AGE	Quantity to administer
< 2 years	2,5 ml (1/2 measure) twice daily
2 - 5 years	2,5-5 ml (1/2-1 measure) thrice daily
5 - 12 years	2,5-5 ml (1/2-1 measure) thrice daily
> 12 years	10 -20 ml thrice daily for the first 2-3 days of therapy, 10 ml twice-thrice daily for the maintenance therapy.

SEKROL®
30MG/5ML ADULTS

First 2 or 3 days of treatment
5 to 10 ml 3 times per day

Maintenance treatment 5ml two to three times a day.

3FISEKE 2021

DAFRA PHARMA INTERNATIONAL

Headquarters
Slachthuisstraat 30/7
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Belgium

SEKROL®

ambroxol HCl

EUROPEAN GMP

BREATHE FREELY AND DEEPLY AGAIN
When coughing becomes distressful and uncomfortable

CHILDREN AND ADULTS

The only mucolytic indicated for children under the age of 2

Dafra PHARMA

Setting the Standard

www.dafrapharma.com

SEKROL®

PROPERTY	CLINICAL IMPLICATION
SECRETOLYTIC	Stimulates serous epithelial cells to secrete a watery mucus. The mucus is easier to cough up.
SECRETOMOTOR	Increases the frequency of the activity of the ciliary structures and mucus is evacuated in an active way (restarting the treadmill).
PROMOTE THE PRODUCTION OF SURFACTANT	To facilitate production of a substance that lines the inner surface of the lungs and reduces the surface tension of the liquid film.
INCREASE GAMMAGLOBULINS	Indirect anti-inflammatory action in the tracheobronchial mucosa by increasing a blood plasma protein belonging to the family of immunoglobulins (antibodies).
ANTIOXIDANT ACTION (anti-free radical properties)	Makes oxidation reduce which is increased during infection and which is harmful to lung tissue.
LOCAL ANESTHETIC EFFECT	Reduces irritations that are often present in a productive cough (emollient effect, sore throat).

- **SEKROL®** is the best available product against productive cough and bronchopulmonar congestion (including sore throat)
- **SEKROL®** allows children and adults to breathe freely and deeply again
- **SEKROL®** is the only mucolytic - expectorant indicated for children under the age of 2
- Excellent Dafra Quality
- Affordable price

PRESCRIBING INFORMATION

Pharmacological properties: Ambroxol is the N-desmethyl metabolite of bromhexine which is a mucolytic agent. It has properties that decreases the viscosity and the adhesiveness of the secretions in the respiratory tract. By this way, it facilitates the removal of secretions from the respiratory tract and therefore eases breathing.
Ambroxol eases the mucociliary transport by stimulating the cilias and secretions via the stimulation of serous glands. Thus, the secretion that covers the respiratory mucosa which has an important role in the natural protection, can be restored. Also, ambroxol scavenges the free radicals (antioxidant effect) and decreases the oxidation which is increased in case of infection and harmful for the lung tissue.
It is shown that ambroxol eases the bronchopulmonary penetration of antibiotics which are used in respiratory tract infections, such as ampicillin, amoxicillin and erythromycin. When administered orally, ambroxol is absorbed completely and has a bioavailability of 70-80%. Following oral administration, it reaches the peak plasma concentration in 2 hours. Mean peak plasma concentration after oral administration of 30mg ambroxol is 88.8ng/ml. Elimination half-life is approximately 10 hours. When plasma levels are evaluated during and after maintenance treatment, no accumulation is observed. Ambroxol binds to plasma proteins with a rate of 90%, and is metabolised to inactive forms that are excreted as water soluble conjugates like glucuronides. 80% of ambroxol is excreted unchanged (5-6%) and as metabolites via the kidneys.

Contraindications: Should not be used in patients with a known hypersensivity to ambroxol and/or bromhexine.

Warnings/Precautions: SEKROL® should not be used concomitantly with codeine or other antitussive drugs, because the excretion of mucus and secretions may become harder. Ambroxol should be used with caution in patients with hepatic and renal failure.

Use in pregnancy and lactation: However the animal studies do not indicate any teratogenicity, it is not confirmed by studies on pregnant women. Ambroxol is not recommended to be used during the first trimester of pregnancy.
It is not known whether ambroxol is excreted in maternal milk. Therefore, caution should be exercised when ambroxol is administered to nursing mothers.

Side effects/adverse effects: SEKROL® is generally well tolerated. Gastrointestinal disorders, diarrhea, vomiting, rash, pruritus, weakness, headache and rarely transient serum aminotransferase elevations have been reported.

Drug interactions and other interactions: SEKROL® does not have any interaction between the drugs used in the treatment of chronic bronchitis such as cardiotonic glycosides, corticosteroids, bronchodilatators and diuretics.
It does not change the serum levels of antibiotics like amoxicillin, erythromycin and cefuroxime. They can be used concomitantly.
Atropine and drugs that have antimuscarinic effects such as amantadin, tricyclic antidepressants, haloperidol, antihistaminics and procainamid (except ipratropium) can reduce the ciliary motility and mucociliary clearance which causes accumulation of mucosal secretions.
Antitussive drugs, in high dosages, can inhibit cough reflex. Thus the excretion of mucosal secretion which has increased in amount and mobilised by **SEKROL®**, may become harder.

Overdosage: To date there are no reported cases of overdosage. There is no specific antidote for ambroxol. If an overdose occurs, it should be treated symptomatically (emesis should be induced and the stomach should be emptied through lavage) and supportive measures should be instituted as required.

For the complete SMPC, please visit www.dafrapharma.com