SUMMARY OF PRODUCT CHARACTERISTICS

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1- Product name:

Sekrol® Pediatric Syrup

2- Qualitative and Quantitative Composition:

Each 5 ml contains;
Ambroxol HCl 15 mg

3- Pharmaceutical Form:

Syrup

4- Clinical Information:

4-1-Therapeutic Indication:

It is used in the symptomatic treatment of the acute and/or chronic respiratory tract diseases where mucus viscosity is increased, secretion is decreased and mucociliary clearance is impaired.

4-2-Administration and dosage:

If your physician does not offer any other therapeutic protocol, recommended oral doses for pediatric patients are as follows:

- 0-2 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: 5-10 ml (1-2 measures) twice daily

4-3-Contraindication:

Should not be used in the patients who have hypersensitivity to ambroxol and/or bromhexine.

4-4-Warnings and Precaution:

Sekrol Pediatric Syrup should not be used concomitantly with codeine or other antitussive syrup, because, the excretion of mucus and secretions may become harder. Ambroxol should be used with caution in patients with hepatic and renal failure.

4-5-Drug and other Interactions:

Sekrol Pediatric Syrup does not have any interaction between the drugs used in the treatment of chronic bronchitis such as cardiotonic glycosides, corticosteroids, bronchodilatators, and diuretics.

4-6-Usage in Pregnancy and Lactation:

Pregnancy category: B

However the animal studies do not indicate any teratogenicity, it is not confirmed by the studies on pregnant women; so ambroxol is not recommended to be used within the first trimester of pregnancy.
It is not known whether ambroxol is excreted to maternal milk or not. Therefore, caution should be exercised when ambroxol is administered to nursing mothers.

4.7- Operating machinery or driving a motor vehicle:

4-8-Side Effects:

Sekrol Pediatric Syrup is generally well tolerated. Rarely vertigo, nausea, vomiting, diarrhea and weakness may be seen. All these adverse reactions disappear with the cessation of the administration of the drug.

All these side affects pass with discontinue of the drug.
IN CASE OF AN UNEXPECTED SIDE EFFECT, CONSULT YOUR PHYSICIAN.

4-9-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 stomach should be emptied through lavage) and supportive measures should be instituted as required.

5- Pharmacological Properties:

5-1-Pharmacodynamic Properties:

Ambroxol is the active N-desmethyl metabolite of a mucolytic, bromhexine. It decreases the adhesiveness and viscosity 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 via the stimulation of the cilia and secretion via the stimulation of the serous glands. On the other hand, it stimulates type II pneumocytes and stimulates surfactant secretion. In the samples collected by the bronchoalveolar lavage from the patients that were treated with ambroxol, secretary immunoglobulin (IgA) was found to be increased. Via these mechanisms, secretion production normalizes and secretion film that covers the respiratory tract regains its natural protective function with the ambroxol treatment. In addition, the free radical scavenger property of ambroxol (antioxidant property) decreases the oxidation that increases in the course of infection and harmful for the lung tissue.

It is also shown that ambroxol increases the bronchoalveolar penetration of the antibiotics that are used in the treatment of bronchoalveolar infections such as ampicillin, amoxicillin and erythromycin.

5-2-Pharmacokinetic Properties:

Ambroxol is totally absorbed following the oral administration. Its bioavailability is about 70-80%. It reaches the peak plasma concentration in 2 hours. Following the administration of single dose of 30 mg ambroxol, its peak plasma concentration is found to be 88,8 ng/mL. Its elimination half-life is approximately 10 hours. When plasma levels are evaluated after repeated administrations, no accumulation is observed. Ambroxol binds to plasma proteins with a rate of 90%, and metabolised to inactive metabolites that are excreted as water soluble conjugates like glucuronides. Eighty percent of ambroxol is eliminated via the kidneys as unchanged drug (5-6%) and metabolites.

5-3-Preclinical safety data :

Not applicable

6- Pharmaceutical Particulars :

6.1.- List of excipients :

Sorbitol (70 % crystalline)
Glycerol
Sodium Metabisulphite
Hydroxyethylcellulose
Tartaric Acid
Ethyl alcohol
Benzoic acid
Cherry Flavour
Purified water

6.2- Incompatibilities : There are no incompatibilities between excipient-excipient or excipient – active ingredient or finished product – packaging material.

6.3– Shelf Life :

24 months

6.4- Special precautions for storage :

Store below 30ºC, at room temperature
Keep out of reach of children and in its original package .

6.5- Nature and contents of container :
150 mL amber coloured type III glass bottle is closed well with white LDPE sealed, screwed plastic cap. The bottle is packed with a 2.5-5 mL measuring spoon and a leaflet in a carton box.

6.6- Instructions for use / handling :
None.

6.7- Special precautions for disposal of unused medicinal products

None.

7.- Classification (dispensation status)
Sold with prescription only

8.- Marketing Authorization Holder :

Registration Holder	:	BİLİM İLAÇ SAN. VE TİC. A.Ş. İSTANBUL/TURKEY
Registration Manufacturer	:	BİLİM İLAÇ SAN. VE TİC.A.Ş. GOSB 41480 Gebze/KOCAELI

9.- Provisional Marketing Authorization Number :
177/99

10.- Data of First Authorization / Renewal of Authorization:
03.05.1996

11.- Date of Last Revision of the Text :
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