Technical Information:

1. NAME OF THE MEDICINAL PRODUCT
SalbuHEXAL® Fertiginhalat, 1.5 mg / 2.5 ml solution for a Nebulizer
SalbuHEXAL® Inhalationslösung (inhalation solution), 6 mg / ml solution for a Nebulizer

Active ingredient: Salbutamolsulphate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
SalbuHEXALFertiginhalat
1 Unit Dose container with 2.5 ml for a Nebulizer solution contains 1.5 mg Salbutamol sulphate, equivalent to 1.25 mg Salbutamol.

SalbuHEXALInhalationslösung (Inhalation Solution)
1 ml Nebulizer solution (equivalent to 20 drops) contains 6 mg Salbutamol sulphate, equivalent to 5 mg Salbutamol.

For a full list of other substances, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for a Nebulizer

Clear, colourless solution for a Nebulizer

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
- Symptomatic treatment of diseases associated with reversible obstruction breathing: such as bronchial asthma or chronic obstructive bronchial disease (COPD) with reversible component
- Prevention of diseases caused by exertion or allergic asthma attacks

SalbuHEXAL is used in adults, adolescents and children aged 4-11 years (for use in infants and children under 4 years see section 4.2).

Notes
A longer-term treatment should be symptom-oriented and only in conjunction with an anti-inflammatory continuous therapy.

SalbuHEXAL is only used when lower dose Beta-2-sympathomimetics containing inhaling medicines have been proven in the treatment of respiratory distress as insufficient.

4.2 Posology and method of administration
The dosage depends on the type and severity of the disease.

SalbuHEXALFertiginhalat
For adults, adolescents and children (aged 4-11 years), the following recommendations apply:

1 single dose = 1 Unit dose container with 2.5 ml Nebulizer solution (equivalent to 1.25 mg Salbutamol)

SalbuHEXALInhalationslösung (Inhalation Solution)
For adults, adolescents and children (aged 4-11 years) the following dosage recommendations apply:

**Adult / Adolescent**
1 Single Dose = 5-10 drops (1.25-2.5 mg Salbutamol accordingly)

**Children (aged 4-11 years)**
1 single dose = 1-2 drops per year of age (equivalent to 0.25-0.5 mg Salbutamol per year of age);
Maximum dose: 8 drops (corresponding to 2 mg Salbutamol)

Patients with an electrical aerosol device at home should dilute the prescribed number of drops with 3 ml of sterile saline.

**SalbuHEXAL Fertiginhalat / Inhalationslösung (Inhalation Solution)**
- For **Acute treatment** of sudden bronchospasm and individual case of breathlessness occurrence (dyspnea), 1 single dose is inhaled.
- In **Occurrence of dyspnea**, 1 single dose is inhaled.
- For **targeted prevention** in exertion induced asthma or in a foreseeable contact with Allergen contact, 1 single dose is inhaled 10-15 minutes earlier.
- Case of **acute attack** of dyspnea leads to a rapid relief of breathing in most cases by a single inhalation. If the breathlessness has not noticeably improved after 4 minutes of inhalation on the first single dose, then a further single dose can be inhaled. In cases of emergency breathing, a second one can also be applied. If single dose is not enough, then more single doses may be necessary. In these cases, medical help should be availed immediately.
- If a treatment is to be carried out during days (e.g., acute exacerbation), then the recommended dose:
  1 Single dose 3-4 times per day. They should be accompanied by an anti-inflammatory continuous therapy. The duration between the individual inhalations should be at least 4 hours.

The total daily dose should not exceed 5 single doses of SalbuHEXALFertiginhalat or 50 drops SalbuHEXALInhalationslösung (Inhalation Solution) in adults and adolescents 30 drops SalbuHEXALInhalationslösung (Inhalation Solution) in children (aged 4-11 years) not in excess since a higher dosage may not result in additional benefit, but the probability of occurrence of serious side effects may be increased.

**SalbuHEXAL Inhalationslösung (Inhalation Solution)**
Application of SalbuHEXAL Inhalationslösung (Inhalation Solution) in association with ventilator SalbuHEXAL inhalant can therefore be diluted with sterile saline in the ratio of 1:50 or 1:100 (0.1 mg or 0.05 mg Salbutamol / ml).

The diluted solution can be administered with at electrical aerosol device in conjunction with a positive pressure ventilator or on an appropriate inhalation mask.

In patients with severe bronchospasm, administration of 1-2 mg Salbutamol per hour by intermittent positive pressure ventilation and with oxygen-enriched air is recommended. The amount of air per breath (tidal volume) should be at least 300-400 ml. For this purpose, it may be necessary to increase the inspiratory pressure up to 40 cm water column (pressure head). When the bronchial spasm subsides - generally after about 15 minutes - and the patient's condition improves, the inspiratory pressure should be lowered to 15-20 cm of water column (pressure head).

**Children and adolescents**
For use in adolescents (from 12 years) and children (aged between 4-11 years), the dosages described above apply.
The safety and efficacy of SalbuHEXAL in children from 18 months to under 4 years is comparable with other inhaled Salbutamol formulations. No dose recommendation can be given.

Other dosage forms are potentially more suitable for use in children under 4 years.

The effect of Nebulized Salbutamol is not always guaranteed in infants and young children under 18 months. As a temporary hypoxemia may occur, supplemental oxygen therapy should be considered as appropriate.

**Mode of Administration**
These drugs are intended for inhalation with an electric Nebulizer device.

SalbuHEXAL should **not** be used for injection or ingestion.

Due to the type of construction of many aerosol devices, it is possible that nebulized inhalation solution remains in the immediate vicinity of the device. Inhalation of SalbuHEXAL should therefore take place in well-ventilated areas. This applies especially to the hospital room, in which several patients use aerosol devices simultaneously.

Inhale as per instruction manual.

*SalbuHEXAL Fertiginhalat*
First, the protective film is cut with scissors on the space provided. After removal of the ampoule strip a plastic cartridge is separated and opened by turning.

The solution is ready to use and need not be diluted. The inhalation takes place over a period of about 10 minutes. Any unused remnants of the solution in the inhaler is to be destroyed.

*SalbuHEXAL Inhalationslösung (Inhalation Solution)*
Patients who inhale at home with an electrical aerosol device should dilute the prescribed number of drops with 3 ml of sterile saline.

The pipette should be held vertically when counting the drops. The inhalation takes place over a period of about 15 minutes. Any unused remnants of the inhalation solution in the inhaler is to be destroyed.

*SalbuHEXAL Fertiginhalat / Inhalationslösung (Inhalation Solution)*
Children should take this medicine only under adult supervision and after physician's prescription.

**Duration of administration**
The duration of treatment depends on the type, severity and nature of the disease and has to be decided by the doctor on individual cases.

**Notes**
To prevent misuse, a thorough briefing of the patient on the proper use is to be made. Children should take this medicine only under adult supervision and after physician's prescription.

Excessive use of beta-2-Sympathomimetic inhalants, such as Salbutamol, can be harmful to health (see section 4.4).

**4.3 Contraindications**
Hypersensitivity to the active substance or to the one referred to in Section 6.1 Other Constituents.

4.4 Special Warnings and Special Precautions for Use
SalbuHEXAL Should be used only under strict indication prescription and used with caution in
- Severe heart disease, especially fresh myocardial infarction, coronary heart disease, hypertrophic obstructive cardiomyopathy, tachycardia and arrhythmias tachycardia
- Use of cardiac glycosides
- Severe and untreated hypertension
- Aneurysms
- (Uncontrolled) Hyperthyroidism
- Severe diabetes mellitus
- Pheochromocytoma
- Untreated hypokalaemia.

The asthma treatment should be according to the severity stages. The success of the therapy should be monitored by medical examinations and pulmonary function tests.

Salbutamol should not be used as a single therapy or basic therapy in patients with persistent asthma.

An increasing need of Beta2-Sympathomimetic, such as SalbuHEXAL, is an indication of a worsening of the disease and a reassessment of the treatment may be required.

Despite treatment, if no satisfactory improvement or even a deterioration of the disease is observed, the treatment plan must be covered by the physician and where appropriate, a combination of anti-inflammatory drugs, a dose adjustment of an existing anti-inflammatory therapy or the addition of other drugs may be required.

In acute or rapidly worsening dyspnea, medical help must be sought immediately.

A significant excess, particularly in the prescribed individual dosage in acute attack the daily dose can be dangerous (cardiac arrhythmia, rise in blood pressure), especially in conjunction with electrolyte abnormalities (hypokalemia) and must therefore be avoided because of cardiac side effects.

In the application of Sympathomimetic agents, including Salbutamol, cardiovascular effects may occur. Based on data from the market monitoring, after authorization, and from published literature there are references to the rare occurrence of myocardial ischemia associated with Beta-agonists. Patients with underlying severe heart disease (e.g., ischemic heart disease, arrhythmia or severe heart failure) who received Salbutamol, should be strongly advised to seek medical advice if you notice chest pain or symptoms of worsening heart disease. In the assessment of symptoms: shortness of breath and chest pain requires special consideration since they may be either of respiratory or cardiac origin.

A Hypokalemia can be enhanced in cases of associated medication with xanthine derivatives (e.g., theophylline), corticosteroids, diuretics, digitalis or coexisting hypoxemia. For this reason, the serum potassium levels must be monitored in patients at risk, especially in the acute treatment of severe forms of asthma with high dosage of SalbuHEXAL.
It is repeated that an increased risk of serious complications and deaths in the treatment of bronchial asthma with Beta-Sympathomimetic has been reported, where precautionary measures could have been performed adequately as explained previously.

When inhaled in high dosage SalbuHEXAL blood sugar level may increase. In diabetics, close monitoring of blood sugar level should be carried out.

An acute and progressive deterioration of asthma control in asthma therapy may be life-threatening. If the effectiveness of SalbuHEXAL subsides, the patient should be advised to seek medical help, because the repeated use of SalbuHEXAL should not delay the onset of additional required therapy. Treatment with elevated corticosteroid dosage should be considered.

There have been reports of lactic acidosis in conjunction with high therapeutic doses of short-acting Beta-sympathomimetic, administered intravenously or inhaled through a Nebulizer, mainly in patients who were treated for acute exacerbation of asthma (see section 4.8). An increase in serum lactate levels may lead to dyspnoea and compensatory hyperventilation, which are mistakenly misinterpreted as to indication of a failure of the asthma therapy and can lead to inappropriate intensification of therapy with short-acting beta-sympathomimetic. Therefore, it is recommended to monitor the patient in the development of elevated serum lactate levels and metabolic acidosis subsequently.

To assess disease progression and therapeutic success a daily self-monitoring is important. According to medical instructions, this is done, e.g., by regular measurement of the maximum respiratory burst strength by peak flow meter.

It has been reported in some cases, on the triggering of seizures in patients with glaucoma: narrow-angle glaucoma, which were retreated with a combination of Nebulized Salbutamol and ipratropium bromide or oxtropium bromide. If there is narrow-angle glaucoma, it should therefore be administered with a combined treatment of Salbutamol with anticholinergic with caution and the patient should be referred to an appropriate administration of the medicines so that the inhalant does not come into contact with eyes.

The use of SalbuHEXAL can lead to positive results in doping controls. For doping control purposes improper use of this product SalbuHEXAL can endanger health.

*In addition, for SalbuHEXAL Inhalationslösung (Inhalation Solution)*

Benzalkonium chloride may cause bronchospasm.

**4.5 Interaction with other medicinal products and other forms of interaction**

The simultaneous application of SalbuHEXAL and Beta receptor blockers leads to opposite effect, which is why these drugs should not be prescribed usually together. The administration of Beta-blockers in patients with bronchial asthma carries risk of triggering severe bronchospasm.

In addition, the hypoglycaemic effect of antidiabetic agents may be reduced upon treatment with SalbuHEXAL. However, these are expected only at higher dosage, as they (as tablets or injection / infusion) are common with systemic administration in general.

A reciprocal effect and gain on increased risk of adverse effects are possible with simultaneous administration of SalbuHEXAL and methylxanthines (search as theophylline) or other Sympathomimetic drugs.

An increased risk of adverse effects is possible in simultaneous use of SalbuHEXAL and digital glycosides.
Even substances that in turn enhance Sympathomimetic effects such as L-Dopa, L-thyroin, oxytocin or alcohol can affect cardiovascular regulation influence with Salbutamol.

A SalbuHEXAL associated treatment with substances of the type of ergot alkaloid search: Ergotamine and Salbutamol should only be used with caution, as the mutual influence of vasomotor is difficult to predict individually and as well as vasoconstrictor can lead to dilatatorischen reactions.

The simultaneous use of monoamine oxidase inhibitors and SalbuHEXAL or tricyclic antidepressants can trigger enhanced effect of Salbutamol on the cardiovascular system.

The associated use of procarbazine can cause hypertensive reactions.

When using halogenated anaesthetics: such as halothane, methoxyflurane or enflurane, needs in patients who are treated with SalbuHEXAL are to be reckoned with at increased risk of severe arrhythmia and blood pressure reduction (see Notes).

Hypokalemia can be enhanced in cases of simultaneous medication with xanthine derivatives, steroids or diuretics (see section 4.4).

A Salbutamol-induced hypokalemia may increase susceptibility to digoxin induced arrhythmia.

Notes
If an anesthetic is planned using halogenated anaesthetics, it should be ensured that Salbutamol is not used within 6 hours possibly prior to the beginning of anesthesia.

During high dose therapy with SalbuHEXAL, hypokalaemia can occur. It can also occur with concomitant use of other drugs, ESPECIALLY methylxanthines (e.g., theophylline), corticosteroids, diuretics or digitalis or coexisting hypoxemia exacerbated. A monitoring of serum electrolyte levels is displayed so that, where appropriate, potassium may be supplied.

4.6 Fertility, Pregnancy and lactation

Pregnancy
Salbutamol crosses the placental barrier. For humans, insufficient experience on application exists during pregnancy.

Tachycardia and hypoglycemia in the new-born have been described in the application of Salbutamol as tocolytic. Studies in animals (rats) have shown very high dose reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

SalbuHEXAL should be used during pregnancy, especially during the first 3 months, only if clearly indicated. The same is true for laboratory-inhibiting effect of the application at the end of pregnancy.

Lactation time
Since Salbutamol probably passes into breast milk, use in lactation is recommended only after careful benefit-risk assessment. A risk to the infant cannot be excluded.
4.7 Effects on ability to drive and use machines

By individually occurring different reactions, especially at higher dosage, the ability to actively participate in road traffic or to operate machinery may be impaired. This applies in enhanced measure at baseline and at interaction with alcohol or sedatives and sleeping pills.

4.8 Undesirable effects

In the following list, the adverse reactions by system organ class and absolute frequency (all reported events) are mentioned. By the frequency of possible side effects, the following categories are listed as a base:

Very Often (≥ 1/10)
Frequently (≥ 1/100 to <1/10)
Occasionally (≥ 1 / 1,000 to <1/100)
Rarely (≥ 1 / 10,000 to <1 / 1,000)
Very rare (<1 / 10,000)

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Side Effect</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disorders of Hypersensitivity reaction</td>
<td>including angioedema, itching, urticaria, Bronchospasm, Hypotension and collapse</td>
<td>Very rare</td>
</tr>
<tr>
<td>Metabolism and Disorders of Nutrition</td>
<td>Hypokalemia*</td>
<td>Rarely</td>
</tr>
<tr>
<td>Heart disease</td>
<td>Tremor, headache, Hyperactivity</td>
<td>Rarely</td>
</tr>
<tr>
<td>Disorders of Tremor, headache</td>
<td>Tachycardia, Palpitations, Cardiac arrhythmias, Including auricular fibrillation, supraventricular tachycardia and Extrasystolie, and Extrasystolie, Myocardial Ischemia #</td>
<td>Frequently</td>
</tr>
<tr>
<td>Disorders of Heart disease</td>
<td>Vascular Diseases</td>
<td>Rarely</td>
</tr>
<tr>
<td>Disorders of Respiratory diseases, of</td>
<td>peripheral vasodilatation</td>
<td></td>
</tr>
<tr>
<td>Thoracic and Mediastinal</td>
<td>parahadoxical bronchospasm§</td>
<td>Very rarely</td>
</tr>
<tr>
<td>Disorders of Gastrointestinal:</td>
<td>Irritation of the mouth or Throat</td>
<td>Occasionally</td>
</tr>
<tr>
<td>Musculoskeletal Connective tissue and</td>
<td>Muscle Cramps</td>
<td>Occasionally</td>
</tr>
<tr>
<td>Bone Diseases</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Under the therapy with Beta-2 agonists may potentially lead to a very pronounced hypokalemia.
** It has been very rarely reported of lactic acidosis in patients receiving treatment for acute asthma exacerbation Salbutamol intravenously or nebulized.
# See also section 4.4.
§ As with other inhalation therapy which can be achieved by the application of SalbuHEXAL, a paradoxical Bronchospasm with immediate increase of wheezing occur. This case could be either due to a different formulation or with any other inhaled bronchodilator with fast onset treated. The treatment with SalbuHEXAL should immediately be discontinued, the patient should be examined by a doctor and if necessary an alternative therapy should be started.

Report on suspicions of adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health professionals are encouraged, every suspected case of an adverse reaction to be informed to:

Federal Institute for Pharmaceuticals and Medical Products
Dept.: Pharmacovigilance
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Website: www.bfarm.de

4.9 Overdose

Symptoms of overdose
In case of overdose, the above-mentioned side effects occur very rapidly and possibly to a greater extent in appearance.

Typical symptoms are: Lactic acidosis, tachycardia, palpitations, arrhythmias agitation, insomnia, chest pain and vigorous tremor, especially on hands but on the whole body.

Above all, after oral intoxication gastrointestinal symptoms, including nausea, occur.

Occasionally psychotic reactions have been observed after excessive Salbutamol dosage.

An overdose of albuterol can increasingly lead to shifts of potassium in the intracellular space, with the consequence of hypokalaemia as well as hyperglycaemia, hyperlipidaemia and hyperketonemia.

Treatment in case of overdose
The treatment by beta-Sympathomimetic overdose is primarily symptomatic. Below are rows listed on recommendatory measures?

- In the event that large quantities of the drug be accidentally are swallowed, gastric lavage should be considered; activated charcoal and laxatives may influence the unwanted absorption of Beta-Sympathomimetic slowly.
- The cardiac symptoms can be treated with cardio selective beta-receptor blockers, but this is an increased risk of triggering a bronchospasms in patients with bronchial asthma observed.
- For cardiac Monitoring ECG monitoring is recommended.
- In case of more pronounced reductions in blood pressure, volume substitution (e.g., plasma substitutes) is recommended.

It is to be expected with the development of hypokalaemia that appropriate controls of the electrolyte balance and where appropriate, substitutions are recommended. Note, therefore that there is a possibility of prior treatment with other drugs can cause hypokalaemia, hyperlipidaemia or ketonemia here.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: bronchodilator / Antiasthmatikum / Beta2-Sympathomimetic
ATC code: R03AC02

Salbutamol is a direct-acting Beta Sympathomimetic agent with predominant Beta-2 selectivity; a stimulation of the Beta-1 receptors occurs at higher dosage.

Salbutamol causes a relaxation of the smooth muscle in the bronchi and blood vessels as well as a relaxation of the uterine muscle. Salbutamol inhibits the release of mediators from mast cells.
Furthermore the mechanism of action is not yet clear on the increase in mucociliary clearance detected in the bronchial system.

These effects are mediated via activation of acetylate cyclase, wherein there is an accumulation of cyclic 3', 5'-adenosine monophosphate (c-AMP), which in turn inhibits the contractile elements of the smooth muscle.

Influence on the metabolism of lipids and glucose (lipolysis, glycogenolysis and hyperglycemia) and relative hypokalemia by increasing the K+ acceptance into the skeletal muscle are pharmacological effects that especially come into play at higher dosage.

Salbutamol has a high Bronchoselectivity. Its effects on the heart - such as increasing the contractility, increase in heart rate (positive inotropic and chronotropic effect) - are mainly explained by direct action on Beta-1 receptors and by reflex stimulation due to peripheral vasodilatation.

After inhalation of Salbutamol, the Broncho-dilator effect occurs within a few minutes.

Information on the possibility of a loss efficacy (tachyphylaxis) at long-term use of Salbutamol is contradictory. It seems that such a loss of potency may occur individually. In seeking a case, the combination with glucocorticoids normalizes the reduced responsiveness of the Beta-2 receptors again.

5.2 Pharmacokinetic Properties
Lung and gastrointestinal tract behave differently in the absorption and metabolism of Salbutamol.

After inhalation from a metered dose reach about 10-20% of the Salbutamol in the deeper portions of the bronchi, while the remainder of the dose deposited in the upper part of the respiratory tract and the mouth and is swallowed subsequently.

Because after inhalation, effect on plasma levels mainly comes through the enteral absorption of swallowed share, the serum levels that did not correlate with the pharmacodynamic time response curve. With equipotent oral doses compared to inhaled plasma levels are lower by a factor of 500-1000 and show a delayed time course similar to that after oral administration. The inhaling effect occurs in contrast much faster.

Salbutamol is well absorbed after oral administration and metabolized in the gastrointestinal tract and the liver partially. In plasma, free Salbutamol and metabolite form are present. The free Salbutamol is fully effective, while the metabolites hardly have beta-stimulating properties.

In studies with radiolabeled Salbutamol 64-98% of the administered dose is excreted in urine within 72 hours, 10-12% in the faeces. About 55% of the radioactivity in urine is taken from the sulphate ester which is identified as a major metabolite of Salbutamol in humans. This high rate of excretion shows that Salbutamol is not stored in the body.

The biological half-life of Salbutamol is in the serum following intravenous infusion at steady state for about 6 hours.
Salbutamol crosses the placental barrier.

### 5.3 Preclinical safety data

#### Acute toxicity (LD₅₀)

<table>
<thead>
<tr>
<th>Species</th>
<th>Route of administration</th>
<th>Toxicity (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>&gt; 2,000</td>
</tr>
<tr>
<td>Mouse</td>
<td>IV (tail vein)</td>
<td>&gt; 2,000</td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 2,000</td>
</tr>
<tr>
<td>Rat</td>
<td>IV (tail vein)</td>
<td>&gt; 2,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Route of administration</th>
<th>Toxicity (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>70.5 for ♂</td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>61.5 for ♂</td>
</tr>
</tbody>
</table>

**Chronic toxicity**

The investigations carried out showed no evidence of chronic toxicity. Dogs, rats and mice were orally given doses of maximum 25 mg / kg / day (dog), 50 mg / kg / day (rats and mice) over a period of 12, 30 or 24 months.

**Carcinogenic and mutagenic potential**

Under long-term administration of very high doses in rats, as with other Beta-Sympathomimetic drugs, formation of benign leiomyoma of the Mesovariums occurs. Transferability to humans according to the prevailing opinion is not given.

Mutagenicity studies revealed no evidence of genotoxic potential.

**Reproductive toxicology**

Reproductive toxicity studies in rats have shown no evidence of teratogenic potential.

Embryo or foetotoxic effects (Decreased birth weight, increased mortality) were observed in rats at daily doses of 50 mg / kg. Infertility in male or female rats did not occur up to a dose of 50 mg / kg / day.

Some rabbit foetus malformations of the skull were found after the mother animals had received the drug orally during the entire gestation period a dose of 50 mg / kg / day. From studies in mice conflicting information are known if whether there is a relationship between the subcutaneous dose of Salbutamol and the incidence of fetal cleft palate for these animal species.

For humans regarding the use during pregnancy, there is inadequate experience. Tachycardia and hypoglycemia in the new-born have been described in the application of albuterol as a tocolytic agent.

For use in humans during pregnancy and lactation, see section 4.6.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

**SalbuHEXALFertiginhalat**

- Sodium chloride
- Sulfuric acid 10%
- Purified Water

**SalbuHEXALInhalationslösung (Inhalation Solution)**

- Benzalkonium chloride
- Sulfuric acid 9.81
- % Purified Water
6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years

*Addition, for SalbuHEXALInhalationslösung (Inhalation Solution)*

**Once opened**
After opening the container, the solution for Nebulization can be stored in the tightly sealed original bottle and protected from light for 6 weeks. After that, it should not be used.

6.4 Special Precautions for Storage
Do not store above 25°C.

Keep the container in the outer carton to protect from light.

6.5 Nature and contents of container
*SalbuHEXALFertiginhalat*
Pack with
50-dose containers, each 2.5 ml Nebulizer solution

*SalbuHEXALInhalationslösung (Inhalation Solution)*
Pack with
10 ml, 50 ml (5x10 ml) and 100 ml (10x10 ml) Nebulizer solution

Not all pack sizes may be marketed.

6.6 Special Precautions for disposal
No special requirements.

7. MARKETING AUTHORISATION HOLDER
Hexal AG
Industriestraße 25
83607 Holzkirchen
Phone: (08024) 908-0
Fax: (08024) 908-1290 E-mail: medwiss@hexal.com

8. MARKETING AUTHORISATION NUMBERS
*SalbuHEXALFertiginhalat*
17377.00.00

*SalbuHEXALInhalationslösung (Inhalation Solution)*
17373.00.00

9. DATE OF ISSUE OF AUTHORISATIONS / RENEWAL OF THE AUTHORISATION
04.07.1996 7.02.2005

10. DATE OF REVISION OF THE TEXT
November 2013
11. DOSIMETRY
Mandatory on prescription