1. NAME OF THE MEDICINAL PRODUCT

Fluticasone Elpen 250 microgram per dose inhalation powder, pre-dispensed
Fluticasone Elpen 500 microgram per dose inhalation powder, pre-dispensed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of <Product name> 250 microgram contains 250 microgram of fluticasone propionate.
Each dose of <Product name> 500 microgram contains 500 microgram of fluticasone propionate

Excipient with known effect:
Each dose of <Product name> 250 microgram & 500 microgram contains approximately 14 mg of lactose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Inhalation powder, pre-dispensed.
White powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bronchial asthma in adults.

For the treatment of severe chronic obstructive pulmonary disease, COPD (FEV1 <50% the predicted normal value) in combination with long-acting bronchodilators in patients with a history of recurrent exacerbations

4.2 Posology and method of administration

<Product name> is intended for oral inhalation only.

Patients should be made aware that treatment with <Product name> is prophylactic and that it must be used daily for optimum therapeutic effect, even in the absence of symptoms.

If the patient experiences that the treatment with a short-acting bronchodilator becomes less effective or that more inhalations than usual are needed, he should seek medical attention.

The dose should be titrated until effective control of symptoms is achieved, or reduced to the lowest effective dose according to individual response.

Asthma
Dosage is individual.

Adults 250 or 500 microgram twice daily.

Prescribers should be aware that fluticasone propionate is as effective as other inhaled steroids at approximately half the daily dose expressed in micrograms, e.g. 100 micrograms fluticasone propionate corresponds to approximately 200 micrograms beclomethasone dipropionate (inhalation spray with freons) or budesonide.
A temporary dose increase may become necessary (in adults, up to 2,000 micrograms/day), as an alternative to oral steroids, in patients with severe asthma or in connection with exacerbations. The response to treatment should be monitored and every attempt should be made to determine the lowest effective dose for maintenance treatment.

**COPD**

**Adult:**
500 micrograms twice daily.
Treatment with <Product name> may in some cases replace oral steroid treatment or in many cases, allow the dose of oral steroids to be reduced.

Recovery of suppressed pituitary-adrenocortical function is possible after a period of treatment with <Product name> following withdrawal of oral steroids.

For patients who are dependent on oral steroids, it is recommended that <Product name> is given for 10 days together with the previously used dose of oral steroids. The oral dose is then reduced successively by e.g. 2.5 mg prednisolone or the equivalent per month to the lowest possible level.

In case of acute deterioration, particularly in connection with increased viscosity and mucus plugs, the treatment should be supplemented with a short course of oral steroids.

**Children and adolescents**
<Product Name> is not recommended for children and adolescents below the age of 18 years.

**Special patient groups:**
No dose adjustment is needed in elderly patients or patients with impaired renal function. There is no experience with treatment of patients with impaired hepatic function.

**Handling:**
A dose is loaded by opening the inhaler. Place the inhaler in your mouth and close your lips around the mouthpiece. The dose can now be inhaled. Close the inhaler after use.

**4.3 Contraindications**

Hypersensitivity to fluticasone propionate or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

**Deterioration of disease**

Any bronchoconstriction should be treated prior to start of medication, as the effect might otherwise be weaker than expected.

<Product name> is not intended for treatment of acute asthmatic symptoms, when a fast and short-acting bronchodilator should be used, but for routine long-term treatment. The patient should be instructed to always have reliever medication available to treat acute asthmatic symptoms.

Increased use of short-acting bronchodilators to relieve symptoms indicates deterioration of asthma control. In such cases, the patient's treatment programme should be reassessed and the patient should therefore be advised to seek medical attention.

Sudden and progressive deterioration of asthma control is potentially life-threatening and the patient should be advised to seek medical attention immediately for assessment. Treatment with an increased
dose of corticosteroids should be considered. In patients considered at risk, daily lung function measurements should be instituted.

In some patients, inhalation of fluticasone propionate may cause hoarseness and soars of the throat. Therefore, immediately after inhalation, the mouth should be rinsed with water. If possible, inhalation should be done before meals. For symptomatic cases of sourness, a local antifungal treatment is recommended with continued inhalation treatment with <Product Name>. For respiratory infections, treatment with antibiotics may be required.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses during long periods of treatment. These effects are much less likely to occur with inhalation therapy than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, reduction in bone density and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is therefore important that the dose of an inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained (see section 4.8).

Visual disturbance
Visual disturbances may be reported with systemic and topical use of corticosteroids. If a patient presents with symptoms such as blurred vision or other visual disturbances, he should be considered for referral to an ophthalmologist for evaluation of possible causes. These may include cataracts, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Patients who receive higher than recommended doses should be carefully monitored and the dose gradually reduced.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored.

Due to the risk of impaired adrenocortical function, patients transferring from oral steroid therapy to inhaled fluticasone propionate therapy should be treated with special care, and their adrenocortical function monitored regularly.

Following introduction of treatment with <Product name>, withdrawal of systemic therapy should be gradual. Patients are encouraged to carry a steroid warning card indicating the possible need for supplemental therapy in times of stress.

The possibility of suppressed adrenal function should always be borne in mind in various situations of stress, including surgery and elective stressful situations, particularly in patients who have used high doses for a prolonged period, in order to introduce appropriate corticosteroid treatment (see section 4.9).

Similarly, replacing systemic steroid treatment with inhalation therapy may unmask allergies such as allergic rhinitis or eczema that were previously controlled by the systemic drug. These patients may initially get symptoms of tiredness, headache, muscle and joint pain, and occasionally nausea and vomiting. These are signs of a reduced general steroid effect.

Treatment with <Product name> should not be stopped abruptly in asthma patients due to the risk of exacerbations. Tapering of the dose should be done under medical supervision. Worsening of symptoms can also be seen in patients with COPD when the treatment is discontinued, and this should therefore be done under medical supervision.

<Product name> should be given with caution to patients with active or quiescent pulmonary tuberculosis.

Hyperglycaemia
There have been very rare reports of increases in blood glucose levels (see section 4.8). This should be considered when prescribing to patients with a history of diabetes mellitus.

**Interactions with potent CYP3A4 inhibitors**

There have been reports of clinically significant drug interactions in patients being treated with fluticasone propionate and the potent CYP3A4 inhibitor, ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenocortical suppression. Ritonavir may considerably increase the levels of fluticasone propionate in plasma. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid adverse reactions. The risk of systemic adverse reactions is also increased when fluticasone propionate is combined with other potent CYP3A4 inhibitors (see section 4.5).

**Paradoxical bronchospasm**

Paradoxical bronchospasm may occur with an increase in wheezing immediately after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. Fluticasone propionate therapy should be discontinued immediately, the patient assessed, and, if necessary, alternative therapy instituted.

**Systemic corticoid effects**

Precautions should be taken when transferring patients to <Product name>, particularly when it is suspected that adrenal function is impaired from previous systemic steroid therapy.

Prolonged treatment with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis. Children and adolescents under 16 years of age who receive high doses of fluticasone propionate (usually ≥ 1,000 micrograms per day) are a special group at risk.

In very rare cases, adrenal suppression and acute adrenal crisis have occurred at doses between 500 and 1,000 micrograms of fluticasone propionate. Acute adrenal crisis can be induced by e.g. trauma, surgery, infection or a rapid reduction of the dose. Initial symptoms are usually uncharacteristic and may include anorexia, abdominal pain, weight loss, tiredness, headache, nausea, vomiting, hypotension, decreased level of consciousness, hypoglycaemia and seizures.

Additional oral corticosteroid cover should be considered during periods of stress or elective surgery.

Patients who have previously needed high doses of corticosteroids in emergency situations may also be at risk. A specialist assessment of the degree of impairment of the adrenal function may be needed prior to elective surgery.

**Pneumonia in patients with COPD**

An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. There is some evidence of an increased risk of pneumonia when the steroid dose is increased, but this has not been demonstrated conclusively across all studies.

There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among inhaled corticosteroid products.

Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical signs of such infections overlap with the symptoms of COPD exacerbations.

Risk factors for pneumonia in patients with COPD include current smoking, old age, low body mass index (BMI) and severe COPD.

**Excipients**

Each dose of <Product name> 250 microgram & 500 microgram contains approximately 14 mg of lactose. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.
4.5 Interaction with other medicinal products and other forms of interaction

Under normal circumstances, only low plasma concentrations of inhaled fluticasone propionate are achieved due to extensive first pass metabolism and high systemic clearance mediated by CYP3A4 metabolism in the gut and liver. Hence, clinically significant drug interactions are unlikely.

A drug interaction study in healthy subjects has shown that ritonavir (a highly potent cytochrome CYP3A4 inhibitor) greatly increased fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. There have been reports of clinically significant drug interactions in patients receiving intranasal or inhaled fluticasone propionate together with ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenocortical suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid adverse reactions.

A small study in healthy volunteers showed that the somewhat less potent cytochrome CYP3A4 inhibitor, ketoconazole, increased the exposure by 150% after a single dose of inhaled fluticasone propionate. This resulted in a marked reduction of plasma cortisol compared with fluticasone propionate alone.

Co-treatment with other potent CYP3A inhibitors, such as medicinal products containing itraconazole and cobicistat, is also expected to increase the systemic exposure to fluticasone propionate and the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the potential increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Therefore, caution should be exercised and prolonged treatment with this kind of medicinal product should be avoided, if possible. Studies have also shown that erythromycin produces a negligible increase in systemic exposure to fluticasone propionate without any notable reduction in the level of serum cortisol.

4.6 Fertility, pregnancy and lactation

Fertility
There are no data on human fertility. Animal studies indicate no effects of fluticasone propionate on male or female fertility.

Pregnancy
There are limited data in pregnant women. Administration of fluticasone propionate during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. The lowest-effective dose of fluticasone propionate needed should be used, while taking into consideration the risk of a worsened asthma condition.

Results from a retrospective epidemiological study did not show any increased risk of major congenital malformations following exposure to fluticasone propionate when compared to other inhaled corticosteroids during the first trimester of pregnancy.

Reproductive studies in animals have shown only effects characteristic of glucocorticosteroids at systemic exposures in excess of those seen at the recommended inhaled therapeutic doses.

Breast-feeding
The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration, there was also evidence of fluticasone propionate in the milk. However, plasma levels in patients following inhalation of fluticasone propionate at recommended doses are expected to be low.
The mother’s need for treatment with <Product name> and the benefits of breast-feeding must be weighed against the potential risks to the child.

4.7 Effects on ability to drive and use machines

Specific studies of whether <Product name> has an effect on the ability to drive and use machines have not been conducted. However, it is unlikely that fluticasone propionate has any such effects unless side effect such as blurred vision occurs.

4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

Very common, common and uncommon adverse reactions are taken from clinical trials. The incidence of placebo was not taken into account. Very rare adverse reactions are taken from spontaneously reported cases (post-marketing).

The adverse reactions are presented within each frequency range in descending order of severity.

<table>
<thead>
<tr>
<th>System organ class</th>
<th>Adverse reactions</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>Candidiasis (oropharyngeal)</td>
<td>Very common</td>
</tr>
<tr>
<td></td>
<td>Pneumonia (in COPD patients)</td>
<td>Common</td>
</tr>
<tr>
<td></td>
<td>Candidiasis (oesophageal)</td>
<td>Rare</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Hypersensitivity reactions in the form of:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cutaneous hypersensitivity reactions</td>
<td>Uncommon</td>
</tr>
<tr>
<td></td>
<td>Angioedema (mainly facial and oropharyngeal), respiratory symptoms (dyspnoea and/or bronchospasm). Anaphylactic reactions</td>
<td>Very rare</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>Cushing's syndrome, Cushingoid features, adrenocortical suppression, growth retardation in children and adolescents, reduced bone density</td>
<td>Very rare</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Increased blood glucose levels</td>
<td>Very rare</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>Anxiety, sleep disorders and behavioural changes, including hyperactivity and irritability (predominantly in children)</td>
<td>Very rare</td>
</tr>
<tr>
<td></td>
<td>Depression, aggression (predominantly in children)</td>
<td>Not known</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Throat irritation</td>
<td>Common</td>
</tr>
<tr>
<td></td>
<td>Hoarseness/dysphonia</td>
<td>Common</td>
</tr>
<tr>
<td></td>
<td>Paradoxical bronchospasm</td>
<td>Very rare</td>
</tr>
<tr>
<td></td>
<td>Epistaxis</td>
<td>Not known</td>
</tr>
</tbody>
</table>
### Skin and subcutaneous tissue disorders

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising</td>
<td><em>Common</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye disorders</td>
<td></td>
</tr>
<tr>
<td>Cataracts and glaucoma</td>
<td>Very rare</td>
</tr>
<tr>
<td>Blurred vision (see also section 4.4)</td>
<td>Not known</td>
</tr>
</tbody>
</table>

*Bruising has been reported during 3 years in a COPD study.

Both hoarseness and candidiasis may be alleviated if the patient gargles with water after each use of *Product name*. Symptom-inducing candidiasis can be treated with topical anti-fungal agents during continued treatment with *Product name*.

Any systemic adverse reactions include Cushing's syndrome, Cushingoid features, adrenocortical suppression, growth retardation in children and adolescents, reduced bone density, cataracts and glaucoma (see section 4.4).

Increased blood glucose levels have been reported in very rare cases (see section 4.4).

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

### 4.9 Overdose

Acute overdose: doses of fluticasone propionate well in excess of those recommended and inhaled during a short period of time may lead to temporary suppression of the adrenal function. This does not usually require emergency action since normal adrenal function is recovered within a few days which may be verified by measurements of cortisol in plasma.

Chronic overdose of inhaled fluticasone propionate leads to risk of significant adrenocortical suppression (see section 4.4). It may then be necessary to check the adrenal function. There have been very rare reports of acute adrenal crisis occurring in children exposed to higher than approved doses (typically 1,000 micrograms daily and above) over prolonged periods (several months or years). Observed reactions include hypoglycaemia and sequelae of decreased consciousness and/or convulsions. Situations which could potentially trigger acute adrenal crisis include trauma, surgery, infection or any rapid reduction of the dose. If overdose of fluticasone propionate has occurred, treatment with *Product name* can continue at a suitable dose for symptom control.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for obstructive airway diseases, inhalants (glucocorticoids)  
ATC code: R03BA05

*Product name* contains fluticasone propionate, a glucocorticoid with anti-inflammatory action. Treatment with inhaled *Product name* powder is a prophylactic therapy. Full effect of Flutide is achieved only after 4–7 days of treatment.

Fluticasone propionate is micronised and mixed with lactose in the inhalation powder. Most particles are less than 5 micrometers in diameter. The inhalation method works even at low inspiratory flow.
Clinical COPD studies

TORCH study
TORCH was a 3-year study to assess the effect of treatment with salmeterol/fluticasone propionate 50 micrograms/500 micrograms twice daily, salmeterol Diskus 50 micrograms twice daily, fluticasone propionate (FP) Diskus 500 micrograms twice daily or placebo on all-cause mortality in patients with COPD. COPD patients with a baseline (pre-bronchodilator) value of FEV₁ <60% of predicted normal were randomised to double-blind medication. During the study, patients were permitted usual COPD therapy with the exception of other inhaled corticosteroids, long-acting bronchodilators and long-term systemic corticosteroids. Survival status at 3 years was determined for all patients regardless of withdrawal from study medication. The primary endpoint was a reduction in all cause mortality at 3 years for salmeterol/fluticasone propionate vs. placebo.

<table>
<thead>
<tr>
<th></th>
<th>Placebo N = 1,524</th>
<th>Salmeterol 50 N = 1,521</th>
<th>FP 500 N = 1,534</th>
<th>salmeterol/fluticasone propionate 50/500 N = 1,533</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cause mortality after 3 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of deaths (%)</td>
<td>231 (15.2%)</td>
<td>205 (13.5%)</td>
<td>246 (16.0%)</td>
<td>193 (12.6%)</td>
</tr>
<tr>
<td>Hazard ratio vs. placebo (CI) p value</td>
<td>N/A</td>
<td>0.879 (0.73, 1.06)</td>
<td>1.060 (0.89, 1.27)</td>
<td>0.825 (0.68, 1.00)</td>
</tr>
<tr>
<td>Hazard Ratio salmeterol/fluticasone propionate 50/500 vs. active substances (CI) p value</td>
<td>N/A</td>
<td>0.932 (0.77, 1.13)</td>
<td>0.774 (0.64, 0.93)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

1. Non significant p-value after adjustment for 2 interim analyses on the primary efficacy comparison from a log-rank analysis stratified by smoking status

CI = confidence interval

There was a trend towards improved survival in subjects treated with salmeterol/fluticasone propionate compared with placebo over the 3-year period. However, this did not achieve the statistical significance level p<0.05.

The number of patients who died within 3 years due to COPD-related causes was 6.0% for placebo, 6.1% for salmeterol, 6.9% for FP and 4.7% for salmeterol/fluticasone propionate.

The number of moderate to severe exacerbations per year was significantly reduced with salmeterol/fluticasone propionate as compared with treatment with salmeterol, FP and placebo (mean rate in the salmeterol/fluticasone propionate group 0.85 compared with 0.97 in the salmeterol group, 0.93 in the FP group and 1.13 in the placebo). This corresponds to a reduction in the rate of moderate to severe exacerbations of 25% (95% CI: 19% to 31%; p<0.001) compared with placebo, 12% compared with salmeterol (95% CI: 5% to 19%, p=0.002) and 9% compared with FP (95% CI: 1% to 16%, p=0.024). Salmeterol and FP significantly reduced exacerbation rates compared with placebo by 15% (95% CI: 7% to 22%; p<0.001) and 18% (95% CI: 11% to 24%; p<0.001) respectively.

Health-related quality of life, as measured by the St George's Respiratory Questionnaire (SGRQ), was improved by all active treatments in comparison with placebo. The average improvement over three years for salmeterol/fluticasone propionate compared with placebo was -3.1 units (95% CI: -4.1 to -2.1; p<0.001), compared with salmeterol was -2.2 units (p<0.001) and compared with FP was -1.2 units (p=0.017). A 4-unit decrease is considered as clinically relevant.

The estimated 3-year probability of having pneumonia reported as an adverse reaction was 12.3% for placebo, 13.3% for salmeterol, 18.3% for FP and 19.6% for salmeterol/fluticasone propionate (Hazard
ratio for salmeterol/fluticasone propionate vs. placebo: 1.64, 95% CI: 1.33 to 2.01, p<0.001). No increase of pneumonia-related deaths was seen. The number of deaths during the treatment period where pneumonia was considered to be the primary cause was 7 for placebo, 9 for salmeterol, 13 for FP and 8 for salmeterol/fluticasone propionate. There was no significant difference in probability of bone fracture (5.1% placebo, 5.1% salmeterol, 5.4% FP and 6.3% salmeterol/fluticasone propionate; hazard ratio for salmeterol/fluticasone propionate vs. placebo: 1.22, 95% CI: 0.87 to 1.72, p=0.248).

5.2 Pharmacokinetic properties

The absolute bioavailability after inhalation of fluticasone propionate varies in healthy subjects and is approximately 5–11% of the nominal dose depending on what inhaler device is used. In patients with asthma or COPD a lesser degree of systemic exposure to inhaled fluticasone propionate has been observed.

The systemic absorption occurs mainly through the lungs and is initially rapid then prolonged. The part of the dose which is swallowed after inhalation contributes minimally to systemic exposure. The oral bioavailability is less than 1% due to low aqueous solubility and extensive first pass metabolism. There is a linear increase in systemic exposure with increasing inhaled dose.

The disposition of fluticasone propionate is characterised by high plasma clearance (1,150 ml/min), a large volume of distribution at steady-state (approximately 300 l) and a terminal half-life of approximately 8 hours.

Plasma protein binding is 91%.

Fluticasone propionate is eliminated rapidly from the systemic circulation. This occurs mainly by the drug being metabolised by CYP3A4 enzymes to produce an inactive carboxylic acid metabolite. Other metabolites of unknown structure have also been found in the faeces.

The renal clearance of fluticasone propionate is negligible. Less than 5% of the dose is excreted in the urine, mainly as metabolites. The main part of the dose is excreted in faeces as metabolites and unchanged drug.

5.3 Preclinical safety data

In animal studies, corticosteroids have been shown to induce malformations (cleft palate, skeletal malformations). However, these animal experimental results do not seem to be of any relevance to humans at the recommended doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (may contain milk proteins)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container

A white plastic device containing alu-alu blisters, is packed in a carton box together with the instruction leaflet.

Each carton box contains:
- 30 doses: one inhaler Elpenhaler with 30 alu-alu blisters.
Or
- 60 doses: one inhaler Elpenhaler with 60 alu-alu blisters.
Or
- 120 doses: two inhalers Elpenhaler with 60 alu-alu blisters each.

6.6 Special precautions for disposal and other handling

To ensure proper administration of the drug, the patient should be shown how to use the inhaler by a physician or other health professional.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

INSTRUCTIONS FOR USE OF THE ELPENHALER

Elpenhaler is a device for the intake of powder for inhalation in doses. Each dose is stored in the blister of a specially designed single dose blister strip.

Elpenhaler device is comprised of 3 parts:
- The mouthpiece and its cap (1).
- The surface (2) on which the blister strip is placed (drug supporting surface).
- The storage case (3) which houses the blister strips.

The three parts are connected to each other and can be opened separately.

The drug supporting surface contains:
- An attachment point (2A) where the blister strip is attached.
- A cavity (2B) which accommodates the blister of the strip.
- Two strip guides (2C) which firmly secure the blister strip in the correct position on the drug supporting surface.
The blister strip consists of:
- Two aluminium sheets (4).
- A blister (5), containing the medicine.
- A hole (6).

USE OF THE ELPHENHALER

A. Preparing the device

- Open the storage case by pressing as in the figure, take a strip and close the storage case again.

- Uncover the mouthpiece completely by applying light pressure on the striped area.
- Unlock and push the mouthpiece backwards so as to reveal the drug supporting surface.
- Hold the blister strip with its shiny surface upwards, so as to see the blue line, as shown by the arrow in the figure. The labeled surface of the strip should face downwards.
- Place the hole of the strip on the attachment point of the drug supporting surface. By applying light pressure make sure that the strip is securely attached on the attachment point.
- The blister of the strip will fit in the cavity of the drug supporting surface and the guides will secure the strip in the correct position.
- Close the mouthpiece and pull away horizontally the embossed protruding end of the strip to be detached.
- The dose is now ready to be inhaled.

B. Inhalation of the dose

Hold the device away from your mouth. Exhale completely. Be careful not to exhale on the mouthpiece of the device. Bring Elpenhaler to your mouth and place your lips tightly around the mouthpiece.
- Breathe in slowly and deeply through your mouth (and not through your nose) until your lungs are full.
- Hold in your breath approximately 5 seconds or as long as you comfortably can and at the same time remove the device from your mouth.
- Exhale and continue to breathe normally.

- Open the mouthpiece.
- You will notice that you have inhaled all the powder and that the blister of the strip is empty.
- Remove the empty strip and proceed to step C.

C. Cleaning the device
- Following each use, wipe the mouthpiece and the drug supporting surface with a dry cloth or dry paper tissue. Do not use water to clean the device.
- Close the mouthpiece and its cap.

7. MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed nationally>

10. DATE OF REVISION OF THE TEXT

<To be completed nationally>  2019-07-15