Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Salmeterol Neolab 25 micrograms per metered dose pressurised inhalation suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose (ex-valve) contains 25 micrograms salmeterol (as xinafoate). This is equivalent to a delivered dose (ex-actuator) of 21 micrograms salmeterol (as xinafoate).

Excipient(s):
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension.

Pressurised aluminium canister containing a white suspension sealed with a metering valve, with a mid-green polypropylene actuator and a pale green polypropylene dust cap.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Regular symptomatic add-on treatment of reversible airways obstruction in patients with asthma, including those with nocturnal asthma, who are inadequately controlled on inhaled corticosteroids in accordance with current treatment guidelines.

Treatment of chronic obstructive pulmonary disease (COPD).

Prevention of exercise-induced asthma.

4.2 Posology and method of administration

For inhalation use .

Salmeterol Neolab 25 micrograms should be used regularly. The full benefits of treatment will be apparent after several doses of the medicinal product. As there may be adverse reactions associated with excessive dosing with this class of medicinal product, the dosage or frequency of administration should only be increased on medical advice.

Recommended Doses:
Asthma

Adults and adolescents 12 years and older:

Two actuations of 25 micrograms salmeterol twice daily.

In asthma patients with more severe airways obstruction up to four inhalations of 25 micrograms of salmeterol twice daily may be of benefit.

Children below twelve years of age:

The safety and efficacy of Salmeterol Neolab 25 micrograms have not been demonstrated in children. The refore Salmeterol Neolab 25 micrograms should not be used in children below twelve years of age.

COPD

Adults:

Two actuations of 25 micrograms salmeterol twice daily.

Children:

There is no relevant indication for use of Salmeterol Neolab 25 micrograms in children.

Special patient groups:

There is no need to adjust the dose in elderly patients or in those with renal impairment. There are no data available on the use of salmeterol in patients with hepatic impairment. **INSTRUCTIONS FOR USE :**
Patients should be carefully instructed in the proper use of their inhaler (see Patient Information Leaflet).

1. Patients should remove the mouthpiece cover by gently squeezing the sides of the cover.

2. Patients should check inside and outside of the inhaler including the mouthpiece for the presence of loose objects and to see that it is clean.

3. Patients should shake the inhaler well, before use to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed. Before using for the first time patients should release two actuations into the air to make sure that it works. After cleaning or if the inhaler has not been used for a week patients should release one actuation into the air .

4. In a sitting or standing position, patients should hold the inhaler upright between fingers and thumb with their thumb on the base, below the mouthpiece .

5. Patients should breathe out as far as is comfortable and then place the mouthpiece in their mouth between their teeth and close their lips around it. Patients should be instructed not to bite the mouthpiece .

6. Just after starting to breathe in through their mouth patients should press down on the top of the inhaler to releases almeterol while still breathing in steadily and deeply.

7. While holding their breath, patients should take the inhaler from their mouth and take their finger from the top of the inhaler. They should continue holding their breath for as long as is comfortable.

8. If patients are going to take a further actuation, they should keep the inhaler up right and wait about half a minute before repeating steps 2 to 10.

9. After use patients should always replace the mouthpiece cover to keep out dust and fluff.

10. The mouthpiece cover isreplaced by firmly pushing and snapping the cap into position.

Important:

Patients should not rush stages 5, 6 and 7. It is important that they start to breathe in as slowly as possible just before opprating their inhaler.

Patients should practise in front of a mirror for the first few times. If they see “mist” coming from the top of their inhaler or the sides of the mouth they should start again from stage 2.

People with weak hands may find it easier to hold the inhaler with both hands. Put the two fore fingers on top of the inhaler and both thumbs on the base be low the mouthpiece .

Salmeterol Neolab 25 micrograms should be used with a Volumatic spacer device by patients who find it difficult to synchronise aerosol actuation with inspiration of breath, which is often the case for children and the elderly.

The patient should be referred to the Volumatic instruction leaflet provided with the spacer device, for full details on its correct use.

If their inhaler has been exposed to low temperatures, the patient should take the metal canister out of the plastic case and warm it in their hands for a few minutes. Following warming, one actuation should be released into the air prior to use.

Cleaning the inhaler:

The inhaler should be cleaned at least once a week by:
1. Removing the mouthpiece cover.
2. The canister must not bere moved from the plastic casing.
3. Wiping the inside and outside of the mouthpiece and the plastic holder with a dry cloth or tissue .
4. Firing one spray to waste before next use .
5. Replacing the mouthpiece cover.

PATIENTS MUST NOT PUT THE METAL CANISTER INTO WATER .

4.3 Contraindications

Salmeterol Neolab 25 micrograms is contraindicated in patients with hypersensitivity to salmeterol xinafoate or to any of the excipients (See Section 6.1).

Salmeterol Neolab 25 micrograms contains soya lecithin and is contraindicated in patients who have peanut or soya allergies.

4.4 Special warnings and precautions for use

The management of asthma should normally follow a stepwise programme and patient response should be monitored clinically and by lung function tests.
Salmeterol should not be used (and is not sufficient) as the first treatment for asthma.

Salmeterol is not a replacement for oral or inhaled corticosteroids. Its use is complementary to them. Patients must be warned not to stop steroid therapy and not to reduce it without medical advice even if they feel better on salmeterol.
Salmeterol should not be used to treat acute asthma symptoms for which a fast and short-acting inhaled bronchodilator is required. Patients should be advised to have their medicinal product to be used for the relief of acute asthma symptoms available at all times.
Increasing use of short-acting bronchodilators to relieve asthma symptoms indicates deterioration of asthma control.
The patient should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective or more inhalations than usual are required. In this situation the patient should be assessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid).
Severe exacerbations of asthma must be treated in the normal way.
Although salmeterol may be introduced as add-on therapy when inhaled corticosteroids do not provide adequate control of asthma symptoms, patients should not be initiated on salmeterol during an acute severe asthma exacerbation, or if they have significantly worsening or acutely deteriorating asthma.

Serious asthma-related adverse events and exacerbations may occur during treatment with salmeterol. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation on salmeterol.
Sudden and progressive deterioration in control of asthma is potentially life-threatening and the patient should undergo urgent medical assessment. Consideration should be given to increasing corticosteroid therapy. Under these circumstances daily peak flow monitoring may be advisable. For maintenance treatment of asthma salmeterol should be given in combination with inhaled or oral corticosteroids. Long-acting bronchodilators should not be the only or the main treatment in maintenance asthma therapy (see Section 4.1).
Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of salmeterol.
Regular review of patients as treatment is stepped down is important. The lowest effective dose of salmeterol should be used.
Paradoxical bronchospasm

As with other inhalational therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing and fall in expiratory flow rate (PEFR) after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator.
Salmeterol therapy should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted (see section 4.8).
The pharmacological side effects of beta-2 agonist treatment, such as tremor, subjective palpitations and headache have been reported, but tend to be transient and reduce with regular therapy (see section 4.8).

Thyrotoxicosis

Salmeterol should be administered with caution in patients with thyrotoxicosis. Blood glucose levels
There have been very rare reports of increases in blood glucose levels (see section 4.8) and this should be considered when prescribing to patients with a history of diabetes mellitus.

Cardiovascular effects

Cardiovascular effects such as increases in systolic blood pressure and heart rate may occasionally be seen with all sympathomimetic drugs, especially at higher than therapeutic doses. For this reason, salmeterol should be used with caution in patients with pre-existing cardiovascular disease.

Hypokalaemia

Potentially serious hypokalaemia may result from beta-2 agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics. Serum potassium levels should be monitored in such situations.

Respiratory-related events

Data from a large clinical trial (the Salmeterol Multi-Center Asthma Research Trial, SMART) suggested African-American patients were at increased risk of serious respiratory-related events or deaths when using salmeterol compared with placebo (see section 5.1). It is not known if this was due to pharmacogenetic or other factors. Patients of black African or Afro-Caribbean ancestry should therefore be asked to continue treatment but to seek medical advice if asthma symptoms remained uncontrolled or worsen whilst using salmeterol.

Ketoconazole

Concomitant use of systemic ketoconazole significantly increases systemic exposure to salmeterol. This may lead to an increase in the incidence of systemic effects (e.g. prolongation in the QTc interval and palpitations). Concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors should therefore be avoided unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment (see section 4.5).

Inhaler technique

Patients should be instructed in the proper use of their inhaler and their technique checked to ensure optimum delivery of the inhaled medicinal drug to the lungs.

As systemic absorption is largely through the lungs, the use of a spacer plus metered dose inhaler may vary the delivery to the lungs. It should be noted that this could potentially lead to an increase in the risk of systemic adverse effects so that dose adjustment may be necessary. However, a pharmacokinetic study has been undertaken comparing Salmeterol Neolab 25 micrograms and another marketed salmeterol CFC-free pressurised metered dose inhaler each delivered through the Volumatic spacer device. The results confirm comparable systemic and pulmonary absorption for both products.

4.5 Interaction with other medicinal products and other forms of interactions

Beta adrenergic blockers may weaken or antagonise the effect of salmeterol. Both non-selective and selective _ blockers should be avoided in patients with asthma unless there are compelling reasons for their use.
Potentially serious hypokalaemia may result from _2 agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics.
Potent CYP3A4 inhibitors

Co-administration of ketoconazole (400 mg orally once daily) and salmeterol (50 µg inhaled twice daily) in 15 healthy subjects for 7 days resulted in a significant increase in plasma salmeterol exposure (1.4-fold Cmax and 15-fold AUC). This may lead to an increase in the incidence of other systemic effects of salmeterol treatment (e.g. prolongation of QTc interval and palpitations) compared with salmeterol or ketoconazole treatment alone (see Section 4.4).

Clinically significant effects were not seen on blood pressure, heart rate, blood glucose and blood potassium levels. Co-administration with ketoconazole did not increase the elimination half-life of salmeterol or increase salmeterol accumulation with repeat dosing.
The concomitant administration of ketoconazole should be avoided, unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment. There is likely to be a similar risk of interaction with other potent CYP3A4 inhibitors (e.g. itraconazole, telithromycin, ritonavir).
Moderate CYP 3A4 inhibitors

Co-administration of erythromycin (500mg orally three times a day) and salmeterol (50 µg inhaled twice daily) in 15 healthy subjects for 6 days resulted in a small but non-statistically significant increase in salmeterol exposure (1.4 fold Cmax and 1.2-fold AUC). Co-administration with erythromycin was not associated with any serious adverse effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

A moderate amount of clinical data on pregnant women (between 300 to 1000 pregnancy outcomes) indicates no malformative or fero/neonatal toxicity of salmeterol.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity with the exception of evidence of some harmful effects on the fetus at very high dose levels (see section 5.3).

As a precautionary measure, it is preferable to avoid the use of salmeterol during pregnancy.

Breast-feeding
Available pharmacodynamic/toxicological data in animals have shown excretion of salmeterol in milk. A risk to the suckling child cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from salmeterol therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Studies of HFA 134a revealed no effects on the reproductive performance and lactation of adult or two successive generations of rats or on the fetal development of rats or rabbits.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Based on the pharmacodynamic profile of salmeterol and reported adverse effects there is no or negligible influence of salmeterol on the ability to drive and use machines.

4.8 Undesirable effects

Adverse effects are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to < 1/10), uncommon (≥1/1000 to < 1/100), rare (≥ 1/10,000 to < 1/1000) and very rare (< 1/10,000), including isolated reports.
Common and uncommon events were generally determined from clinical trial data. The incidence on placebo was not taken into account. Very rare events are generally determined from post-marketing spontaneous data.
The following frequencies are estimated at the standard dose of 50 µg twice daily. Frequencies at the higher dose of 100 µg twice daily have also been taken to account where appropriate.

Immune system disorders:
Hypersensitivity reactions with the following manifestations:
Uncommon: rash (itching and redness)
Very rare: anaphylactic reactions including oedema andangioedema, bronchospasm and anaphylactic shock

Metabolism and nutrition disorders:
Rare: hypokalaemia
Very rare: hyperglycaemia

Cardiac disorders:
Common: palpitations (see section 4.4)
Uncommon: tachycardia
Very rare: cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles)

Respiratory, thoracic and mediastinal disorders:
Very rare: oropharyngeal irritation
paradoxical bronchospasm (see section 4.4)

Gastrointestinal disorders:
Very rare: nausea

Musculoskeletal, connective tissue and bone disorders:
Common: muscle cramps
Very rare: arthralgia

General disorders and administration site conditions:
Very rare: non-specific chest pain

The pharmacological side effects of beta-2-agonist treatment, such as tremor, headache and palpitations have been reported, but tend to be transient and to reduce with regular therapy. Tremor and tachycardia occur more commonly when administered at doses higher than 50 µg twice daily.
As with other inhalational therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing and fall in expiratory flow rate (PEFR) after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. Salmeterol therapy should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted (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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms

The signs and symptoms of a salmeterol overdose are typical of beta-adrenergic stimulation including: dizziness, increases in systolic blood pressure, tremor, headache and tachycardia.

Additionally, hypokalaemia can occur and therefore serum potassium levels should be monitored. Potassium replacement should be considered.

Management

If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

The preferred antidotes are cardioselective β blocking agents, which should be used with extreme caution in patients with a history of bronchospasm.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Selective beta-2- adrenoceptor agonists

ATC code: R03AC12

Salmeterol is a selective long-acting (12 hour) beta-2-adrenoceptor agonist with a long side chain which binds to the exo-site of the receptor.

These pharmacological properties of salmeterol offer more effective protection against histamine-induced bronchoconstriction and produce a longer duration of bronchodilation, lasting for at least 12 hours, than recommended doses of conventional short-acting β2 agonists. In man salmeterol inhibits the early and late phase response to inhaled allergen; the latter persisting for over 30 hours after a single dose when the bronchodilator effect is no longer evident.

Single dosing with salmeterol attenuates bronchial hyper-responsiveness. These properties indicate that salmeterol has additional non-bronchodilator activity, but the full clinical significance is not yet clear. The mechanism is different from the anti-inflammatory effect of corticosteroids which should not be stopped or reduced when salmeterol is prescribed.

Salmeterol has been studied in the treatment of conditions associated with COPD, and has been shown to improve symptoms, pulmonary function and quality of life.

Asthma Clinical Trials

The Salmeterol Multi-center Asthma Research Trial (SMART)

SMART was a multi-centre, randomised, double blind, placebo-controlled, parallel group 28- week study in the US which randomised 13,176 patients to salmeterol (50 µg twice daily) and 13,179 patients to placebo in addition to the patients' usual asthma therapy. Patients were enrolled if ≥12 years of age, with asthma and if currently using asthma medication (but not a long-acting β2 agonist - LABA). Baseline inhaled corticosteroid (ICS) use at study entry was recorded, but not required in the study. The primary endpoint in SMART was the combined number of respiratory-related deaths and respiratory-related life-threatening experiences.

Key findings from SMART: primary endpoint

Patient group	Number of primary endpoint events /number of patients		Relative Risk (95% confidence intervals)
	salmeterol	placebo	
All patients	50/13,176	36/13,179	1.40 (0.91, 2.14)
Patients using inhaledcorticosteroids	23/6,127	19/6,138	1.21 (0.66, 2.23)
Patients not using inhaled corticosteroids	27/7,049	17/7,041	1.60 (0.87, 2.93)
African-American patients	**20/2,366**	**5/2,319**	**4.10 (1.54, 10.90)**

(Risk in bold is statistically significant at the 95% level.)

Key findings from SMART by inhaled steroid use at baseline: secondary endpoints

	Number of secondary endpoint events /number of patients		Relative Risk (95% confidence intervals)
	salmeterol	placebo	
Respiratory -related death			
Patients using inhaled corticosteroids	10/6127	5/6138	2.01 (0.69, 5.86)
Patients not using inhaled corticosteroids	14/7049	6/7041	2.28 (0.88, 5.94)
Combined asthma-related death or life-threatening experience			

Patients using inhaled corticosteroids	16/6127	13/6138	1.24 (0.60, 2.58)
Patients not using inhaled corticosteroids	**21/7049**	**9/7041**	**2.39 (1.10, 5.22)**
Asthma-related death			
Patients using inhaled corticosteroids	4/6127	3/6138	1.35 (0.30, 6.04)
Patients not using inhaled corticosteroids	9/7049	0/7041	*

(*=could not be calculated because of no events in placebo group). Risk in bold figures is statistically significant at the 95% level. The secondary endpoints in the table above reached statistical significance in the whole population.) The secondary endpoints of combined all-cause death or life-threatening experience, all cause death or all cause hospitalisation did not reach statistical significance in the whole population.

COPD clinical trials

TORCH study

TORCH was a 3-year study to assess the effect of treatment with a salmeterol/fluticasone propionate dry powder (SFP) 50/500 µg combination bd, salmeterol dry powder 50 µg bd, fluticasone propionate (FP) dry powder 500 µg bd or placebo on all-cause mortality in patients with COPD. COPD patients with a baseline (pre-bronchodilator) 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 reduction in all cause mortality at 3 years for SFP vs Placebo.

	Placebo N = 1524	**Salmeterol 50 N = 1521**	**FP 500 N = 1534**	**SFP 50/500 N = 1533**
All cause mortality at 3 years				
Number of deaths (%)	231 (15.2%)	205 (13.5%)	246 (16.0%)	193 (12.6%)
Hazard Ratio vs Placebo (CIs) p value	N/A	0.879 (0.73, 1.06) 0.180	1.060 (0.89, 1.27) 0.525	0.825 (0.68, 1.00) 0.052[1]
Hazard Ratio SFP 50/500 vs components (CIs) p value	N/A	0.932 (0.77, 1.13) 0.481	0.774 (0.64, 0.93) 0.007	N/A
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				

There was a trend towards improved survival in subjects treated with SFP compared with placebo over 3 years however this did not achieve the statistical significance level $p \leq 0.05$.

The percentage 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 SFP.

The mean number of moderate to severe exacerbations per year was significantly reduced with SFP as compared with treatment with salmeterol, FP and placebo (mean rate in the SFP group 0.85 compared with 0.97 in the salmeterol group, 0.93 in the FP group and 1.13 in the placebo). This translates 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 SFP 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 clinically relevant.

The estimated 3-year probability of having pneumonia reported as an adverse event was 12.3% for placebo, 13.3% for salmeterol, 18.3% for FP and 19.6% for SFP (Hazard ratio for SFP vs placebo: 1.64, 95% CI: 1.33 to 2.01, p<0.001). There was no increase in pneumonia related deaths; deaths while on treatment that were adjudicated as primarily due to pneumonia were 7

for placebo, 9 for salmeterol, 13 for FP and 8 for SFP. There was no significant difference in probability of bone fracture (5.1% placebo, 5.1% salmeterol, 5.4% FP and 6.3% SFP; Hazard ratio for SFP vs placebo: 1.22, 95% CI: 0.87 to 1.72, p=0.248).

5.2 Pharmacokinetic properties

Salmeterol acts locally in the lung and previous studies have suggested that plasma levels are not necessarily an indication of therapeutic effects. In addition there are only limited data available on the pharmacokinetics of salmeterol because of the technical difficulty of assaying the active substance in plasma due to the low plasma concentrations at therapeutic doses (approximately 200 picogram/ml or less) achieved after inhaled dosing.

5.3 Preclinical safety data

The only findings in animal studies with relevance for clinical use were the effects associated with exaggerated pharmacological activity.

In reproduction and developmental toxicity studies with salmeterol xinafoate, there were no effects in rats. In rabbits, typical _2 agonist embryo fetal toxicity (cleft palate, premature opening of eyelids, sternebral fusion and reduced ossification rate in the frontal cranial bones) occurred at high exposure levels (approximately 20 times the maximum recommended daily dosage for humans, based on the comparison of areas under the curve (AUCs).

Salmeterol xinafoate was negative in a range of standard genotoxicity studies.

The non-CFC propellant, norflurane (HFA 134a), has been shown to have no toxic effect at very high vapour concentrations, far in excess of those likely to be experienced by patients, in a wide range of animal species exposed daily for periods of up to two years including no effects on the reproductive performance or embryofetal development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous ethanol
Soya lecithin (E322)
Norflurane (HFA 134a), a hydrofluoroalkane (non-chlorofluorocarbon) propellant.

This product does not contain any chlorofluorocarbon propellants.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30ºC.
Do not freeze.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50ºC. Do not puncture, break or burn even when apparently empty

6.5 Nature and contents of container

Pressurised aluminium canister containing a white suspension sealed with a metering valve, with a mid-green polypropylene actuator and a pale green polypropylene dust cap.
Each canister provides 120 actuations, each actuation containing 25 micrograms of salmeterol (as xinafoate) corresponding to a delivered dose (ex-actuator) of 21 micrograms salmeterol (as xinafoate).

Pack sizes: 1 or 2 (bundled package 2 x 1) canisters containing 120 metered doses.

Not all pack sizes may be maerketed.

6.6 Special precautions for disposal

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

Fannin Limited
Fannin House
South County Business Park
Leopardstown
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1457/024/001.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2011
Date of last renewal: 9th February 2016

10 DATE OF REVISION OF THE TEXT

March 2019
CRN008KJ6