Safeguarding public health

MHRA

Public Assessment Report

Besavar XL 10mg Tablets

(alfuzosin hydrochloride)

PL 17780/0221

BESAVAR XL 10MG TABLETS

(ALFUZOSIN HYDROCHLORIDE)

PL 17780/0221

UKPAR

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BESAVAR XL 10MG TABLETS

(ALFUZOSIN HYDROCHLORIDE)

PL 17780/0221

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Winthrop Pharmaceuticals UK Limited a Marketing Authorisation (licence) for the medicinal product Besavar XL 10mg Tablets (PL 17780/0221). This is a prescription only medicine [POM] for treating benign prostatic hypertrophy (BPH), a condition caused by the prostate gland becoming too big and obstructing the flow of urine from the bladder.

Besavar XL 10mg Tablets contain alfuzosin hydrochloride which works by relaxing the muscle of the prostate gland and bladder exit, and widening the urethra (the tube through which urine passes from the bladder to the outside of the body).

This is a simple abridged application that cross-refers to a previously granted licence for Xatral XL 10mg Tablets (PL 11723/0370).

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Besavar XL 10mg Tablets outweigh the risks, hence a Marketing Authorisation has been granted.

BESAVAR XL 10MG TABLETS

(ALFUZOSIN HYDROCHLORIDE)

PL 17780/0221

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Besavar XL 10mg Tablets (PL 17780/0221) to Winthrop Pharmaceuticals UK Limited on 10 May 2006. The product is a prescription only medicine [POM].

This application was submitted as a simple abridged application according to Article 10.1(a)i of Directive 2001/83/EC, cross-referring to Xatral XL 10mg Tablets (PL 11723/0370, approved on 30 June 2000).

Besavar XL 10mg Tablets contain alfuzosin hydrochloride. Alfuzosin is an orally active quinazoline derivative. It is a selective, peripherally acting antagonist of postsynaptic α_1-adrenoceptors.

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

Besavar XL 10mg Tablets is used for treating the functional symptoms of benign prostatic hypertrophy.

PHARMACEUTICAL ASSESSMENT

PL Number: **17780/0221**
Name of Product: **Besavar XL 10mg Tablets**
Active (s): **Alfuzosin hydrochloride**
Company Name: **Winthrop Pharmaceuticals UK Limited**
E.C. Article: **10.1(a)(i)**
Legal Status: **POM**

INTRODUCTION

Legal basis

This is a simple abridged application for Besavar XL 10mg Tablets, containing 10mg of alfuzosin hydrochloride per tablet.

The applicant claims essential similarity, under article 10.1(a)(i), to Xatral XL 10mg Tablets (PL 11723 / 0370). The licence for this reference product is held by Sanofi-Synthelabo Limited, granted 30 June 2000 as change of ownership from PL 15819/0042 (granted 9 March 2000).

Letters of access

A satisfactory letter of access to the Drug Master File and manufacturing consent is provided. The manufacturer and licence holder are from the same group of companies.

The applicant has also provided satisfactory written confirmation for MHRA to use all the data provided for the reference product.

Reference product

There were outstanding variations for SPC sections 5.1 and 5.2 update and renewal standard. There were no outstanding Issues with the reference product.

TSE status

The product contains no material sourced from animals. It has been confirmed that magnesium stearate is of plant origin.

SUMMARIES

Introduction

A satisfactory product profile is provided.

Quality Overall Summary

The Quality Overall Summary confirms the application to be identical to the reference product in all particulars.

Nonclinical Overview

The Nonclinical Overview confirms the application to be identical to the reference product in all particulars.

Clinical Overview

The Clinical Overview confirms the application to be identical to the reference product in all particulars.

PRODUCT NAME

The brand name Besavar XL 10mg Tablets is acceptable. The name "Besavar" was previously used by Sanofi-Synthelabo in licences for products that were never marketed. Sanofi-Synthelabo has since requested cancellation of these licences.

MARKETING AUTHORISATION APPLICATION FORM

The sites of manufacture, assembly and batch release are in line with those of the reference product.

ADDITIONAL INFORMATION

The method of manufacture, drug substance specification and finished product specification are the same as for the reference product.

PRODUCT PARTICULARS

Summary of Product Characteristics

This is in line with the reference product with minor cosmetic changes.

Labelling

Text versions and mock-ups of the carton (30 tablets) and blister foil label are provided. An assurance has been provided that mock-ups of other pack sizes will be submitted if marketed.

Patient Information Leaflet (PIL)

A text version and mock-up of the PIL has been provided.

CONCLUSION

A product licence may be granted for this product.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the cross-referenced product and as such have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to a previously granted application for Xatral XL 10mg Tablets.

No new or unexpected safety concerns arose from this application.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-referenced product.

RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-referenced product. Extensive clinical experience with the active ingredient alfuzosin is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.

BESAVAR XL 10MG TABLETS

(ALFUZOSIN HYDROCHLORIDE)

PL 17780/0221

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Besavar XL 10mg Tablets on 21 June 2004.
2	The MHRA's assessment of the submitted data was completed on 29 October 2004.
3	Further information was requested from the company on 29 October 2004.
4	The applicant submitted its responses to further information request in a letter dated 3 March 2005.
5	Further information was requested from the company on 1 April 2005.
6	The applicant submitted its response to further information request by CD (13 March 2006) and by e-mails (23 and 31 March 2006).
7	Additional information was requested from the company on 6 and 7 April 2006.
8	The applicant submitted its responses to additional information request on 6, 7, 13, 27 and 28 April 2006.
9	The MHRA completed its assessment of the application on 9 May 2006.
10	The application was determined on 10 May 2006.

BESAVAR XL 10MG TABLETS

(ALFUZOSIN HYDROCHLORIDE)

PL 17780/0221

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Besavar XL 10mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10mg alfuzosin hydrochloride in a sustained release formulation. For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Prolonged-release tablets.
Round, biconvex three layer tablets; one white layer between 2 yellow layers.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment of the functional symptoms of benign prostatic hypertrophy (BPH).

For information on use in acute urinary retention (AUR) related to BPH see sections 4.2 and 5.1.

4.2. Posology and method of administration

Besavar XL tablets should be swallowed whole.

BPH: The recommended dose is one 10mg tablet to be taken once daily after a meal.

AUR: In patients 65 years and older, one 10 mg tablet daily after a meal to be taken from the first day of catheterisation. The treatment should be administered for 3-4 days, 2-3 days during catheterisation and 1 day after its removal. In this indication no benefit has been established in patients under 65 years of age or if treatment is extended beyond 4 days.

4.3. Contraindications

Hypersensitivity to the product. History of orthostatic hypotension. Combination with other α-blockers. Hepatic insufficiency.

4.4. Special warnings and precautions for use

Warnings
As with all alpha$_1$-blockers in some subjects, in particular patients receiving antihypertensive medications, postural hypotension with or without symptoms (dizziness, fatigue, sweating) may develop within a few hours following administration. In such cases, the patient should lie down until the symptoms have completely disappeared.
These effects are transient and do not usually prevent the continuation of treatment after adjustment of the dose. The patient should be warned of the possible occurrence of such events.

Precautions
Treatment should be initiated gradually in patients with hypersensitivity to α-1-blockers. Besavar XL 10mg Tablets should be administered carefully to patients being treated with antihypertensives. Blood pressure should be monitored regularly, especially at the beginning of treatment.

In patients with coronary insufficiency specific anti-anginal therapy should be continued, but if the angina reappears or worsens Besavar XL 10mg Tablets should be discontinued.
Experience in patients with severe renal impairment is limited and cautious use in these patients is recommended.

Patients should be warned that the tablet should be swallowed whole. Any other mode of administration, such as crunching, crushing, chewing, grinding or pounding to powder should be prohibited. These actions may lead to inappropriate release and absorption of the drug and therefore possible early adverse reactions.

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

Combinations contra-indicated:
- Alpha$_1$-receptor blockers (see 4.3 Contra-indications).

Combinations to be taken into account:
- Antihypertensive drugs (see 4.4 Special Warnings and Precautions for Use).
- Nitrates.

The administration of general anaesthetics to patients receiving Besavar XL 10mg Tablets could cause profound hypotension. It is recommended that the tablets be withdrawn 24 hours before surgery.

Other forms of interaction
No pharmacodynamic or pharmacokinetic interaction has been observed in healthy volunteers between alfuzosin and the following drugs: warfarin, digoxin, hydrochlorothiazide and atenolol.

4.6. Pregnancy and lactation

Due to the type of indication this section is not applicable.

4.7. Effects on ability to drive and use machines

There are no data available on the effect on driving vehicles. Adverse reactions such as vertigo, dizziness and asthenia may occur. This has to be taken into account when driving vehicles and operating machinery.

4.8. Undesirable effects

- **CNS and psychiatric disorders**

Common: faintness/dizziness, headache
Uncommon: vertigo, malaise, drowsiness

- **Cardiovascular disorders**

Uncommon: tachycardia, palpitations, hypotension (postural), syncope
Very rare: aggravation or recurrence of angina pectoris (see 4.4)

- **Gastro-intestinal disorders**

Common: nausea, abdominal pain
Uncommon: diarrhoea, dry mouth

- **Skin and appendages**

Uncommon: rash, pruritus

- **Body as a whole**

Common: asthenia
Uncommon: flushes, oedema, chest pain

Although only reported in isolated cases with alfuzosin, occurrence of priapism can not be excluded as it is generally accepted as being attributable to all other alpha adrenoreceptor blockers.

4.9. Overdose

In case of overdosage, the patient should be hospitalized, kept in the supine position, and conventional treatment of hypotension should take place.
Alfuzosin is not dialysable because of its high degree of protein binding.

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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Alfuzosin is an orally active quinazoline derivative. It is a selective, peripherally acting antagonist of postsynaptic α_1-adrenoceptors.

In vitro pharmacological studies have documented the selectivity of alfuzosin for the alpha$_1$-adrenoreceptors located in the prostate, bladder base and prostatic urethra.

Clinical manifestations of Benign Prostatic Hypertrophy are associated with infra vesical obstruction which is triggered by both anatomical (static) and functional (dynamic) factors. The functional component of obstruction arises from the tension of prostatic smooth muscle which is mediated by α-adrenoceptors. Activation of α_1-adrenoceptors stimulates smooth muscle contraction, thereby increasing the tone of the prostate, prostatic capsule, prostatic urethra and bladder base, and, consequently, increasing the resistance to bladder outflow. This in turn leads to outflow obstruction and possible secondary bladder instability.

Alpha-blockade decreases infra vesical obstruction via a direct action on prostatic smooth muscle.

In vivo, animal studies have shown that alfuzosin decreases urethral pressure and therefore, resistance to urine flow during micturition. Moreover, alfuzosin inhibits the hypertonic response of the urethra more readily than that of vascular muscle and shows functional uroselectivity in conscious normotensive rats by decreasing urethral pressure at doses that do not affect blood pressure.

In man, alfuzosin improves voiding parameters by reducing urethral tone and bladder outlet resistance, and facilitates bladder emptying.

In placebo controlled studies in BPH patients, alfuzosin:

- significantly increases peak flow rate (Qmax) in patients with Qmax ≤ 15ml/s by a mean of 30%. This improvement is observed from the first dose,
- significantly reduces the detrusor pressure and increases the volume producing a strong desire to void,
- significantly reduces the residual urine volume.

In addition, the efficacy of alfuzosin 10 mg od on peak flow rate and the limited effect on blood pressure have been demonstrated to be related to its pharmacokinetic profile. Moreover, the efficacy on peak flow rate is maintained up to 24 hours after intake.

These favourable urodynamic effects lead to an improvement of lower urinary tract symptoms ie. filling (irritative) as well as voiding (obstructive) symptoms.

Alfuzosin may cause moderate antihypertensive effects.

A lower frequency of acute urinary retention is observed in the alfuzosin treated patient than in the untreated patient.

AUR (related to BPH):
In the ALFAUR study, the effect of alfuzosin on the return of normal voiding was evaluated in 357 men over 50 years, presenting with a first episode of acute urinary retention (AUR), related to BPH. In this multicentre, randomised double blind parallel group study comparing alfuzosin 10mg/day and placebo, the evaluation of voiding was performed 24 hours after catheter removal, the morning after 2-3 days of treatment.

In men aged 65 years and over alfuzosin significantly increased the success rate of spontaneous voiding after catheter removal – see table. No benefit has been established in patients under 65 years of age or if treatment is extended beyond 4 days.

ALFAUR study: Percentage of patients (ITT population) successfully voiding post-catheter removal

Age	**Placebo N (%)**	**Alfuzosin N (%)**	**Relative difference vs placebo 95%CI**	**p value**
65 years and above	30 (35.7%)	88 (56.1%)	1.57 (1.14-2.16)	0.003
Below 65 years	28 (75.7%)	58 (73.4%)	0.97 (0.77-1.22)	0.80
All patients (50 years and above)	58 (47.8%)	146 (61.9%)	1.29 (1.04-1.60)	0.012

5.2. Pharmacokinetic properties

Prolonged-release formulation:

The mean value of the relative bioavailability is 104.4 % versus the immediate release formulation (2.5 mg tid) in middle-aged healthy volunteers and the maximum plasma concentration is being achieved 9 hours after administration compared to 1 hour for the immediate release formulation.

The apparent elimination half-life is 9.1 hours.

Studies have shown that consistent pharmacokinetic profiles are obtained when the product is administered after a meal.

Under fed conditions, mean Cmax and Ctrough values are 13.6 (SD=5.6) and 3.1 (SD=1.6) ng/ml respectively. Mean AUC_{0-24} is 194 (SD=75) ng.h/ml. A plateau of concentration is observed from 3 to 14 hours with concentrations above 8.1 ng/ml (Cav) for 11 hours.

Compared to healthy middle aged volunteers, the pharmacokinetic parameters (Cmax and AUC) are not increased in elderly patients.

Compared to subjects with normal renal function, mean Cmax and AUC values are moderately increased in patients with renal impairment, without modification of the apparent elimination half-life. This change in the pharmacokinetic profile is not considered clinically relevant. Therefore, this does not necessitate a dosing adjustment.

The binding of alfuzosin to plasma proteins is about 90%. Alfuzosin undergoes extensive metabolism by the liver, with only 11 % of the parent compound being excreted unchanged in the urine. The majority of the metabolites (which are inactive) are excreted in the faeces (75 to 91 %).

The pharmacokinetic profile of alfuzosin is not affected by chronic cardiac insufficiency.

5.3. Preclinical safety data

No data of therapeutic relevance.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Ethylcellulose
Hydrogenated castor oil
Hypromellose
Yellow ferric oxide (E172)
Magnesium stearate
Microcrystalline cellulose
Povidone,
Colloidal hydrated silica
Mannitol.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

No special precautions for storage.
Store in the original container.

6.5. Nature and contents of container

Boxes with 10, 30, 50, 100 and 500 tablets in pvc/foil blister strips.

6.6. Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Winthrop Pharmaceuticals UK Limited
One Onslow Street
Guildford
Surrey
GU1 4YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 17780/0221

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/05/2006

10 DATE OF REVISION OF THE TEXT

10/05/2006

Patient Information Leaflet

BESAVAR XL 10MG TABLETS

(ALFUZOSIN HYDROCHLORIDE)

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BESAVAR XL 10MG TABLETS
(alfuzosin hydrochloride)

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Your doctor may have given you this medicine before from another company and it may have looked slightly different. Either brand will have the same effect.

In this leaflet:

The name of this medicine is Besavar XL 10mg Tablets (referred to as Besavar XL throughout this leaflet).

Each tablet contains 10mg alfuzosin hydrochloride as the active substance.
The other ingredients are: ethylcellulose, hydrogenated castor oil, hypromellose, yellow ferric oxide (E172), magnesium stearate, microcrystalline cellulose, povidone, colloidal hydrated silica, mannitol.

Besavar XL tablets are made in a 'sustained release' form. This means they release their active substance gradually and therefore you only have to take the tablet once a day.

The Marketing Authorisation holder is: Winthrop Pharmaceuticals, PO Box 611, Guildford, Surrey, GU1 4YS, UK
The Manufacturer is: Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle upon Tyne, NE3 3TT

1.WHAT BESAVAR XL IS AND WHAT IT IS USED FOR?

Besavar XL 10mg Tablets are round biconvex 3 layered tablets consisting of one white layer in between two yellow layers.

They are supplied in blister packs of 30 tablets

Besavar XL belongs to a group of medicines known as alpha blockers. It is used to treat benign prostatic hyperplasia (BPH). This condition is caused by the prostate gland growing too big and obstructing the flow of urine from the bladder. The usual symptoms are weak or interrupted urine flow, a need to pass water more frequently and/or a sudden need to pass water. BPH is not cancerous, and occurs mainly in older men and is fairly common.

Your tablets work by relaxing the muscle of the prostate gland and bladder exit, widening the urethra (the tube through which urine passes from the bladder to the outside of the body) and so relieving the symptoms of BPH.

In a few patients who suffer from BPH, the prostate gland becomes so enlarged that it completely stops the flow of urine. This painful condition is known as Acute Urinary Retention (AUR) and may require a short stay in hospital. A thin flexible tube known as a catheter is passed through the urethra into the bladder which drains the urine and relieves the pain. The catheter may need to stay in the bladder for a few days during which time Besavar XL may be used to relax the muscle in the prostate gland. In many patients aged 65 years and above, this will allow the urine to flow again once the catheter is removed. In younger men with AUR this benefit has not been noted.

2.BEFORE YOU TAKE BESAVAR XL

Do not take Besavar XL if you:
- are allergic to alfuzosin hydrochloride or any of the other ingredients in the tablets
- are taking other alpha blockers (e.g. doxazosin, indoramin, prazosin, tamsulosin)
- have or have had postural hypotension (feeling faint or light-headed when you stand up)
- have liver problems.

DUMMY

Special care is needed (check with your doctor) if you:
- are allergic to other alpha blockers
- are taking medicines for high blood pressure. If you have high blood pressure, your doctor should monitor your blood pressure regularly while you are taking this medicine. This is particularly important at the start of treatment.
- have angina (chest pain)
- have kidney problems.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Driving and using machines
Your tablets may make you feel weak or dizzy when you start taking them. If affected, do not drive a car or operate machinery.

Taking other medicines
If taken with some other medicines the effects of Besavar XL or the effects of other medicines may be changed. Please check with your doctor if you are taking any of the following:
- other alpha-blockers and antihypertensive agents (medicines used to treat high blood pressure), as this may cause your blood pressure to fall too low.

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- general anaesthetics. If you are to undergo an operation which requires a general anaesthetic, you should tell the anaesthetist during your pre-operative assessment and these tablets should be stopped 24 hours before your operation, as your blood pressure could fall too low.

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine – even those not prescribed.

3.HOW TO TAKE BESAVAR XL

Adults and the elderly
The usual dose is one 10mg tablet each day.

Taking your tablets
Swallow your tablet whole with a glass of water at about the same time each day after a meal. DO NOT BREAK, CRUSH OR CHEW your tablet as this will affect the gradual release mechanism of your medication.

For patients suffering from Acute Urinary Retention:
Your doctor will start Besavar XL on the first day of catheterisation, and you should continue taking your medication once a day after a meal, until the day after the catheter is removed (3-4 days in total).

If you take more Besavar XL than you should:
An overdose of this medicine may be dangerous as your blood pressure could fall very low. If you or someone else, has taken too many tablets, tell your doctor or go to the nearest hospital casualty department immediately. Lie down as much as possible, as this will help minimise the side effects.

If you forget to take Besavar XL:
If you forget to take a dose at the right time, take it as soon as you remember, then go on as before. However you must not take two doses at the same time.

Effects when treatment with Besavar XL is stopped:
Benign Prostatic Hyperplasia (BPH) symptoms are best controlled by maintaining your daily dose of this medicine. Do not stop taking your tablets just because your symptoms improve. It is important to keep taking your tablets unless your doctor tells you to stop.

DUMMY

4.POSSIBLE SIDE EFFECTS

Like all medicines, Besavar XL can have side effects. Side effects are most likely to happen at the start of treatment.

If you experience any of the following, stop taking Besavar XL and tell your doctor or go to the casualty department at your nearest hospital immediately:

- **an allergic reaction consisting of swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty breathing or swallowing, itching of the skin and nettle rash.**
- **angina (chest pain). This usually only happens if you have had angina before.**

The most common side effects are:

- dizziness
- headache
- digestive system problems, including: feeling sick and stomach pains
- lack of energy.

Less common side effects are:

- feeling faint/fainting, especially on getting up from a sitting or lying position, low blood pressure.
- a general feeling of being unwell
- tachycardia (fast heart beat)
- palpitations
- chest pain
- tiredness/drowsiness
- diarrhoea
- dry mouth
- rash/itching
- flushes
- swelling, usually of the lower legs.

Very rarely, priapism (persistent and often painful erection in the absence of sexual stimulation) has been reported in patients receiving Besavar XL or other similar medicines.

Do not be alarmed by this list. Most people take Besavar XL without any problems. If you experience these or any other unusual side effects not mentioned in this leaflet, please contact your doctor or pharmacist as soon as possible. If your symptoms are severe or last for more than a few days, contact your doctor immediately.

5.STORING BESAVAR XL

Keep your medicine in a safe place out of the reach and sight of children.

Store in the original container.

Do not take this medicine after the expiry date which you will find on the pack.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in February 2006.

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Labelling

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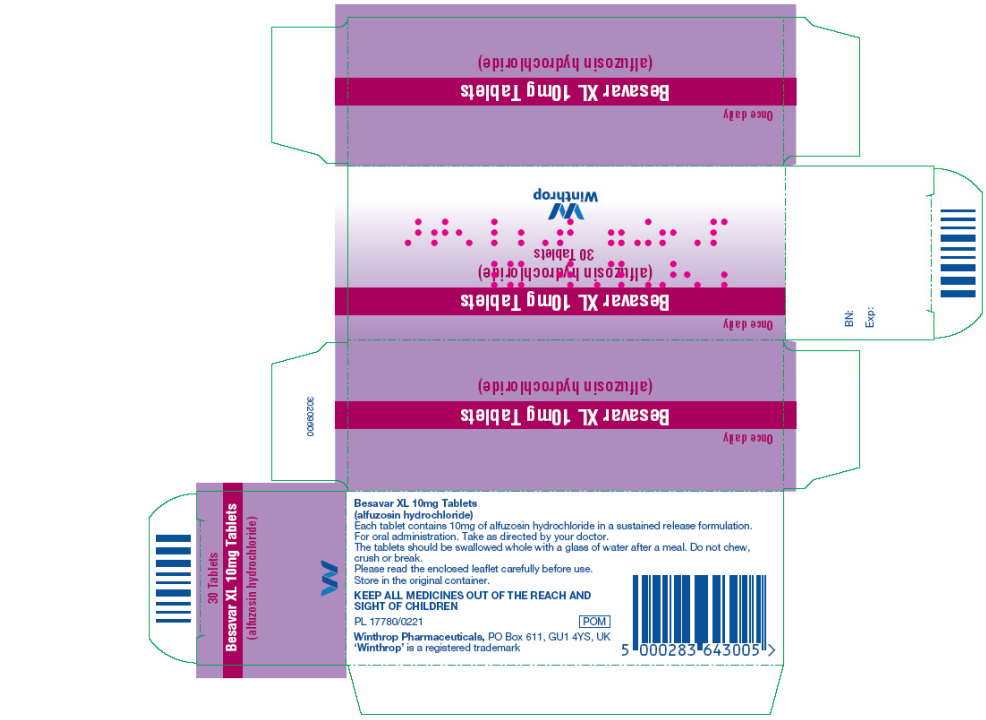
Carton



BRAILLE EXPLANATIONS AND TRANSLATIONS

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Blister foil