ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS
PL 17780/0220

UKPAR

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LAY SUMMARY

The MHRA granted Winthrop Pharmaceuticals UK Ltd Marketing Authorisations (licences) for the medicinal product Alfuzosin Hydrochloride 2.5mg Tablets (PL 17780/0220) on 31 July 2007. This prescription only medicine (POM) is used to treat benign prostatic hyperplasia (BPH), a condition caused by the prostate gland growing too big and obstructing the flow of urine from the bladder.

Alfuzosin Hydrochloride 2.5mg Tablets contain the active ingredient alfuzosin hydrochloride which is an alpha blocker.

This application is a duplicate of a previously granted application for Xatral (Sanofi-Synthelabo Ltd) and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Alfuzosin Hydrochloride 2.5mg Tablets outweigh the risks, hence Marketing Authorisations have been granted.

ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS
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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Alfuzosin Hydrochloride 2.5mg Tablets (PL 17780/0220) to Winthrop Pharmaceuticals UK Ltd on 31 July 2007. This product is a prescription only medicine.

The application was submitted as a simple abridged application according to article 10.1(a)(i) of Directive 2001/83/EC, referring to Xatral (Sanofi-Synthelabo Ltd).

No new data was submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted reference product. As the reference product was granted prior to the introduction of current legislation, a Public Assessment Report (PAR) was not generated for it.

The product contains the active ingredient alfuzosin hydrochloride which is an agent that blocks alpha-adrenergic receptors found in the muscle in the prostate gland therefore improving urine flow and relieves the urinary symptoms.

PHARMACEUTICAL ASSESSMENT

1. INTRODUCTION

This is a simple, piggy back application for Alfuzosin Hydrochloride 2.5mg Tablets submitted under Article 10.1(a)(i) of Directive 2001/83/EC. The proposed MA holder is Winthrop Pharmaceuticals UK Ltd.

This application refers to a new active substance application for Xatral which is currently registered in the UK. This application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Alfuzosin Hydrochloride 2.5mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains 2.5mg alfuzosin hydrochloride. It is to be stored in polypropylene containers or blister packs of 30, 60 and 90 tablets. The proposed shelf-life (3 years) and storage conditions (Do not store above 30^{o}C; Store in the original package) are consistent with the details registered for the reference product.

2.3 Legal status

On approval, the products will be subject to a medical prescription.

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guilford, Surrey, GU1 4YS.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the reference product.

2.10 TSE Compliance

No materials of animal or human origin are included in the product.

3. EXPERT REPORTS

The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to the reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The proposed SPC is consistent with the details registered for the reference product.

6. PATIENT INFORMATION LEAFLET/CARTON

PIL
The patient information leaflet has been prepared in-line with the details registered for the reference product.

Carton and blister
The proposed artwork is comparable to the artwork registered for the reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

As this is a duplicate application, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with that previously assessed for the reference product and as such it has been judged to be satisfactory.

PRECLINICAL

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

EFFICACY

Alfuzosin hydrochloride is a well known drug and has been used as an alpha blocker for many years. This application is identical to the previously granted application for Xatral in which the applicant provided full clinical data.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the reference 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 has been shown to be interchangeable with the innovator product. Extensive clinical experience with alfuzosin hydrochloride is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS
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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the Marketing Authorisation application on 21 October 2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 02 November 2004.
3	Following assessment of the application the MHRA requested further information on 11 February 2005, 01 December 2005 and 03 April 2007.
4	The applicant responded to the MHRA's requests, providing further information on 14 February 2006 and 04 June 2007.
7	The application was determined on 31 July 2007.

ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS
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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Alfuzosin Hydrochloride 2.5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5mg alfuzosin hydrochloride.

Excipients:

Each tablet contains 61 mg lactose anhydrous.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

White round, film coated tablet for oral administration marked Xatral 2.5 on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of the functional symptoms of benign prostatic hypertrophy.

4.2 Posology and method of administration

Alfuzosin Hydrochloride 2.5mg Tablets should be swallowed whole. The first dose should be given just before bedtime.

Adults

The usual dose is one tablet three times daily. The dose may be increased to a maximum of 4 tablets (10mg) per day depending on the clinical response.

Elderly and treated hypertensive patients

As a routine precaution when prescribing alfuzosin to elderly patients (aged over 65 years) and the treated hypertensive patient, the initial dose should be 1 tablet in the morning and 1 tablet in the evening.

Renal insufficiency

In patients with renal insufficiency, as a precaution, it is recommended that the dosing be started at Alfuzosin Hydrochloride 2.5mg Tablets twice daily adjusted according to clinical response.

Hepatic insufficiency

In patients with mild to moderate hepatic insufficiency, it is recommended that therapy should commence with a single dose of Alfuzosin Hydrochloride 2.5mg Tablets/day to be increased to Alfuzosin Hydrochloride 2.5mg Tablets twice daily according to clinical response.

Lactose

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or

glucose-galactose malabsorption should not take this medicine.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients. History of orthostatic hypotension. Combination with other α-blockers. Severe hepatic insufficiency.

4.4 Special warnings and precautions for use

Warnings

The 'Intraoperative Floppy Iris Syndrome' (IFIS, a variant of small pupil syndrome) has been observed during cataract surgery in some patients on or previously treated with tamsulosin. Isolated reports have also been received with other alpha-1 blockers and the possibility of a class effect cannot be excluded. As IFIS may lead to increased procedural complications during the cataract operation current or past use of alpha-1 blockers should be made known to the ophthalmic surgeon in advance of surgery.

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. Alfuzosin Hydrochloride 2.5mg 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 Alfuzosin Hydrochloride 2.5mg Tablets should be discontinued.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations contraindicated:

- $Alpha_1$-receptor blockers (see section 4.3)

Combinations to be taken into account:

- Antihypertensive drugs (see section 4.4.2)
- Nitrates
- Potent CYP3A4 inhibitors such as ketoconazole, itraconazole and ritonavir.

The administration of general anaesthetics to patients receiving Alfuzosin Hydrochloride 2.5mg Tablets could cause profound hypotension. It is recommended that Alfuzosin Hydrochloride 2.5mg 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

- **Nervous system disorders**

  Common: faintness/dizziness, vertigo, malaise, headache

  Uncommon: drowsiness

- **Eye disorders**

  Uncommon: vision abnormal

- **Cardiac disorders**

  Common: hypotension (postural)

  Uncommon: tachycardia, palpitations, syncope

  Very rare: New onset, aggravation or recurrence of angina pectoris in patients with pre-existing coronary artery disease (see section 4.4.)

- **Respiratory system disorders**

  Uncommon: rhinitis

- **Gastro-intestinal disorders**

  Common: nausea, abdominal pain, diarrhoea, dry mouth

- **Skin and subcutaneous tissue disorders**

  Uncommon: rash, pruritus

  Very rare: urticaria, angiœdema

- **General disorders**

  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 hospitalised, kept in the supine position, and conventional treatment of hypotension should take place.

Alfuzosin is not easily dialysable because of its high degree of protein binding.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: alpha adrenoreceptor antagonists

ATC code: G04C A01

Alfuzosin is an orally active quinazoline derivative. It is a selective, peripherally acting antagonist of post synaptic 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 $\leq$ 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.

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.

5.2 Pharmacokinetic properties

Alfuzosin Hydrochloride 2.5mg Tablets are well absorbed with a mean bioavailability of 64%, peak plasma levels are generally reached in 0.5-3 hours. Kinetics within the therapeutic range are linear. The kinetic profile is characterised by large interindividual fluctuations in plasma concentrations. The terminal half-life is 3-5 hours. Alfuzosin is 90% protein bound in plasma, 68.2% to human serum albumin and 52.5% to human serum alpha-glycoprotein. It is partially metabolised and excreted mainly in the bile and faeces.

None of the metabolites found in man has any pharmacodynamic activity. The pharmacokinetic profile is not affected by taking Alfuzosin Hydrochloride 2.5mg Tablets with food.

In subjects over 75 years, absorption is more rapid and peak plasma levels are higher. Bioavailability may be increased and in some patients the volume of distribution is reduced. The elimination half-life does not change.

The volume of distribution and clearance of alfuzosin are increased in renal insufficiency, with or without dialysis, owing to an increase in the free fraction. Chronic renal insufficiency even when severe (creatinine clearance between 15 and 40 mls/min) is not adversely affected by alfuzosin.

In patients with severe hepatic insufficiency, the elimination half-life is prolonged. A two-fold increase in Cmax values and a three-fold increase in the AUC is observed. Bioavailability is increased compared with healthy volunteers.

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

Metabolic interactions: CYP3A4 is the principal hepatic enzyme isoform involved in the metabolism of alfuzosin (see section 4.5)

5.3 Preclinical safety data

No data of therapeutic relevance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core: Microcrystalline cellulose, lactose, povidone, sodium starch glycollate, magnesium stearate.

Coating: Methylhydroxypropylcellulose, polyethylene glycol 400, titanium dioxide suspension (E171).

6.2 Incompatibilities

Not known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30ºC. Store in the original package

6.5 Nature and contents of container

Boxes with 30, 60 or 90 tablets in pvc/foil blister strips.

PP containers with 30, 60, 90 tablets.

Not all pack sizes may be marketed.

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

Winthrop Pharmaceuticals UK Limited

One Onslow Street

Guildford

Surrey

GU1 4YS

United Kingdom

Trading as: Winthrop Pharmaceuticals, PO Box 611, Guildford, Surrey, GU1 4YS

8 MARKETING AUTHORISATION NUMBER(S)

PL 17780/0220

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/07/2007

10 DATE OF REVISION OF THE TEXT

31/07/2007

PATIENT INFORMATION LEAFLET

ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS

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 Alfuzosin Hydrochloride 2.5mg Tablets (referred to as Alfuzosin throughout this leaflet).

Each tablet contains 2.5mg alfuzosin hydrochloride as the active substance.
The other ingredients are: microcrystalline cellulose, lactose, povidone, sodium starch glycollate, magnesium stearate, methylhydroxypropylcellulose, polyethylene glycol 400, titanium dioxide suspension (E171).

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

Or

Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37000 Tours, France

(Final printed leaflet to include only the actual site of batch release)

1. WHAT ALFUZOSIN IS AND WHAT IT IS USED FOR?

Alfuzosin Hydrochloride 2.5mg Tablets are white film-coated tablets marked Xatral 2.5 on one side

They are supplied in blister packs of 60 tablets

Alfuzosin 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.

1

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.

2. BEFORE YOU TAKE ALFUZOSIN

Do not take Alfuzosin 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 severe liver problems.

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)
- you are undergoing eye surgery because of cataract (cloudiness of the lens). Please inform your eye specialist before the operation that you are using or have previously used Alfuzosin. This is because Alfuzosin may cause complications during the surgery which can be managed if your specialist is prepared in advance.

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

Taking other medicines
If taken with some other medicines the effects of Alfuzosin 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 they may cause your blood pressure to fall too low.
- 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.
- products such as ketoconazole and itraconazole which treat fungal infections or ritonavir which is used for HIV. These products affect the way that alfuzosin works

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

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

Important information about some of the ingredients in Alfuzosin
Alfuzosin contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ALFUZOSIN

The actual dose of Alfuzosin depends on your needs and the condition being treated but the usual doses are listed below:

Adults (under 65 years of age)
The usual dose is one tablet three times a day. Your doctor may increase this to four times a day if needed.

Elderly (over 65 years of age), patients with high blood pressure or patients with kidney problems
The usual dose is one tablet in the morning and one tablet in the evening,

Patients with liver problems
The usual dose is one tablet per day. Your doctor may increase this to one tablet in the morning and one tablet in the evening.

Taking your tablets
Swallow your tablets whole with plenty of water. The first dose should be taken just before bedtime.

If you take more Alfuzosin 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 Alfuzosin:
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 Alfuzosin 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Alfuzosin 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 Alfuzosin 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 difficulties in breathing or swallowing, itching of the skin and nettle rash.**
- **angina (chest pain). This usually only happens if you have had angina before.**

3

The most common side effects are:
- dizziness
- headache
- a general feeling of being unwell
- feeling faint/fainting, especially on getting up from a sitting or lying position, low blood pressure.
- digestive system problems, including: feeling sick and diarrhoea
- dry mouth
- lack of energy.

Less common side effects are:
- tiredness/drowsiness
- problems with your vision
- tachycardia (fast heart beat)
- palpitations
- allergy symptoms such as sneezing, runny nose, and itchy and/or burning eyes
- rash/itching
- flushes
- swelling, usually of the lower legs
- chest pain.

In isolated cases priapism has been reported. This is a painful erection of the penis that will not go away.

Do not be alarmed by this list. Most people take Alfuzosin 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 ALFUZOSIN

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

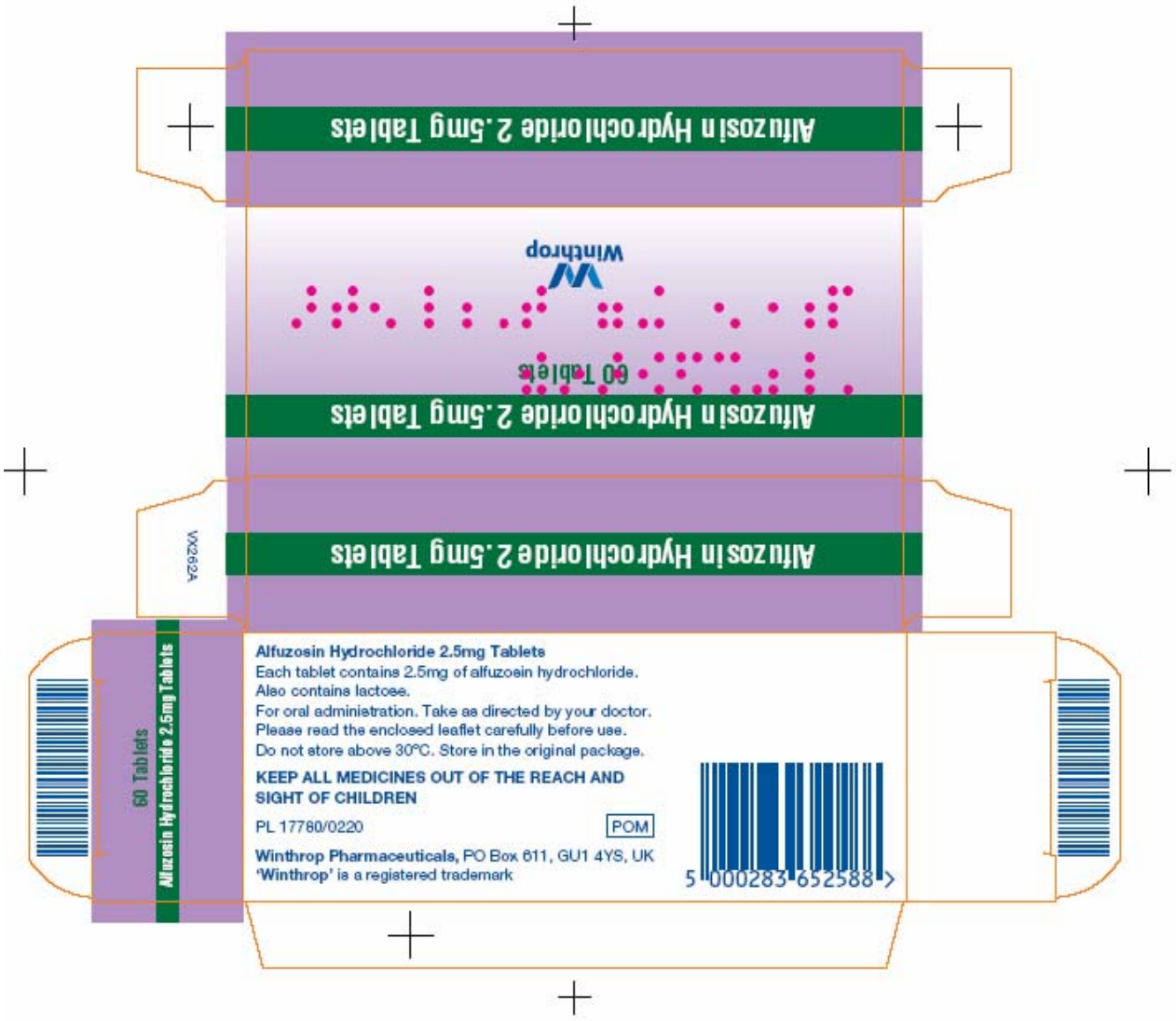
Do not store above 30°C. Store in a dry place in the original package.

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 May 2007.

LABELLING


Alfuzosin Hydrochloride 2.5mg Tablets
Winthrop
60 Tablets
Alfuzosin Hydrochloride 2.5mg Tablets
Alfuzosin Hydrochloride 2.5mg Tablets
VX262A
60 Tablets
Alfuzosin Hydrochloride 2.5mg Tablets
Alfuzosin Hydrochloride 2.5mg Tablets
Each tablet contains 2.5mg of alfuzosin hydrochloride.
Also contains lactose.
For oral administration. Take as directed by your doctor.
Please read the enclosed leaflet carefully before use.
Do not store above 30°C. Store in the original package.
KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN
PL 17780/0220
POM
Winthrop Pharmaceuticals, PO Box 611, GU1 4YS, UK
'Winthrop' is a registered trademark
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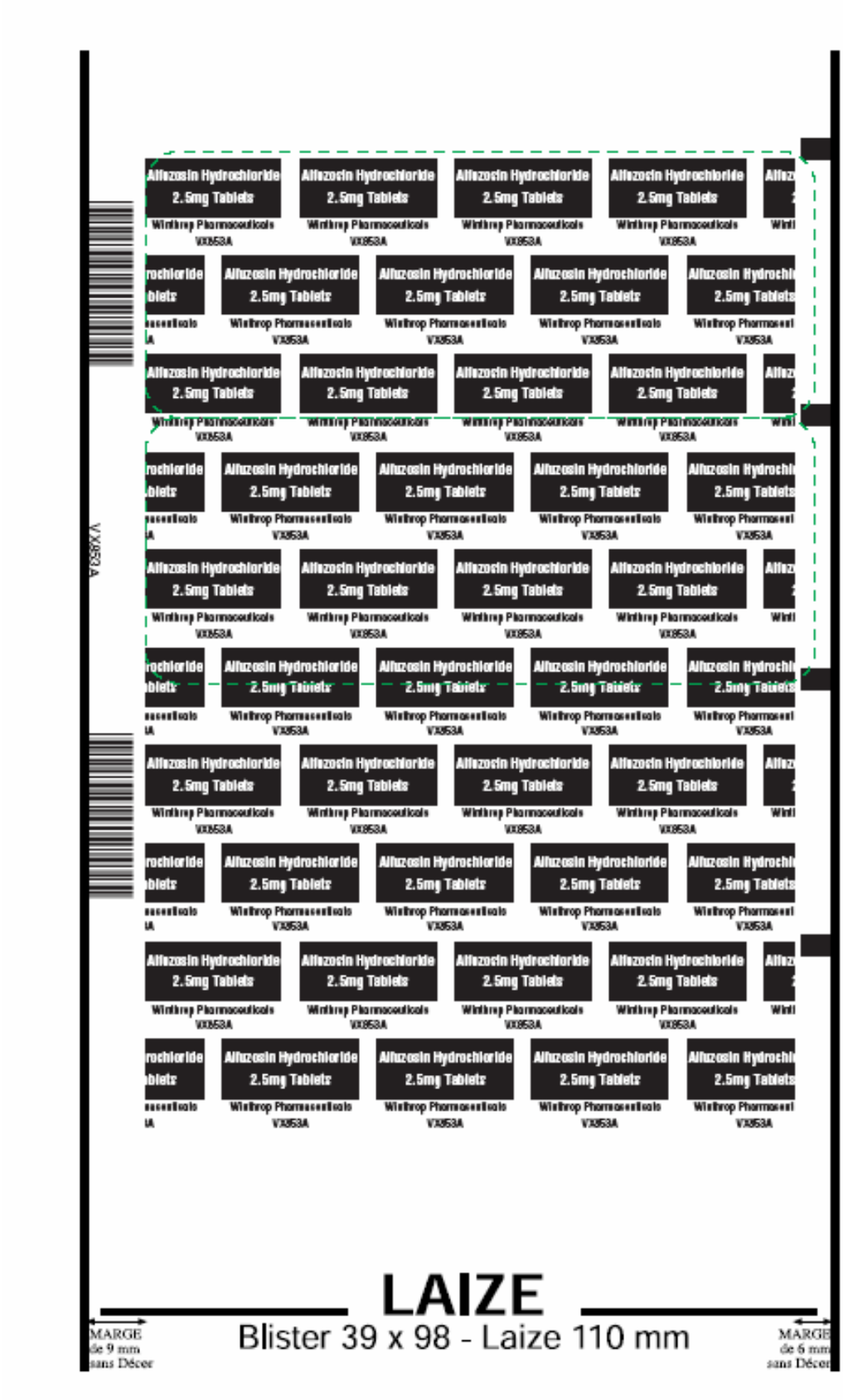
Alfuzosin Hydrochloride
2.5mg Tablets
Winthrop Pharmaceuticals
VX853A
LAIZE
Blister 39 x 98 - Laize 110 mm
MARGE
de 9 mm
sans Décor
MARGE
de 6 mm