ATENOLOL 25MG TABLETS
PL 17907/0167

UKPAR

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ATENOLOL 25MG TABLETS
PL 17907/0167

LAY SUMMARY

On 30th March 2010, the MHRA granted Bristol Laboratories Limited a Marketing Authorisation (licence) for Atenolol 25mg Tablets (PL 17907/0167).

Atenolol 25mg Tablets contain atenolol which belongs to a group of medicines called beta-blockers.

Atenolol 25mg Tablets are used to:

- Reduce high blood pressure (hypertension).
- Relieve chest pain (angina pectoris) which is caused by inadequate blood supply to the heart.
- Maintain a regular heartbeat and to protect the heart from further damage after a heart attack (myocardial infarction).

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Atenolol 25mg Tablets outweigh the risks; hence a Marketing Authorisation has been granted.
# SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Atenolol 25mg Tablets (PL 17907/0167) to Bristol laboratories Limited on 30th March 2010. This prescription only medicine is indicated for the:

- The management of hypertension
- The management of angina pectoris
- The management of cardiac dysrhythmias
- Myocardial infarction: Early intervention in the acute phase and long-term prophylaxis after recovery from myocardial infarction.

This application for Atenolol 25mg Tablets is submitted as an abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Atenolol 25mg Tablets, which was originally approved and licensed to Sandoz Limited (PL 04416/0278) on 30th July 1997.

No new data were submitted nor were they necessary for this simple application, as the data is identical to that of the previously granted cross-reference product.

The pharmacovigilance system as described by the applicant fulfils the requirements. It also provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring.

The Marketing Authorisation Holder has provided adequate justification for not submitting a risk management plan (RMP).
PHARMACEUTICAL ASSESSMENT

1. INTRODUCTION
This is a simple, piggy-back application for Atenolol 25mg Tablets (PL 17907/0167) submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom.

The application cross-refers to Atenolol 25mg Tablets, which was originally approved and licensed to Sandoz Limited (PL 04416/0278) on 30th July 1997.

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed name of the product is Atenolol 25mg 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 atenolol.

The finished product is packaged in:

1. Amber glass bottles with closures of LD-polyethylene
2. Securitainers
3. Blister packs made of clear poly-vinyl chloride (PVC) plastic foil and aluminium foil, hard tempered, laminated against 30g PVC.
4. Blister packs made of 250µm PVC coated with 60gm² polyvinylidene chloride (PVdC) and 20µm aluminium lidding foil.

Pack sizes are 28, 100 and 250 tablets.

The proposed shelf-life for unopened containers for pack types 1, 2 and 3 is 5 years. The proposed shelf-life for pack types 4 is 3 years. Storage conditions are ‘Store below 25°C’.

These are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the product will be available on prescription only (POM).

2.4 Marketing authorisation holder/Contact Persons/Company
Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom.

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 cross-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 cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size for each product is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
With the exception of lactose monohydrate, none of the excipients used contain material of animal or human origin.
The applicant has provided a declaration that milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as those intended for human consumption.
The magnesium stearate contained in this product is sourced from vegetable origin and therefore no European Pharmacopoeia Certificates of suitability for TSE is required.
This information is consistent with the cross-reference 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 cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product. The package leaflet has been submitted to the MHRA along with
results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that they contain.

Labelling

The proposed artwork is comparable to the artwork registered for the cross-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 packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application is acceptable. The grant of a Marketing Authorisation is recommended.
PRECLINICAL ASSESSMENT

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

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environmental Risk Assessment.
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 is consistent with that previously assessed for the cross-reference product and, as such, has been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for applications of this type.

EFFICACY
This application is identical to a previously granted application Atenolol 25mg Tablets, which was originally approved and licensed to Sandoz Limited (PL 04416/0278) on 30th July 1997.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-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 is identical to the cross-reference product. Extensive clinical experience with atenolol is considered to have demonstrated the therapeutic value of the compounds. The risk:benefit is, therefore, considered to be positive.
### STEPS TAKEN FOR ASSESSMENT

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<td>The MHRA received the marketing authorisation applications on 22\textsuperscript{nd} May 2006.</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 13\textsuperscript{th} July 2006.</td>
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<td>Following assessment of the application further information was requested regarding the quality section of the dossier on 8\textsuperscript{th} August 2006, 3\textsuperscript{rd} May 2007, 9\textsuperscript{th} October 2007 and 21\textsuperscript{st} July 2009.</td>
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<td>The applicant responded to the MHRA’s requests, providing further information on the quality sections of the dossier on 20\textsuperscript{th} April 2007, 9\textsuperscript{th} October 2007, 20\textsuperscript{th} October 2008 and 27\textsuperscript{th} July 2009.</td>
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<td>The applications were determined on 30\textsuperscript{th} March 2010.</td>
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### STEPS TAKEN AFTER ASSESSMENT

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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Atenolol 25mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains Atenolol BP 25mg
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Tablets
Orange, circular, film-coated tablet with convex sides with ‘A25’ embossed on one side.

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
i. The management of hypertension
ii. The management of angina pectoris
iii. The management of cardiac dysrhythmias
iv. Myocardial infarction: Early intervention in the acute phase and long-term prophylaxis after recovery from myocardial infarction.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
For oral administration

Adults
Hypertension:
Most patients respond to 100mg daily given as a single dose. Some patients, however, will respond to 50mg given as a single daily dose. The effect will be fully established after one to two weeks. A further reduction in blood pressure may be achieved by combining Atenolol with other antihypertensive agents. For example, co-administration of Atenolol with a diuretic provides a highly effective and convenient antihypertensive therapy.

Angina:
Most patients with angina pectoris will respond to 100mg given orally once daily or 50mg given twice daily. It is unlikely that additional benefit will be gained by increasing the dose.

Dysrhythmias:
Having controlled the dysrhythmias with intravenous Atenolol a suitable maintenance dosage is 50 mg - 100 mg daily, given as a single dose.

Myocardial infarction:
15 minutes after the administration of the intravenous dose an oral dose of 50 mg may be given provided that no untoward effect occur from the intravenous dose. This should be followed by a further 50mg 12 hours after the intravenous dose and then 12 hours later by 100 mg to be given once daily for up to ten days. If bradycardia and/or hypotension requiring treatment or any other untoward effects occur, Atenolol should be discontinued.

Renal failure:
Atenolol is excreted via the kidneys, dosage adjustment should therefore be considered in patients with severe impairment of renal function. As a guide, for patients with a serum creatinine of 300 - 600 μMol/Litre, the Atenolol oral dose should be 50mg daily or 100mg once every two days, for patients with a serum creatinine of > 600 μMol/Litre, the Atenolol oral dose should be 50mg on alternate days or 100mg once every four days.

Patients on haemodialysis should be given 50mg Atenolol orally following each dialysis. Because of the possibility of marked falls in blood pressure, this should be carried out under hospital supervision.

Elderly:
Dosage requirements may be reduced, especially in patients with impaired renal function.
Children:
There is no paediatric experience with atenolol and for this reason it is not recommended for use in children.

4.3 CONTRAINDICATIONS
1. Atenolol is contraindicated in patients with second degree or third degree heart block.
2. Atenolol should not be used in patients with severe bradycardia.
3. Uncontrolled or digitalis/diuretic-refractory heart failure.
4. Atenolol should not be used in patients with cardiogenic shock.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Sudden withdrawal of Beta-adrenoceptor blocking agents in patients with ischaemic heart disease may result in the appearance of anginal attacks of increased frequency or severity or deterioration in cardiac state. Discontinuation of therapy should be gradual.

Anaesthesia:
Care should be taken when using anaesthetic agents with Atenolol. The anaesthetist should be informed to enable the necessary precautions to be taken.

Atenolol should only be used with caution in patients with controlled congestive cardiac failure or with a family history of asthma. Evidence of development of either condition should be regarded as a signal to discontinue therapy.

The initial treatment of severe malignant hypertension should be so designed as to avoid sudden reduction in diastolic blood pressure with impairment of autoregulatory mechanisms.

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
1. The beta blocker should only be used with great caution in patients who are receiving concomitant myocardial depressants such as chloroform, lignocaine, procainamide, Beta-adrenoceptor stimulants such as isoprenaline, or verapamil or alpha-adrenoceptor stimulants such as noradrenaline, adrenaline (which reverse the hypotensive effects and increase the vasoconstrictor activities).

2. Neurone blocking agents such as Guanethidine, Reserpine, diuretics and other antihypertensive agents, including the vasodilator group, will have an additive effect on the hypotensive action of the drug.

3. The Beta-blocker may mask the symptoms of thyrotoxicosis.

4. Caution should be exercised when transferring patients from Clonidine to beta-adrenoceptor blocking drugs. If the Beta-blocker and Clonidine are given concurrently, the Clonidine should not be discontinued until several days after withdrawal of the Beta-blocker.

4.6 PREGNANCY AND LACTATION
Atenolol should not be given during pregnancy and lactation unless it is considered essential by the physician.
Atenolol has been used effectively under close supervision for the treatment of hypertension associated with pregnancy. Animal studies do not suggest a teratogenic effect with the drug. There is an accumulation of Atenolol in breast milk. However detrimental effects in the baby during breast feeding have not been reported.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Atenolol may occasionally produce drowsiness, dizziness, light-headedness, blurred vision. Patients should observe caution while driving or performing other tasks requiring alertness.
4.8 UNDESIRABLE EFFECTS
Atenolol is generally well-tolerated, side effects associated with it are infrequent and generally mild. Coldness of the extremities and muscular fatigue may occur and, in isolated cases, bradycardia. Sleep disturbances which are associated with some other Beta-blocking preparations are rare.

There have been reports of skin rashes and/or dry eyes associated with the use of Beta-adrenergic blocking drugs. The reported incidence is small and in most cases the symptoms have cleared when treatment was withdrawn. Discontinuance of the drug should be considered if any such reaction is not otherwise explicable. Cessation of therapy with a Beta-blocker should be gradual.

4.9 OVERDOSE
From first principles, excessive bradycardia may be countered by Atropine 1 - 2 mg intravenously, and if necessary, this may be followed by a Beta-stimulant, such as Isoprenaline 25 micrograms initially, or Orciprenaline 0.5 mg given by slow intravenous injection. Care must be taken to ensure that the blood pressure does not fall too low if the dose of the Beta-receptor agonist has to be increased. Glucagon has also been reported to be useful as a cardiac stimulant in a dose of 10mg intravenously.

5 PHARMACOLOGICAL PROPERTIES
5.1 PHARMACODYNAMIC PROPERTIES
Beta-adrenergic blocking agents (hereafter called Beta-blockers) compete with Beta-adrenergic agonists for available Beta receptor sites. Unselective Beta-blockers inhibit both the Beta, receptors (located chiefly in cardiac muscle) and Beta; receptors (located chiefly in the bronchial and vascular musculature), inhibiting the chronotropic, inotropic and vasodilator responses to Beta-adrenergic stimulation. Atenolol is cardioselective and preferentially inhibits Betal adrenoceptors. Betal selectivity has been confirmed by the inability of Atenolol to reverse the Beta; mediated vasodilating effects of Epinephrine or Isoproterenol. This contrasts with the effect of nonselective Beta-blockers which completely reverse the vasodilating effects of Epinephrine.

Atenolol does not have membrane stabilising effects, little direct myocardial depressant activity and little or no intrinsic sympathomimetic activity.

Clinical response to Beta-blockade includes slowing of sinus heart rate, depressed AV conduction, decreased cardiac output at rest and on exercise, reduction of systolic blood pressure on exercise, reduction of both supine and standing blood pressure, inhibition of Isoproterenol-induced tachycardia and reduction of reflex orthostatic tachycardia.

5.2 PHARMACOKINETIC PROPERTIES
Absorption: Atenolol is consistently absorbed when administered orally; with approximately 50 - 60 % of the dose administered being absorbed. After an oral dose of 100mg a mean peak serum level of 880 ng/ml was reached in approximately 3 hours, declining to approximately 63 ng/ml in 24 hours.

Distribution: Atenolol is widely distributed throughout the body, but only a small amount of the drug reaches the brain, Atenolol is not significantly bound to serum proteins.

In pregnancy, atenolol readily crosses the placenta, the umbilical and maternal serum being approximately equal at birth.

Metabolism: Metabolism of atenolol in man is minimal. In animal studies a hydroxylated compound with minor Beta-blocking activity, has been identified as a minor metabolite of Atenolol, but Atenolol does not appear to be metabolised to a significant extent in man.

Excretion: Atenolol is excreted unchanged, mainly through the kidneys. About 40 - 50 % of a single oral dose is excreted in the urine of healthy subjects. The elimination half-life of Atenolol is approximately 6 - 7 hours.

In renal dysfunction, the elimination of Atenolol is closely related to the glomerular filtration rate, although important accumulation probably only occurs if the glomerular filtration is less than 30 ml/minute.
5.3 PRECLINICAL SAFETY DATA
No further data is presented given the well-known pre-clinical and clinical profile of Atenolol.

6 PHARMACEUTICAL PARTICULARS
6.1 LIST OF EXCIPIENTS
Lactose Monohydrate
Sodium starch glycollate
Magnesium stearate E 572
Microcrystalline cellulose E 460 (i)
Sodium Lauryl Sulphate
Colloidal anhydrous silica
Hypermellose
Ethyl cellulose
Diethylphthalate
Opaspray Orange K-1-2433 (contains E110 (Sunset Yellow FCF) and E171 (Titanium Dioxide)

6.2 INCOMPATIBILITIES
None known.

6.3 SHELF LIFE
Shelf-life unopened container for pack types 1, 2 & 3: 5 years.
Shelf-life for pack type 4: 3 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER
1. Amber glass bottles with closures of LD-polyethylene.
2. Securitaners
3. Blister packs made of clear PVC plastic foil and aluminium foil, hard tempered, laminated against 30g PVC.
4. Blister packs made of 250µm PVC coated with 60gm2 PVdC and 20µm aluminium lidding foil.

Pack sizes 28, 100, and 250

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
No special Instructions

7 MARKETING AUTHORISATION HOLDER
Bristol Laboratories Ltd
Unit 3, Canalside
Northbridge Road
Berkhamsted
Herts
HP4 1EG

8 MARKETING AUTHORISATION NUMBER(S)
PL 17907/0167

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
30/03/2010

10 DATE OF REVISION OF THE TEXT
30/03/2010
PACKAGE LEAFLET: INFORMATION FOR THE USER
ATENOLOL TABLETS 25mg
Active substance: Atenolol

Read all of this leaflet carefully before you start taking this medicine. Even if you have just had a repeat prescription, some of the information in your previous leaflet may have changed.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to other. It may harm them, even if the symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Atenolol Tablets are and what are they used for

The active ingredient, Atenolol, belongs to a group of medicines known as beta-blockers. Atenolol Tablets are prescribed to you for one or more of the following reasons:
- to reduce high blood pressure (hypertension)
- to relieve chest pain (angina pectoris) which is caused by inadequate blood supply to the heart.
- to maintain a regular heart beat and to protect the heart from further damage after a heart attack (myocardial infarction).

2. Before you take Atenolol Tablets

DO NOT take Atenolol Tablets before telling your doctor if you:
- are, or might be pregnant or are breast feeding
- have previously experienced sensitivity to Atenolol or any of the other ingredients in this medicine (these are listed in Section 6, Further Information)
• have low blood pressure or slow heart rate or heart block
• suffer from asthma
• suffer from kidney problems
• have an overactive thyroid gland (thyrotoxicosis)
• Suffer from heart failure which is poorly controlled

Take special care with this medicine if you:
- have a family history of asthma
- suffer from congestive heart failure which is controlled

Taking with other medicines
It is very important that you tell your doctor if you are taking or have taken any of the following medicines, as they may interact with your Atenolol Tablets:
• verapamil, adrenaline (epinephrine), noradrenaline (norepinephrine), isoprenaline, lignocaine, procainamide and clonidine used for the treatment of heart conditions
• water tablets (diuretics) and medicines used for thyroid disease for example thyroxine.
• medicines for coughs, colds, hayfever or sinus problems may increase your blood pressure if they are taken whilst you are receiving Atenolol treatment.

It is very important to tell your doctor if you are taking or have recently taken any other medicines including medicines obtained you may obtain without prescription.
If you have to go to the dentist, hospital or are seen by a different doctor for any reason tell them you are taking atenolol tablets. This is very important if you are likely to have an anaesthetic or an operation.
Tell your pharmacist that you are taking atenolol tablets before buying any other medicines.

Pregnancy and Breastfeeding
It is not recommended to give Atenolol tablets during pregnancy or breastfeeding unless considered essential by your doctor.
Ask your doctor or pharmacist for advice before taking any medicine

Driving and using machines
You should not drive or operate machinery if you experience drowsiness, dizziness, light headedness or blurred vision whilst taking Atenolol.

Important information about some of the ingredients of Atenolol Tablets
These tablets contain lactose if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.
3. How to take Atenolol Tablets

Always take Atenolol tablets exactly as your doctor has told you. If you do not understand these instructions, ask your doctor or pharmacist to explain them to you.

Swallow the tablet with a drink of water. Do not take your medicine more often than directed.

**Adults**

- High Blood Pressure
  The usual dose is two to four tablets, once a day.

- Angina
  The usual dose is 100mg once a day or 50mg twice a day. For example, four tablets once a day, or two tablets twice a day.

- Irregular Heart Beats
  The usual dose is 50mg to 100mg once a day. For example, two to four tablets, once a day.

- After a Heart Attack
  Initial treatment normally consists of an intravenous injection. 15 minutes after the injection you will normally be given 50mg (two 25mg tablets). 12 hours after the injection, you will normally be given 50mg (two 25mg tablets). After a further 12 hours you will be given 100mg (four 25mg tablets). You will need to take 100mg (four 25mg tablets) a day for up to 10 days.

**Elderly**
The above dosages may be reduced especially in patients with impaired renal function.

**Children**

These tablets are not recommended for children.

Your doctor may prescribe a different dose depending on your condition. Your dose may be reduced if you have kidney damage.

**If you take more Atenolol tablets than you should**
If you accidentally take too many tablets contact your doctor or local casualty department as soon as possible.

**If you forget to take Atenolol tablets**
If you forget to take your medicine take it as soon as you remember. If your next dose is due within six hours, do not take the missed dose, but take the next dose at the usual time.
If you stop taking Atenolol tablets
Do not stop taking your medicine without discussing it with your doctor, as sudden withdrawal may cause unwanted effects.

4. Possible Side Effects
Like all medicines Atenolol tablets can cause side effects, although not everybody gets them. You may suffer from coldness of the hands and feet, tiredness, slow heart beat (bradycardia), sleep disturbances have been reported but these are rare. There have been a few reports of skin rashes and/or dry eyes associated with taking Atenolol.

If any of these effects become worse or upsetting, or you experience any other unexpected effects which you think could be due to taking Atenolol tablets, consult your doctor or pharmacist for advice.

5. How to store Atenolol tablets
Keep all medicines out of the reach and sight of children. Your medicines can harm them. Do not use Atenolol tablets after the “expiry” or “use by” date shown on the pack. Keep the medicine in its original container at normal room temperature (below 25°C). Any out of date medicines should be returned to your pharmacist for disposal.

6. Further Information

What Atenolol tablets contain
- The active substance in Atenolol Tablets is Atenolol
- The other ingredients in Atenolol tablets are Lactose Monohydrate, Sodium starch glycollate, Magnesium stearate E 572, Microcrystalline cellulose E 460(i), Sodium Lauryl Sulphate, Colloidal anhydrous silica, Hypermellose, Ethyl cellulose, Diethylphthalate, Opaspray orange K-1-2433 (contains E110 (Sunset yellow FCF) and E171 (Titanium Dioxide)

What Atenolol tablets look like and contents of the pack.
- Atenolol 25 mg tablets are orange, circular, film-coated tablet with convex sides with 'A25' embossed on one side.
- The containers are available in pack size of 100 and 250 tablets
- The blister packs are available in sizes of 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bristol Laboratories Ltd, Unit 3, Canal side, Northbridge Road Berkhamsted, Herts, HP4 1EG
This leaflet was last approved in October 2008.