Public Assessment Report

UKPAR

Thiamine Hydrochloride 50 mg and 100 mg Tablets
(thiamine hydrochloride)

UK Licence No: PL 30464/0136-0137

Athlone Pharmaceuticals Limited
LAY SUMMARY
Thiamine Hydrochloride 50 mg and 100 mg Tablets
(thiamine hydrochloride)

This is a summary of the Public Assessment Report (PAR) for Thiamine Hydrochloride 50 mg and 100 mg Tablets (PL 30464/0136-0137). These medicinal products will be referred to as Thiamine Hydrochloride Tablets in the remainder of this summary, for ease of reading.

This summary explains how Thiamine Hydrochloride Tablets were assessed and their authorisations recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

For practical information about using Thiamine Hydrochloride Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Thiamine Hydrochloride Tablets and what are they used for?
Thiamine Hydrochloride Tablets are ‘generic medicines’. This means that Thiamine Hydrochloride Tablets are similar to ‘reference medicines’ authorised in the UK called Benerva 50 mg and 100 mg Tablets (Bayer PLC: PL 00010/0610-0611).

Thiamine Hydrochloride Tablets are vitamin tablets which contain thiamine (vitamin B₁). They are used to treat thiamine deficiency (when the body does not have enough of the vitamin).

How do Thiamine Hydrochloride Tablets work?
The active substance in Thiamine Hydrochloride Tablets, thiamine hydrochloride, helps the body convert food into fuel (glucose), which is used to produce energy.

How are Thiamine Hydrochloride Tablets used?
Thiamine Hydrochloride Tablets are taken by mouth. The whole tablet should be swallowed with water without chewing.

The recommended dose in adults and children over 12 years of age is as follows:

50 mg:
Mild deficiency: 1-2 tablets once a day
Severe deficiency: 2 tablets 2-3 times a day

100 mg:
Mild deficiency: 1 tablet once a day
Severe deficiency: 1 tablet 2-3 times a day

The Patient should follow the recommendation of a doctor or pharmacist. The tablets can be taken as long as symptoms persist or a dietary supplement is required.

These medicinal products are not recommended in children under 12 years of age.

Thiamine Hydrochloride Tablets can be obtained from a pharmacy.

For further information on how Thiamine Hydrochloride Tablets are used, refer to the Summaries of Product Characteristics or the package leaflet available on the MHRA website.
What benefits of Thiamine Hydrochloride Tablets have been shown in studies?
As Thiamine Hydrochloride Tablets are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines, Benerva 50 mg and 100 mg Tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Thiamine Hydrochloride Tablets?
Because Thiamine Hydrochloride Tablets are generic medicines and are bioequivalent to the reference medicines, Benerva 50 mg and 100 mg Tablets, their benefits and possible side effects are taken as being the same as those of the reference medicines.

For the full list of all side effects reported with Thiamine Hydrochloride Tablets, see section 4 of the package leaflet available on the MHRA website.

Why were Thiamine Hydrochloride Tablets approved?
It was concluded that, in accordance with EU requirements, Thiamine Hydrochloride Tablets have been shown to have comparable quality and to be bioequivalent to Benerva 50 mg and 100 mg Tablets. Therefore, the MHRA decided that, as for Benerva 50 mg and 100 mg Tablets, the benefits of Thiamine Hydrochloride Tablets outweigh the risks and the grant of Marketing Authorisations was recommended.

What measures are being taken to ensure the safe and effective use of Thiamine Hydrochloride Tablets?
A risk management plan (RMP) has been developed to ensure that Thiamine Hydrochloride Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics and the package leaflet for Thiamine Hydrochloride Tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored or reviewed continuously as well.

Other information about Thiamine Hydrochloride Tablets
Marketing Authorisations were granted in the UK on 15th May 2015.

The full PAR for Thiamine Hydrochloride Tablets follows this summary.

For more information about treatment with Thiamine Hydrochloride Tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in July 2015.
TABLE OF CONTENTS

<table>
<thead>
<tr>
<th></th>
<th>Introduction</th>
<th>Page 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Quality aspects</td>
<td>Page 6</td>
</tr>
<tr>
<td>II</td>
<td>Non-clinical aspects</td>
<td>Page 7</td>
</tr>
<tr>
<td>III</td>
<td>Clinical aspects</td>
<td>Page 8</td>
</tr>
<tr>
<td>IV</td>
<td>User consultation</td>
<td>Page 10</td>
</tr>
<tr>
<td>V</td>
<td>Overall conclusion, benefit/risk assessment and recommendation</td>
<td>Page 10</td>
</tr>
</tbody>
</table>

Table of content of the PAR update Page 23
I INTRODUCTION
Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Athlone Pharmaceuticals Limited Marketing Authorisations for the medicinal products Thiamine Hydrochloride 50 mg and 100 mg Tablets (PL 30464/0136-0137). These pharmacy (P) medicines are indicated for the treatment of thiamine deficiencies due to increased dietary requirements, reduced intakes, reduced absorption or increased excretion. They are also used for the treatment of Wernicke-Korsakoff syndrome, beriberi and thiamine deficiency related to chronic alcoholism.

Situations often accompanied by marginal thiamine deficiency and requiring supplementation include but are not limited to:

- Regular heavy drinking / chronic alcohol consumption
- High carbohydrate intakes
- Heavy physical exertion
- Compromised nutritional status
- High dose diuretics
- Type I and Type II diabetes mellitus

These applications were submitted under Article 10(1) of Directive 2001/83/EC, as amended. The applicant has cross-referred to Benerva 50 mg and 100 mg Tablets, which were originally authorised to Bayer PLC (PL 00010/0610-0611) on 13th August 2008.

Thiamine pyrophosphate (TPP), the coenzymatic form of thiamine, is involved in two main types of metabolic reactions: decarboxylation of α-ketoacids (e.g. pyruvate, α-ketoglutarate and branched-chain keto acids) and transketolation (e.g. among hexose and pentose phosphates). Therefore, the principal physiological role of thiamine is as a coenzyme in carbohydrate metabolism, where TPP is required for several stages in the breakdown of glucose to provide energy.

No bioequivalence study was submitted and these applications are based on a Biopharmaceutics Classification System (BCS) class III biowaiver.

No new or unexpected safety concerns arose during the review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of taking Thiamine Hydrochloride 50 mg and 100 mg Tablets outweigh the risks and Marketing Authorisations were granted.
II  QUALITY ASPECTS

II.1  Introduction
These products are tablets and contain 50 mg or 100 mg of thiamine hydrochloride, as active ingredient. The excipients present are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, stearic acid and magnesium stearate. Appropriate justification for the inclusion of each excipient has been provided.

All excipients comply with their respective European Pharmacopoeia monographs. Satisfactory Certificates of Analysis have been provided for these excipients.

The only excipient used that contains material of animal or human origin is lactose monohydrate. The applicant has provided a declaration that the milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as that for human consumption. Confirmation has also been given that the magnesium stearate used in the tablets is of vegetable origin.

The finished product is packed either in white opaque polyvinylchloride (PVC)/polyvinylidene chloride (PVdC)/aluminium foil blisters containing 84 tablets, or in polypropylene snap secure pots each with a high density polyethylene (HDPE)/low density polyethylene (LDPE) closure with a pack size of 100 tablets.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2.  Drug Substance
INN: Thiamine hydrochloride
Chemical name(s): 3-[(4-Amino-2-methylpyrimidin-5-yl)-5-(2-hydroxyl ethyl)-4-methylthiazolium chloride hydrochloride

Structural formula:

![Structural formula of thiamine hydrochloride](image)

Molecular formula:  C_{12}H_{17}ClN_{4}OS, HCl
Molecular mass:  337.3 g/mol
Appearance:  White or almost white, crystalline powder or colourless crystals.
Solubility:  Freely soluble in water, soluble in glycerol and slightly soluble in alcohol.

Thiamine hydrochloride is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, thiamine hydrochloride, are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3.  Medicinal Product
Pharmaceutical Development
The objective of the development programme was to formulate safe, efficacious, stable tablets containing thiamine hydrochloride that are bioequivalent to Benerva 50 mg and 100 mg Tablets (Bayer PLC).
A satisfactory account of the pharmaceutical development has been provided.

Comparative impurity and in-vitro dissolution profiles have been provided for the proposed and originator products.

**Manufacture of the products**
Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing processes. The manufacturing processes have been validated using pilot scale batches that have shown satisfactory results. A commitment has been provided that process validation will be performed on commercial scale batches of each tablet strength.

**Finished Product Specifications**
The finished product specifications are acceptable. The test methods have been described and have been adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for all working standards used.

**Stability of the Products**
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 2 years for the blister pack and the unopened pot with storage conditions ‘Store below 25°C’ and ‘Store in the original package’. Once the pot is opened the tablets should be used within 100 days. These are satisfactory.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**
There are no objections to the approval of these applications from a pharmaceutical point of view.

**III NON-CLINICAL ASPECTS**

**III.1 Introduction**
As the pharmacodynamic, pharmacokinetic and toxicological properties of thiamine hydrochloride are well-known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The applicant’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

**III.2 Pharmacology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.3 Pharmacokinetics**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.4 Toxicology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.5 Environmental Risk Assessment (ERA)**
Since these products are intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.
III.6 Discussion on the non-clinical aspects
No new non-clinical studies were conducted, which is acceptable given that the applications were based on being generic medicinal products of originator products that have been licensed for over 10 years.

There are no objections to the approval of these applications from a non-clinical point of view.

IV CLINICAL ASPECTS
IV.1 Introduction
For these generic applications, the Applicant applied for a Biopharmaceutics Classification System (BCS) based biowaiver. No bioequivalence study was performed.

No new clinical data have been submitted and none are required for applications of this type. A clinical overview has been submitted to justify the biowaiver. The applicant’s clinical overview has been written by an appropriately qualified person and is considered acceptable.

IV.2 BCS Biowaiver
The Applicant applied for a BCS based biowaiver for both tablet strengths. In line with the ‘Note for Guidance on the investigation of bioavailability and bioequivalence’ (CPMP/EWP/QWP/1401/98 Rev 1/Corr**), this was considered acceptable as thiamine hydrochloride is highly soluble with low absorption and low permeability (BCS class III) and is considered to have a wide-therapeutic index with low toxicity. These products are immediate release solid dose preparations for oral use with the same pharmaceutical form as the reference products. Satisfactory data has been submitted to justify the BCS biowaiver.

IV.3 Pharmacokinetics
No new data have been submitted and none are required for applications of this type.

IV.4 Pharmacodynamics
No new data have been submitted and none are required for applications of this type.

IV.5 Clinical efficacy
No new data on efficacy have been submitted and none are required for this type of applications.

IV.6 Clinical safety
No new safety data were submitted and none are required.

IV.7 Risk Management Plan (RMP)
The Marketing Authorisation Holder (MAH) has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Thiamine Hydrochloride 50 mg and 100 mg Tablets.
A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, is listed below:

<table>
<thead>
<tr>
<th>Safety concern</th>
<th>Routine risk minimisation measures</th>
<th>Additional risk minimisation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypersensitivity,</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>Use in patients with</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>the Lapp lactose deficiency</td>
<td>PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>Use with thiamine antagonists</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>Gastrointestinal events</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>Interaction with Laboratory test (false positive results)</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>Overdose</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>Pregnancy and lactation,</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
<tr>
<td>Use in children under 12 years of age</td>
<td>Routine reporting ICSRs, preparation and submission of PSURs and signal detection will be done as per applicable legislation. Warnings are also located in the relevant sections of the SPC and PIL. This product is only available from your pharmacy.</td>
<td>N/A</td>
</tr>
</tbody>
</table>
IV.8 Discussion on the clinical aspects
The grant of Marketing Authorisations is recommended for these applications.

V User consultation
For Thiamine Hydrochloride 50 mg and 100 mg Tablets a user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Calcitriol 0.5 microgram Capsules (Approved Prescription Services Limited). The bridging report submitted by the applicant is acceptable.

The PILs for these products are based on the in-house style used for the PILs for Betahistine Hydrochloride 8 mg and 16 mg Tablets (PL 30464/0019-0020) and Flucloxacillin 250 mg/5 ml Oral solution (PL 30464/0002).

VI Overall conclusion, benefit/risk assessment and recommendation
The quality of the products is acceptable, and no new non-clinical or clinical concerns have been identified. The data provided by the applicant showed that the test products are comparable to the reference products. Extensive clinical experience with thiamine hydrochloride is considered to have demonstrated the therapeutic value of the compound. The benefit risk is, therefore, considered to be positive.
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for Thiamine Hydrochloride 50 mg and 100 mg Tablets is presented below:

<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON &lt;THE OUTER PACKAGING&gt; &lt;AND&gt; &lt;THE IMMEDIATE PACKAGING&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Carton – blister outer]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. NAME OF THE MEDICINAL PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiamine Hydrochloride 50mg Tablets</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. STATEMENT OF ACTIVE SUBSTANCE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each tablet contains 50mg of the active substance thiamine hydrochloride (vitamin B1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. LIST OF EXCIPIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Also contains lactose monohydrate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. PHARMACEUTICAL FORM AND CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>28, 84 Tablets</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. METHOD AND ROUTE(S) OF ADMINISTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>For oral use</td>
</tr>
</tbody>
</table>

DOSAGE: (Adults and children over 12 years of age)
Mild thiamine deficiency: 1-2 tablets once a day.
Severe thiamine deficiency: 2 tablets 2-3 times a day.

The tablets should be swallowed with water. Do not chew the tablets.

<table>
<thead>
<tr>
<th>6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN</th>
</tr>
</thead>
</table>

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

<table>
<thead>
<tr>
<th>7. OTHER SPECIAL WARNING(S), IF NECESSARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>If your condition does not improve, tell your doctor.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. EXPIRY DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXP:</td>
</tr>
</tbody>
</table>

| 9. SPECIAL STORAGE CONDITIONS |
Store below 25°C. Store in the original pack.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PL Holder:
Athlone Pharmaceuticals Limited,
Ballymurray, Co. Roscommon, Ireland.

12. MARKETING AUTHORISATION NUMBER(S)

PL 30464/0136

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

P

15. INSTRUCTIONS ON USE

Read the package leaflet carefully before using this product

16. INFORMATION IN BRAILLE

Thiamine Hydrochloride #50mg Tablets
**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

<table>
<thead>
<tr>
<th>{Blister}</th>
</tr>
</thead>
</table>

| 1. **NAME OF THE MEDICINAL PRODUCT** |
| Thiamine Hydrochloride 50mg Tablets |

| 2. **NAME OF THE MARKETING AUTHORISATION HOLDER** |
| Athlone Pharmaceuticals Ltd. |

| 3. **EXPIRY DATE** |
| EXP: |

| 4. **BATCH NUMBER</DONATION AND PRODUCT CODES>** |
| BN: |

| 5. **OTHER** |
| N/A |
PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{Pot – outer}

1. NAME OF THE MEDICINAL PRODUCT

Thiamine Hydrochloride 50mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 50mg of the active substance thiamine hydrochloride (vitamin B1)

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate

4. PHARMACEUTICAL FORM AND CONTENTS

100 Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use

DOSAGE: (Adults and children over 12 years of age)
Mild thiamine deficiency: 1-2 tablets once a day.
Severe thiamine deficiency: 2 tablets 2-3 times a day.

The tablets should be swallowed with water. Do not chew the tablets.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

If your condition does not improve, tell your doctor.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Store below 25°C. Store in the original pack.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pl. Holder:
Athlone Pharmaceuticals Limited,
Ballymurray, Co. Roscommon, Ireland.

12. MARKETING AUTHORISATION NUMBER(S)

Pl. 30464/0136

13. BATCH NUMBER-, DONATION AND PRODUCT CODES>

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

P

15. INSTRUCTIONS ON USE

Read the package leaflet carefully before using this product.

After opening please use in 100 days
Use by date.....................

16. INFORMATION IN BRAILLE

Thiamine Hydrochloride #50mg Tablets
PAR Thiamine Hydrochloride 50 mg and 100 mg Tablets

PL 30464/0136-0137
PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{Pot – outer }

1. NAME OF THE MEDICINAL PRODUCT

Thiamine Hydrochloride 100mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 50mg of the active substance thiamine hydrochloride (vitamin B₁)

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate

4. PHARMACEUTICAL FORM AND CONTENTS

100 Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use

**DOSAGE:** (Adults and children over 12 years of age)
Mild thiamine deficiency: 1 tablet once a day.
Severe thiamine deficiency: 1 tablet 2-3 times a day.

The tablets should be swallowed with water. Do not chew the tablets.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**

7. OTHER SPECIAL WARNING(S), IF NECESSARY

If your condition does not improve, tell your doctor.

8. EXPIRY DATE

**EXP:**

9. SPECIAL STORAGE CONDITIONS

Store below 25°C. Store in the original pack.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PL Holder:
Athlone Pharmaceuticals Limited,
Ballymurray, Co. Roscommon, Ireland.

12. MARKETING AUTHORISATION NUMBER(S)

PL 30464/0137

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

P

15. INSTRUCTIONS ON USE

Read the package leaflet carefully before using this product.

After opening please use in 100 days
Use by date.....................

16. INFORMATION IN BRAILLE

Thiamine Hydrochloride #100mg Tablets
MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

| Blister |

1. **NAME OF THE MEDICINAL PRODUCT**

Thiamine Hydrochloride 100mg Tablets

2. **NAME OF THE MARKETING AUTHORIZATON HOLDER**

Athlone Pharmaceuticals Ltd.

3. **EXPIRY DATE**

EXP:

4. **BATCH NUMBER<, DONATION AND PRODUCT CODES>**

BN:

5. **OTHER**

N/A
Thiamine Hydrochloride Tablets 100mg

Each tablet contains 100mg of the active substance thiamine hydrochloride (vitamin B1). Also contains lactose monohydrate. For oral use. The tablets should be swallowed with water. Do not chew the tablets.

Read the package leaflet carefully before using this product.

DOSAGE:
- Adults and children over 12 years of age: mild thiamine deficiency: 1 tablet once a day. Severe thiamine deficiency: 1 tablet 2-3 times a day. If your condition does not improve, tell your doctor.
- Store below 25°C. Store in the original pack.

PL Holder:
Ashline Pharmaceuticals Limited,
Ballymurray Co. Roscommon, Ireland.

Distributor:
Kent Pharmaceuticals Limited,
Rapton Road, Maidstone, ME12 7DT, U.K.
**Table of content of the PAR update**

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitment)

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>