Gabapentin Zentiva 600mg film-coated tablets  
(gabapentin)  
PL 17780/0421

Gabapentin Zentiva 800mg film-coated tablets  
(gabapentin)  
PL 17780/0422

UK Public Assessment Report

TABLE OF CONTENTS

Lay Summary  Page 2
Scientific discussion  Page 4
Steps taken for assessment  Page 13
Steps taken after authorisation  Page 14
Summary of Product Characteristics  Page 15
Product Information Leaflet  Page 15
Labelling  Page 16
LAY SUMMARY

Gabapentin Zentiva 600mg film-coated tablets
Gabapentin Zentiva 800mg film-coated tablets
(gabapentin)

This is a summary of the public assessment report (PAR) for Gabapentin Zentiva 600mg film-coated tablets (PL 17780/0421) and Gabapentin Zentiva 800mg film-coated tablets (PL 17780/0422). It explains how Gabapentin Zentiva 600mg and 800mg film-coated tablets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Gabapentin Zentiva 600mg and 800mg film-coated tablets.

For practical information about using Gabapentin Zentiva 600mg and 800mg film-coated tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Gabapentin Zentiva 600mg and 800mg film-coated tablets and what are they used for?

Gabapentin Zentiva 600mg and 800mg film-coated tablets are ‘generic medicines’. This means that Gabapentin Zentiva 600mg and 800mg film-coated tablets are similar to ‘reference medicines’ already authorised in the European Union (EU) called Neurontin 600mg Tablets and Neurontin 800mg Tablets.

Gabapentin Zentiva 600mg and 800mg film-coated tablets are used to treat epilepsy and to relieve long lasting pain caused by damage to the nerves (known as neuropathic pain).

How are Gabapentin Zentiva 600mg and 800mg film-coated tablets used?
The dose of Gabapentin will usually be built up gradually. For the treatment of neuropathic pain and for the treatment of epilepsy in adults and adolescents over 12 years old, the usual starting dose is generally between 300mg and 900 mg each day. If a lower dose than 600mg is prescribed, a pharmacist will give the patient the adapted dosage. Thereafter, the dose may be increased progressively to a maximum of 3600mg each day. Gabapentin should be taken in three divided doses i.e. once in the morning, once in the afternoon and once in the evening.

For the treatment of epilepsy in children aged 6 years old and older, the dose will be calculated based upon the child’s weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days. The usual dose to control epilepsy is 25-35 mg/kg/day. It is usually given in 3 divided doses, by taking the tablet(s) each day, usually once in the morning, once in the afternoon and once in the evening. Gabapentin is not recommended for use in children under 6 years old.

These medicines can only be obtained with a prescription.

How do Gabapentin Zentiva 600mg and 800mg film-coated tablets work?
These medicinal products contain the active ingredient gabapentin, which belongs to a group of medicines called anti-epileptics. Gabapentin helps to control electrical activity in the brain.

How have Gabapentin Zentiva 600mg and 800mg film-coated tablets been studied?
Because Gabapentin Zentiva 600mg and 800mg film-coated tablets are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the
reference medicines, Neurontin 600mg Tablets and Neurontin 800mg Tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Gabapentin Zentiva 600mg and 800mg film-coated tablets?
Because Gabapentin Zentiva 600mg and 800mg film-coated tablets are generic medicines that are bioequivalent to the reference medicines, their benefits and risks are taken as being the same as the reference medicines.

Why are Gabapentin Zentiva 600mg and 800mg film-coated tablets approved?
It was concluded that, in accordance with EU requirements Gabapentin Zentiva 600mg and 800mg film-coated tablets have been shown to have comparable quality and to be bioequivalent to Neurontin 600mg Tablets and Neurontin 800mg Tablets. Therefore, the view was that, as for Neurontin 600mg Tablets and Neurontin 800mg Tablets, the benefit outweighs the identified risk.

What measures are being taken to ensure the safe and effective use of Gabapentin Zentiva 600mg and 800mg film-coated tablets?
Safety information has been included in the Summary of Product Characteristics and the package leaflet for Gabapentin Zentiva 600mg and 800mg film-coated tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Gabapentin Zentiva 600mg and 800mg film-coated tablets
The MHRA agreed to grant Marketing Authorisations for Gabapentin 600mg film-coated tablets/Dolevor 600mg film-coated tablets (PL 06506/0007) and Gabapentin 800mg film-coated tablets/Dolevor 800mg film-coated tablets (PL 06506/0008) to Zambon Group Spa on 14 August 2008. The licences subsequently underwent a Change of Ownership to Winthrop Pharmaceuticals UK Limited (trading as Zentiva) on 08 September 2008 (PLs 17780/0421 and 17780/0422, respectively).

On 10 February 2014 variations were granted to change the names of the products from Gabapentin 600mg and 800mg film-coated tablets to Gabapentin Zentiva 600mg and 800mg film-coated tablets. Subsequently, on 20 March 2014, variations were granted to delete the names Dolevor 600mg film-coated tablets and Dolevor 800mg film-coated tablets from the licences. Throughout the rest of this PAR the original names of Gabapentin 600mg film-coated tablets/Dolevor 600mg film-coated tablets and Gabapentin 800mg film-coated tablets/Dolevor 800mg film-coated tablets are used.

The full PAR for Gabapentin Zentiva 600mg and 800mg film-coated tablets follows this summary. For more information about treatment with Gabapentin Zentiva 600mg and 800mg film-coated tablets, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in April 2014.
Gabapentin Zentiva 600mg film-coated tablets
(gabapentin)
PL 17780/0421

Gabapentin Zentiva 800mg film-coated tablets
(gabapentin)
PL 17780/0422

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>5</td>
</tr>
<tr>
<td>Pharmaceutical assessment</td>
<td>6</td>
</tr>
<tr>
<td>Preclinical assessment</td>
<td>9</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>9</td>
</tr>
<tr>
<td>Overall conclusion and risk benefit assessment</td>
<td>12</td>
</tr>
</tbody>
</table>
INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Zambon Group Spa Marketing Authorisations for the medicinal products Gabapentin 600mg film-coated tablets/Dolevor 600mg film-coated tablets (PL 06506/0007) and Gabapentin 800mg film-coated tablets/Dolevor 800mg film-coated tablets (PL 06506/0008) on 14th August 2008. The licences subsequently underwent Change of Ownership to Winthrop Pharmaceuticals UK Limited on 8th September 2008, as PLs 17780/0421 and 17780/0422 respectively. The products are prescription-only medicines.

These are abridged applications for Gabapentin 600mg film-coated tablets/Dolevor 600mg film-coated tablets and Gabapentin 800mg film-coated tablets / Dolevor 800mg film-coated tablets. These are two strengths of Gabapentin, submitted under Article 10.1 of Directive 2001/83/EC, as amended, claiming to be generic medicinal products of the reference products Neurontin Tablets 600mg and Neurontin Tablets 800mg (PL 00019/0192 & 0193) respectively, granted to Warner Lambert (UK) Ltd on 26/11/1999. The original product is stated as Neurontin 400mg Capsules (PL 00019/0174, Warner Lambert (UK) Ltd) which was licensed in December 1997 in the UK. This was a change in ownership from PL 00018/0204 (Parke Davis & Company Limited) which was licensed in February 1993. The original product has been authorised in the UK for more than 10 years, so the period of data exclusivity has expired.

The active ingredient, gabapentin, belongs to the pharmacotherapeutic group of drugs called ‘other anti-epileptics’ that are structurally related to the neurotransmitter gamma-aminobutyric acid (GABA). The products are indicated for the treatment of neuropathic pain and epilepsy.

These applications for Gabapentin/Dolevor 600mg and 800mg film-coated tablets were submitted at the same time and depend on the bioequivalence studies presented comparing the applicant’s test 600mg and 800mg strength products with the reference products Neurontin 600mg and 800mg Tablets, Parke Davis (Germany). Consequently, all sections of the Scientific Discussion refer to both products.

On 10 February 2014 variations were granted to change the names of the products from Gabapentin 600mg and 800mg film-coated tablets to Gabapentin Zentiva 600mg and 800mg film-coated tablets. Subsequently, on 20 March 2014 variations were granted to delete the names Dolevor 600mg film-coated tablets and Dolevor 800 mg film-coated tablets from the licences.
ACTIVE SUBSTANCE

Gabapentin

Nomenclature:
INN: Gabapentin
Chemical name: 1-(aminomethyl)cyclohexanecetic acid
Structure:

\[
\begin{align*}
H_2N & \\
& \\
& \\
& \\
& \\
& \\
\end{align*}
\]

Molecular formula: C_{19}H_{17}NO_{2}
Molecular weight: 171.24
CAS No: 60142-96-3
Physical form: White to almost white crystalline powder

The active substance, gabapentin, is not the subject of a European Pharmacopeia (EP) monograph.

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specifications are in place for all starting materials and reagents and these are supported by relevant Certificates of Analysis. Confirmation has been provided that the raw materials, intermediates and auxiliary agents used in synthesis of the active are not of animal or biological origin, and therefore comply with the TSE requirements.

An appropriate specification has been provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analysis data are provided and comply with the proposed specification. Satisfactory Certificates of Analysis have been provided for reference standards used by the active substance manufacturer during validation studies.

The active substance is stored in appropriate packaging. It is packed in transparent, double HDPE (high density polyethylene) bags. Each bag is tied with a plastic tie and placed into a fibre drum. Specifications and Certificates of Analysis have been provided for the packaging materials used. The polythene bags in direct contact with the active substance satisfy Directive 2002/72/EC (as amended), and are suitable for contact with foodstuffs.

Appropriate stability data have been generated for the active substance stored in the proposed packaging. These data demonstrate the stability of the active substance and an appropriate retest period has been set.

DRUG PRODUCT

Description and Composition
Gabapentin/Dolevor 600mg and 800mg film-coated tablets are white, capsule-shaped, film-coated tablets, containing 600mg or 800mg of the active ingredient, Gabapentin.

Other ingredients consist of pharmaceutical excipients, namely macrogol 4000, pregelatinised starch, colloidal anhydrous silica, and magnesium stearate making up the tablet cores; and polyvinyl alcohol, titanium dioxide (E171), talc, lecithin and xanthan gum making up the film-coat. Appropriate justification for the inclusion of each excipient has been provided.

All excipients used comply with their respective European Pharmacopoeia monograph, apart from lecithin, which complies with the National Formulary (NF). Satisfactory Certificates of Analysis have been provided for all excipients.

The magnesium stearate is of vegetable origin. There are no excipients containing material of animal or human origin.

There were no novel excipients used and no overages.

**Dissolution and impurity profiles**

Dissolution profiles for the applicant’s test products (Gabapentin/Dolevor 600mg and 800mg film-coated tablets) were found to be similar to those for the equivalent reference products and the products used in the bioequivalence study, and were satisfactory.

Impurity profiles for Gabapentin / Dolevor 600mg and 800mg film-coated tablets were similar, and impurities were within the specification limits.

**Pharmaceutical development**

Details of the pharmaceutical development of the drug products have been supplied and are satisfactory.

**Manufacture**

A description and flow-chart of the manufacturing method has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation studies have been conducted and are satisfactory.

**Finished product specification**

The finished product specifications proposed for both release and shelf life are acceptable, and provide an assurance of the quality and consistency of the finished products. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specifications. Certificates of Analysis have been provided for any reference standards used.

**Container Closure System**

The tablets are packaged in ‘Bulk packaging’ polyethylene bags which conform to Directive 2002/72/EC.

The finished product is marketed in PVC (polyvinylchloride) / aluminium blister strips, which are placed with the Patient Information Leaflet (PIL) into cardboard outer cartons. The
product is packaged in carton pack sizes of 50, 90, 100 and 200 film-coated tablets. The MA Holder has stated that not all pack sizes may be marketed.

Specifications and Certificates of Analysis for all packaging components used have been provided. These are satisfactory. All primary product packaging complies with EU legislation, Directive 2002/72/EC (as amended), and is suitable for contact with foodstuffs.

**Stability**

Finished product stability studies have been conducted in accordance with current guidelines and results were within the proposed specification limits. Based on the results, a shelf-life of 12 months has been set for the marketed packs, which is satisfactory. Storage conditions are “Store below 25°C”.

**Bioequivalence Study**

Two bioequivalence studies were presented. One compared the test product, Gabapentin/Dolevor 600mg film-coated tablets to the reference product, Neurontin 600mg Tablets (Parke Davis, Germany). The second compared the test product, Gabapentin/Dolevor 800mg film-coated tablets to the reference product, Neurontin 800mg Tablets (Parke Davis, Germany).

An evaluation of the bioequivalence studies is found in the Clinical Assessment section.

**Expert Report**

A satisfactory quality overview is provided, and has been prepared by an appropriately qualified expert. An appropriate CV for the expert has been supplied.

**Product Information**

The approved SmPCs and text versions of the leaflet and labelling are satisfactory. No PIL or label mock-ups have been provided for these products. In accordance with medicines legislation, the products shall not be marketed in the UK until approval of the label and leaflet mock-ups has been obtained.

**Conclusion**

The test products are pharmaceutically equivalent to the reference products which have been licensed in the UK for over 10 years. The drug products correspond to the current EU definition of a generic medicinal product because they comply with the criteria of having the same qualitative and quantitative composition in terms of the active substance and pharmaceutical form. On this basis, and considering the bioequivalence data provided, the applicant’s claim that Gabapentin/Dolevor 600mg and 800mg film-coated tablets are generic medicinal products of Neurontin 600mg and 800mg Tablets is justified.

All pharmaceutical issues have been resolved and the quality grounds for these applications are considered adequate. Marketing Authorisations were, therefore, granted.
PRECLINICAL ASSESSMENT

These abridged applications for Gabapentin/Dolevor 600mg and 800mg film-coated tablets were submitted according to Article 10.1 of Directive 2001/83/EC, as amended.

No new preclinical data have been supplied with these applications and none are required for applications of this type. A preclinical overview has been written by a suitably qualified expert and is satisfactory.

CLINICAL ASSESSMENT

INDICATIONS
Gabapentin/Dolevor 600mg and 800mg film-coated tablets are indicated for the treatment of epilepsy and neuropathic pain.

The indications are identical to those for the reference products and are satisfactory.

POSOLOGY AND METHOD OF ADMINISTRATION
The posology is consistent with that for the reference products and is satisfactory.

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

CLINICAL PHARMACOLOGY

Pharmacodynamics
Gabapentin is structurally related to the neurotransmitter \( \gamma \)-aminobutyric acid (GABA) but its mechanism of action differs from that of several active substances which interact with GABA synapses.

Pharmacokinetics
Absorption: Mean plasma gabapentin concentrations (\( C_{\text{max}} \)) occur at approximately 3 hours (\( T_{\text{max}} \)) following single oral doses of gabapentin regardless of dose size or formulation. Mean \( C_{\text{max}} \) and AUC values increase with escalating dose, although the increase is less than dose proportional.

Based on the results of bioavailability studies performed with gabapentin tablets, 600 and 800mg tablets are bioequivalent to gabapentin capsules. 600mg gabapentin tablets were found to be bioequivalent to 2 x 300mg capsules based on a similar rate and extent of drug absorption. Likewise, 800mg tablets were found to be bioequivalent to 2 x 400mg capsules.

Distribution: Gabapentin does not bind to plasma protein and has a volume of distribution of approximately 57.7 litres.

Metabolism: Gabapentin is not metabolised in humans and does not induce hepatic mixed function oxidase enzymes.
Elimination: Gabapentin elimination from plasma following IV administration is described by linear pharmacokinetics, with the elimination half-life ($t_{1/2}$) ranging from 5 to 7 hours.

Renal clearance is the sole elimination pathway for gabapentin, and as gabapentin is not metabolised in humans the amount of gabapentin recovered in urine is indicative of its bioavailability. Renal function (as determined by creatinine clearance) decreases with increasing age, therefore gabapentin oral clearance, renal clearance and elimination-rate constant decrease proportionally.

Bioequivalence studies

The applicant has presented two bioequivalence studies; one comparing the test product, Gabapentin 600mg film-coated tablets, to the reference product, Neurontin 600mg tablets (Parke-Davis, Germany); and the other comparing the test product, Gabapentin 800mg film-coated tablets, to the reference product, Neurontin 800mg tablets (Parke-Davis, Germany). The studies were of an appropriate design and were conducted to principles of Good Clinical Practice.

The studies were both of an open label, single dose, randomised, two-period, crossover design and were conducted in healthy, human subjects (22 subjects for the 600mg tablets study and 24 subjects for the 800mg tablets study) under fasting conditions. Single oral doses were separated by a washout period of 14 days. Blood samples were collected pre-dose and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48 and 60 hours post-dose in each period. Plasma samples were analysed for gabapentin using an appropriate, validated method.

The AUC$_{0-t}$, AUC$_{0-\infty}$, AUC/AUC$_{\infty}$, C$_{\text{max}}$, t$_{\text{max}}$, half-life pharmacokinetic parameters were calculated for plasma gabapentin. Statistical evaluation was performed for AUC$_{0-t}$, AUC$_{0-\infty}$, and C$_{\text{max}}$ with ANOVA and the 90% confidence intervals for the ratio of test formulation over the reference formulation were calculated. The results are summarised in the following tables.

Pharmacokinetic results of gabapentin for a randomised single dose crossover study between the test and reference product – 600mg strength. Log transformed. ANOVA. N = 22 healthy adult subjects, dosed fasted. 14 day washout period

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>RATIO T/R (%)</th>
<th>90% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC$_{0-t}$</td>
<td>103.70</td>
<td>95.80-112.20</td>
</tr>
<tr>
<td>AUC$_{0-\infty}$</td>
<td>103.20</td>
<td>95.70-111.40</td>
</tr>
<tr>
<td>C$_{\text{max}}$</td>
<td>101.50</td>
<td>92.40-111.40</td>
</tr>
</tbody>
</table>

Pharmacokinetic results of gabapentin for a randomised single dose crossover study between the test and reference product – 800mg strength. Log transformed. ANOVA. N = 24 healthy adult subjects, dosed fasted. 14 day washout period

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>RATIO T/R (%)</th>
<th>90% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC$_{0-t}$</td>
<td>96.00</td>
<td>85.90-107.20</td>
</tr>
<tr>
<td>AUC$_{0-\infty}$</td>
<td>96.40</td>
<td>86.50-107.40</td>
</tr>
<tr>
<td>C$_{\text{max}}$</td>
<td>92.20</td>
<td>80.90-105.20</td>
</tr>
</tbody>
</table>
The 90% confidence intervals for the parameters AUC$_0$-$t$, AUC$_{\text{inf}}$, and $C_{\text{max}}$ are within the CPMP acceptance criteria of 80-125% for inferring bioequivalence. Based on these results, it is concluded that the applicant’s Gabapentin 600mg and 800mg film-coated tablets are bioequivalent to their respective reference products, Neurontin 600mg and 800mg tablets (Parke-Davis, Germany).

**Efficacy**

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

Efficacy is reviewed in the clinical overview. The reference products are established and the applications depend upon the bioequivalence studies.

**Safety**

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

Safety is reviewed in the clinical overview. The reference products are established and the applications depend upon the bioequivalence studies.

**EXPERT REPORT**

A satisfactory clinical overview is provided, and has been prepared by an appropriately qualified expert. An appropriate CV for the expert has been supplied.

**PRODUCT INFORMATION:**

**Summary of Product Characteristics (SmPC)**

The approved SmPCs are consistent with those for the reference products and are satisfactory.

**Patient Information Leaflet (PIL)**

The PIL is in line with the approved SmPCs and is satisfactory.

**Labelling**

The labelling is satisfactory.

**CONCLUSIONS**

All issues have been adequately addressed by the applicant. The bioequivalence studies were of an appropriate design and demonstrate the bioequivalence of the test (Gabapentin 600mg and 800mg film-coated tablets) and reference (Neurontin 600mg and 800mg tablets) products within general acceptance limits.

Sufficient clinical information has been submitted to support these applications. Marketing Authorisations were, therefore, recommended to be granted on medical grounds.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Gabapentin/Dolevor 600mg and 800mg film-coated tablets are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

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

EFFICACY

Bioequivalence has been demonstrated between the applicant’s Gabapentin 600mg and 800mg film-coated tablets, and their respective reference products Neurontin 600mg and 800mg tablets (Parke-Davis, Germany).

No new or unexpected safety concerns arise from these applications.

PRODUCT LITERATURE

The SmPCs and text versions of the PIL and labelling are satisfactory and consistent with those for Neurontin 600mg and 800mg tablets. No PIL or label mock-ups have been provided for these products. In accordance with medicines legislation, the products shall not be marketed in the UK until approval of the label and leaflet mock-ups has been obtained.

A 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 it contains.

RISK BENEFIT ASSESSMENT

The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The bioequivalence studies support the claim that the applicant’s products and their respective reference products are interchangeable. Extensive clinical experience with gabapentin is considered to have demonstrated the therapeutic value of the active substance. The risk: benefit is, therefore, considered to be positive.
Gabapentin Zentiva 600mg film-coated tablets
(gabapentin)
PL 17780/0421

Gabapentin Zentiva 800mg film-coated tablets
(gabapentin)
PL 17780/0422

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the marketing authorisation applications for PL 06506/0007 & 0008 on 30\textsuperscript{th} March 2005.

2. Following standard checks and communication with the applicant the MHRA considered the applications valid on 21\textsuperscript{st} April 2005.

3. Following assessment of the applications, the MHRA requested further information relating to the quality dossiers on 27\textsuperscript{th} February 2006 and 18\textsuperscript{th} April 2007.

4. The applicant responded to the MHRA’s requests, providing further information for the quality sections on 16\textsuperscript{th} October 2006 and 31\textsuperscript{st} October 2007 respectively.

5. The applications PL 06506/0007 & 0008 were determined on 14\textsuperscript{th} August 2008.

Gabapentin Zentiva 600mg film-coated tablets
(gabapentin)
PL 17780/0421

Gabapentin Zentiva 800mg film-coated tablets
(gabapentin)
PL 17780/0422

**STEPS TAKEN AFTER AUTHORISATION - SUMMARY**

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>19/12/2013</td>
<td>IB</td>
<td>To update sections 4.8 and 5.2 of the SmPC in line with reference product; to update section 4.2 of the SmPC to correct a typographical error; and to remove the product names Dolevor 600mg &amp; 800mg film-coated tablets from section 1. As a consequence, the leaflet has been updated.</td>
<td>Granted: 20/03/2014</td>
</tr>
</tbody>
</table>

SUMMARY OF PRODUCT CHARACTERISTICS
The current approved UK versions of the Summaries of Product Characteristics (SmPCs) for these products are available on the MHRA website.

PATIENT INFORMATION LEAFLET
The current approved UK versions of the Patient Information Leaflets (PILs) for these products are available on the MHRA website.
LABELLING

The following text is the approved label text for Gabapentin Zentiva 600mg film-coated tablets (PL 17780/0421). No label mock-ups have been provided for this product. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock ups has been obtained.

<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON THE OUTER PACKAGING (CARTON)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. NAME OF THE MEDICINAL PRODUCT</td>
</tr>
<tr>
<td>Gabapentin Zentiva 600mg film-coated tablets</td>
</tr>
<tr>
<td>2. STATEMENT OF ACTIVE SUBSTANCE(S)</td>
</tr>
<tr>
<td>Each film-coated tablet contains 600mg of gabapentin</td>
</tr>
<tr>
<td>3. LIST OF EXCIPIENTS</td>
</tr>
<tr>
<td>4. PHARMACEUTICAL FORM AND CONTENTS</td>
</tr>
<tr>
<td>100 Capsules</td>
</tr>
<tr>
<td>5. METHOD AND ROUTE(S) OF ADMINISTRATION</td>
</tr>
<tr>
<td>For oral administration</td>
</tr>
<tr>
<td>6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN</td>
</tr>
<tr>
<td>Keep out of the reach and sight of children</td>
</tr>
<tr>
<td>Please read the enclosed leaflet carefully before use</td>
</tr>
<tr>
<td>7. OTHER SPECIAL WARNING(S), IF NECESSARY</td>
</tr>
<tr>
<td>8. EXPIRY DATE</td>
</tr>
<tr>
<td>EXP MM/YYYY</td>
</tr>
<tr>
<td>9. SPECIAL STORAGE CONDITIONS</td>
</tr>
<tr>
<td>Store below 25°C.</td>
</tr>
<tr>
<td>10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE</td>
</tr>
<tr>
<td>11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</td>
</tr>
<tr>
<td>Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK</td>
</tr>
</tbody>
</table>

Zentiva is a registered trademark
12. **MARKETING AUTHORISATION NUMBER(S)**

PL 17780/0421

13. **BATCH NUMBER**

BN xxxx

14. **GENERAL CLASSIFICATION FOR SUPPLY**

POM

15. **INSTRUCTIONS ON USE**

Use as directed by your doctor.

16. **INFORMATION IN BRAILLE**

Gabapentin Zentiva 600mg film-coated tablets

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

1. **NAME OF THE MEDICINAL PRODUCT**

Gabapentin Zentiva 600mg film-coated tablets

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

Zentiva

3. **EXPIRY DATE**

EXP MM/YYYY

4. **BATCH NUMBER**

BN xxxx
The following text is the approved label text for Gabapentin Zentiva 800mg film-coated tablets (PL 17780/0422). No label mock-ups have been provided for this product. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock ups has been obtained.

<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON THE OUTER PACKAGING</th>
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<tbody>
<tr>
<td>(CARTON)</td>
</tr>
</tbody>
</table>

1. **NAME OF THE MEDICINAL PRODUCT**

Gabapentin Zentiva 800mg film-coated tablets

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Each film-coated tablet contains 800mg of gabapentin

3. **LIST OF EXCIPIENTS**

4. **PHARMACEUTICAL FORM AND CONTENTS**

100 Capsules

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral administration.

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

Keep out of the reach and sight of children

Please read the enclosed leaflet carefully before use.

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

8. **EXPIRY DATE**

EXP MM/YYYY

9. **SPECIAL STORAGE CONDITIONS**

Store below 25°C.

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**

Zentiva, One Ouslow Street, Guildford, Surrey, GU1 4YS, UK

Zentiva is a registered trademark
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<table>
<thead>
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<tbody>
<tr>
<td>12.</td>
<td><strong>MARKETING AUTHORISATION NUMBER(S)</strong></td>
</tr>
<tr>
<td>PL</td>
<td>17780/0422</td>
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<tr>
<td>13.</td>
<td><strong>BATCH NUMBER</strong></td>
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<tr>
<td>BN</td>
<td>xxxx</td>
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<td>14.</td>
<td><strong>GENERAL CLASSIFICATION FOR SUPPLY</strong></td>
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<td>POM</td>
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<td>15.</td>
<td><strong>INSTRUCTIONS ON USE</strong></td>
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<tr>
<td>Use as directed by your doctor.</td>
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<tr>
<td>16.</td>
<td><strong>INFORMATION IN BRAILLE</strong></td>
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<tr>
<td>Gabapentin Zentiva 800mg film-coated tablets</td>
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**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

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<tbody>
<tr>
<td>1.</td>
<td><strong>NAME OF THE MEDICINAL PRODUCT</strong></td>
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<td>Gabapentin Zentiva 800mg film-coated tablets</td>
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<td>2.</td>
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<td>Zentiva</td>
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<td>3.</td>
<td><strong>EXPIRY DATE</strong></td>
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<td>EXP MM/YYYY</td>
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<td>BN XXXX</td>
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Annex 1

Reference: PL 17780/0421-0046
           PL 17780/0422-0047
Product:  Gabapentin Zentiva 600 mg film-coated tablets
           Gabapentin Zentiva 800 mg film-coated tablets
Marketing Authorisation Holder: Winthrop Pharmaceuticals UK Limited (trading as Zentiva)
Active Ingredient(s): Gabapentin

Reason:
To update sections 4.8 and 5.2 of the SmPC in line with reference product; to update section 4.2 of the SmPC to correct a typographical error; and to remove the product name Dolevor 600mg & 800mg film-coated tablets from section 1 of the SmPC. As a consequence, the leaflet has been updated.

Supporting Evidence
Revised SmPC fragments and a revised Patient information leaflet (PIL) have been provided.

Evaluation
The amended sections of the SmPC and the amended PIL are satisfactory.

The current approved UK versions of the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflet (PIL) for these products are available on the MHRA website.

Decision
Approved on 20 March 2014.