

Public Assessment Report

Scientific discussion

**Eletriptan Viatris 20 mg and 40 mg, film-coated
tablets**

(eletriptan hydrobromide)

NL/H/4584/001-002/DC

Date: 1 March 2023

This module reflects the scientific discussion for the approval of Eletriptan Viatris 20 mg and 40 mg, film-coated tablets. The procedure was finalised in the United Kingdom (UK/H/5351/001-002/DC). After a transfer in 2018, the current RMS is the Netherlands. The report presented below reflects the original procedure at the time of finalisation in the UK and has not been changed or updated since.

Public Assessment Report

Decentralised Procedure

**ELETRIPTAN 20 MG FILM-COATED TABLETS
ELETRIPTAN 40 MG FILM-COATED TABLETS**

(eletriptan hydrobromide)

Procedure No: UK/H/5351/001-002/DC

UK Licence No: PL 00057/1491-1492

Pfizer Limited

LAY SUMMARY

Eletriptan 20 mg film-coated tablets
Eletriptan 40 mg film-coated tablets
(eletriptan hydrobromide)

This is a summary of the public assessment report (PAR) for Eletriptan 20 mg film-coated tablets (PL 00057/1491) and Eletriptan 40 mg film-coated tablets (PL 00057/1492). It explains how Eletriptan 20 mg and 40 mg 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 Eletriptan 20 mg and 40 mg film-coated tablets.

For practical information about using Eletriptan 20 mg and 40 mg film-coated tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Eletriptan 20 mg and 40 mg film-coated tablets and what are they used for?

Eletriptan 20 mg and 40 mg film-coated tablets are 'generic medicines'. This means that Eletriptan 20 mg and 40 mg film-coated tablets are similar to 'reference medicines' already authorised in the European Union (EU) called Relpax 20 mg and 40 mg film-coated tablets.

Eletriptan 20 mg and 40 mg film-coated tablets are used to treat migraine headache with or without aura in adults. Before the start of a migraine headache, some people may experience a phase called an aura, which can involve vision disorders, numbness and speech disorders.

How are Eletriptan 20 mg and 40 mg film-coated tablets used?

Eletriptan 20 mg and 40 mg film-coated tablets can be taken at any time after the start of the migraine headache, but it is best to take them as soon as possible. Eletriptan tablets should only be taken during the headache phase of the migraine and should not be taken to prevent a migraine attack.

The usual starting dose in adults is one 40 mg tablet. The tablet should be swallowed whole with a drink of water. If the first tablet does not relieve the migraine, a second tablet should not be taken for the same attack. If after taking the first tablet the migraine is relieved and then comes back, a second tablet may be taken. However, at least two hours must have passed before taking the second tablet. No more than 80 mg (2 x 40 mg tablets) should be taken within 24 hours.

These medicines can only be obtained with a prescription.

How do Eletriptan 20 mg and 40 mg film-coated tablets work?

Eletriptan 20 mg and 40 mg film-coated tablets contain the active ingredient eletriptan in a form known as the hydrobromide form. Eletriptan is one of a group of medicines called serotonin receptor agonists. Serotonin is a natural substance found in the brain that helps to narrow the blood vessels.

How have Eletriptan 20 mg and 40 mg film-coated tablets been studied?

The company provided data from the published literature on eletriptan hydrobromide. No additional studies were needed as Eletriptan 20 mg and 40 mg film-coated tablets are identical to the reference medicines and the licences are held by the same Marketing Authorisation Holder (Pfizer Limited).

What are the benefits and risks of Eletriptan 20 mg and 40 mg film-coated tablets?

Because Eletriptan 20 mg and 40 mg film-coated tablets are generic medicines that are identical to the reference medicines, their benefits and risks are taken as being the same as the reference medicines.

Why are Eletriptan 20 mg and 40 mg film-coated tablets approved?

It was concluded that, in accordance with EU requirements, Eletriptan 20 mg and 40 mg film-coated tablets have been shown to have comparable quality and to be comparable to Relpax 20 mg and 40 mg

film-coated tablets. Therefore, the view was that, as for Relpax 20 mg and 40 mg film-coated tablets, the benefit outweighs the identified risk.

What measures are being taken to ensure the safe and effective use of Eletriptan 20 mg and 40 mg film-coated tablets?

A risk management plan has been developed to ensure that Eletriptan 20 mg and 40 mg film-coated tablets are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Eletriptan 20 mg and 40 mg film-coated tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Eletriptan 20 mg and 40 mg film-coated tablets

Austria, Belgium, Cyprus, Germany, Denmark, Greece, Spain, Finland, France, Iceland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Sweden and the UK agreed to grant Marketing Authorisations for Eletriptan 20 mg and 40 mg film-coated tablets on 03 October 2013. Marketing Authorisations were granted in the UK on 30 October 2013.

The full PAR for Eletriptan 20 mg and 40 mg film-coated tablets follows this summary. For more information about treatment with Eletriptan 20 mg and 40 mg film-coated tablets, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in December 2013.

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Module 1

Information about initial procedure

| | |
|--------------------------------------|---|
| Product Name | Eletriptan 20 mg film-coated tablets Eletriptan 40 mg film-coated tablets |
| Type of Application | Generic, Article 10(1) |
| Active Substances | Eletriptan hydrobromide |
| Form | Film-coated tablets |
| Strength | 20 mg and 40 mg |
| MA Holder | Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom |
| Reference Member State (RMS) | UK |
| Concerned Member States (CMS) | Austria, Belgium, Cyprus, Germany, Denmark, Greece, Spain, Finland, France, Iceland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal and Sweden |
| Procedure Number | UK/H/5351/001/DC UK/H/5351/002/DC |
| Timetable | Day 210 – 03 October 2013 |

Module 2

Summary of Product Characteristics

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) for products that have been granted Marketing Authorisations at a national level are available on the MHRA website.

Module 3

Patient Information Leaflet

In accordance with Directive 2010/84/EU the Patient Information Leaflets for products that are granted Marketing Authorisations at a national level are available on the MHRA website.

Module 4

Labelling

The following text is the approved label text for Eletriptan 20 mg film-coated tablets (PL 00057/1491). 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.

| |
|---|
| 1. NAME OF THE MEDICINAL PRODUCT |
|---|

Eletriptan 20 mg Film-Coated Tablets

| |
|--|
| 2. STATEMENT OF ACTIVE SUBSTANCE(S) |
|--|

Each film-coated tablet contains 20 mg of eletriptan (as hydrobromide).

| |
|------------------------------|
| 3. LIST OF EXCIPIENTS |
|------------------------------|

Contains lactose and sunset yellow (E110).

| |
|--|
| 4. PHARMACEUTICAL FORM AND CONTENTS |
|--|

Film-coated tablet

2 film-coated tablets
3 film-coated tablets
4 film-coated tablets
6 film-coated tablets
10 film-coated tablets
18 film-coated tablets
30 film-coated tablets
100 film-coated tablets

| |
|---|
| 5. METHOD AND ROUTE(S) OF ADMINISTRATION |
|---|

For oral use.
Read the package leaflet before use.

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

Keep out of the sight and reach of children.

| |
|--|
| 7. OTHER SPECIAL WARNING(S), IF NECESSARY |
|--|

Sealed Pack
Do not use if box has been opened

| |
|-----------------------|
| 8. EXPIRY DATE |
|-----------------------|

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONSBlister pack

No special storage conditions.

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**

Pfizer Limited
Sandwich
Kent, CT13 9NJ
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 00057/1491

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**

Eletriptan 20 mg film-coated tablet

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters strip (2, 3, 4, 6, 10, 18, 30 and 100 film-coated tablets)

1. NAME OF THE MEDICINAL PRODUCT

Eletriptan 20 mg Film-Coated Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pfizer (logo)

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch

5. OTHER

The following text is the approved label text for Eletriptan 40 mg film-coated tablets (PL 00057/1492). 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.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING (CARTON)

Carton with blisters (2, 3, 4, 6, 10, 18, 30 and 100 film-coated tablets)

1. NAME OF THE MEDICINAL PRODUCT

Eletriptan 40 mg Film-Coated Tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 40 mg of eletriptan (as hydrobromide).

3. LIST OF EXCIPIENTS

Contains lactose and sunset yellow (E110).

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

2 film-coated tablets
3 film-coated tablets
4 film-coated tablets
6 film-coated tablets
10 film-coated tablets
18 film-coated tablets
30 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Sealed Pack
Do not use if box has been opened

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Blister pack

No special storage conditions.

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

Pfizer Limited
Sandwich
Kent, CT13 9NJ
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 00057/1492

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Eletriptan 40 mg film-coated tablet

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters strip (2, 3, 4, 6, 10, 18, 30 and 100 film-coated tablets)

1. NAME OF THE MEDICINAL PRODUCT

Eletriptan 40 mg Film-Coated Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pfizer (logo)

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch

5. OTHER

Module 5

Scientific discussion during initial procedure

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Member States considered that the applications for Eletriptan 20 mg and 40 mg film-coated tablets (PL 00057/1491-1492; UK/H/5351/001-002/DC) could be approved. The applications were submitted via the Decentralised Procedure, with the UK as Reference Member State (RMS), and Austria, Belgium, Cyprus, Germany, Denmark, Greece, Spain, Finland, France, Iceland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal and Sweden as Concerned Member States (CMS).

These products can only be obtained with a prescription (legal classification POM).

These applications were made under the Decentralised Procedure (DCP), according to Article 10(1) of Directive 2001/83/EC, as amended, claiming to be generic medicinal products of Relpax 20 mg and 40 mg film-coated tablets (PL 00057/0452-0453), which were initially granted marketing authorisations to the same Marketing Authorisation Holder (Pfizer Limited) in the UK on 12 February 2001.

Eletriptan 20 mg and 40 mg film-coated tablets are indicated in adults for acute treatment of the headache phase of migraine attacks, with or without aura. These products contain the active substance eletriptan (as eletriptan hydrobromide), which is a selective serotonin receptor agonist at the vascular 5-HT_{1B} and neuronal 5-HT_{1D} receptors. It also exhibits high affinity for the 5-HT_{1F} receptor, which may contribute to its anti-migraine mechanism of action.

No new clinical or non-clinical studies were conducted, which is acceptable given that these applications were based on being generic medicinal products of originator products that have been licensed for over 10 years.

The applicant is also the Marketing Authorisation Holder of the reference products (Relpax 20 mg and 40 mg film-coated tablets, PL 00057/0452-0453) and has confirmed that Eletriptan 20 mg and 40 mg film-coated tablets are identical to the reference products, with the same qualitative and quantitative composition and the same manufacturing sites and processes. As a consequence, a bioavailability study was not required to demonstrate bioequivalence, and none was provided.

The RMS has been assured that acceptable standards of Good Manufacturing Practice are in place for this product type at all sites responsible for the manufacture, assembly and batch release of these products.

The RMS and CMS considered that the applications could be approved at the end of procedure on 03 October 2013. After a subsequent national phase, marketing authorisations were granted in the UK on 30 October 2013.

II. ABOUT THE PRODUCT

| | |
|---|---|
| Name of the product in the Reference Member State | Eletriptan 20 mg film-coated tablets Eletriptan 40 mg film-coated tablets |
| Name(s) of the active substance(s) (INN) | Eletriptan hydrobromide |
| Pharmacotherapeutic classification (ATC code) | Selective Serotonin (5HT ₁) receptor agonists (NO2C C06) |
| Pharmaceutical form and strength(s) | Film-coated tablets 20 mg and 40 mg |
| Reference numbers for the Decentralised Procedure | UK/H/5351/001/DC UK/H/5351/002/DC |
| Reference Member State | UK |
| Member States concerned | Austria, Belgium, Cyprus, Germany, Denmark, Greece, Spain, Finland, France, Iceland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal and Sweden |
| Marketing Authorisation Number(s) | PL 00057/1491 PL 00057/1492 |
| Name and address of the authorisation holder | Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom |

III SCIENTIFIC OVERVIEW AND DISCUSSION

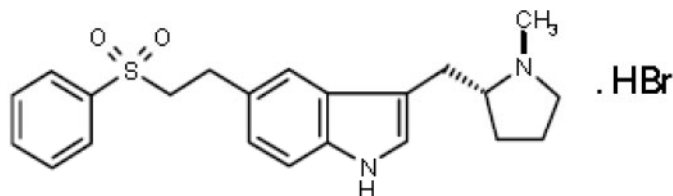
III.1 QUALITY ASPECTS

S. Active substance – Eletriptan hydrobromide

rINN: Eletriptan

Chemical name: (R)-3-(1-methyl-2-pyrrolidinylmethyl)-5-[2-(phenylsulfonyl)ethyl]-1H-indole hydrobromide

Structure:



Molecular formula: $C_{22}H_{27}BrN_2O_2S$

Molecular weight: 463.43

Appearance: White to off-white solid

Solubility: Slightly soluble in water and aqueous buffers at pH 8 and below, sparingly soluble in acetonitrile and soluble in methanol

Synthesis of the drug substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the specification. Satisfactory Certificates of Analysis have been provided for all working standards. Batch analysis data are provided that comply with the specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

P. Medicinal Product

Other Ingredients

Other ingredients consist of the pharmaceutical excipients, as follows:

Tablet core:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and magnesium stearate

Film-coating:

Titanium dioxide (E171), hypromellose, lactose monohydrate, glycerol triacetate and Sunset Yellow FCF Aluminium Lake (E110).

With the exception of the Sunset Yellow FCF Aluminium Lake (E110), all excipients used comply with their respective European Pharmacopoeia monographs. Sunset Yellow FCF Aluminium Lake (E110) complies with a suitable in-house specification and is in compliance with current EU Directives concerning the use of colouring agents.

With the exception of the lactose monohydrate, none of the excipients are sourced from animal or human origin. No genetically modified organisms (GMO) have been used in the preparation of this product.

The milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as that for human consumption.

Pharmaceutical Development

The objective of the development programme was to formulate globally acceptable and stable products that could be considered generic medicinal products of the currently licensed products Relpax 20 mg and 40 mg film-coated tablets (PL 00057/0452-0453).

A satisfactory account of the pharmaceutical development has been provided.

Manufacturing Process

Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. Suitable in-process controls are in place to ensure the quality of the finished product.

Process validation has been carried out on two commercial-scale batches of each strength of finished product. The results are satisfactory.

Finished Product Specification

The finished product specifications proposed are acceptable. Test methods have been described that 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.

Container-Closure System

The finished product is packaged in opaque polyvinylchloride (PVC)/aclear/aluminium blisters in pack sizes of 2, 3, 4, 6, 10, 18, 30 and 100 tablets.

The Marketing Authorisation Holder has stated that not all pack sizes are intended for marketing. However, they have committed to providing the relevant licensing authority with the mock-ups for any pack size before marketing it in that country.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

Stability of the product

Stability studies were performed, in accordance with current guidelines, on batches of finished product manufactured by the finished product manufacturer and packed in the packaging proposed for marketing. The results from these studies support a shelf-life of 3 years with no special storage conditions.

Bioequivalence/bioavailability

As Eletriptan 20 mg and 40 mg film-coated tablets are identical to the reference products, with the same qualitative and quantitative composition and the same manufacturing sites and processes, bioavailability studies were not required to demonstrate bioequivalence, and none were provided.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

The SmPCs, PILs and text versions of the labels are acceptable from a pharmaceutical perspective.

The results of consultations with target patient groups ('user testing'), in accordance with Article 59 of Council Directive 2001/83/EC (as amended) for the package leaflet for the reference products was provided. 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. As the PILs for Eletriptan 20 mg and 40 mg film-coated tablets are consistent with the approved PIL for Relpax 20 mg and 40 mg film-coated tablets (PL 00057/0452-0453) in their content and layout, additional readability testing is not deemed necessary.

Marketing Authorisation Application (MAA) form

The MAA forms are satisfactory from a pharmaceutical perspective.

Quality Overall Summary (Expert report)

The pharmaceutical expert report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical dossier.

Conclusion

The grant of Marketing Authorisations is recommended.

III.2 NON-CLINICAL ASPECTS

As the pharmacodynamic, pharmacokinetic and toxicological properties of eletriptan hydrobromide are well-known, no further non-clinical studies are required and none have been provided.

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

Suitable justification has been provided for the non-submission of an environmental risk assessment. As this product is intended for generic substitution with products that are currently marketed, no increase in environmental burden is expected.

There are no objections to the approval of these products from a non-clinical viewpoint.

III.3 CLINICAL ASPECTS

Pharmacokinetics

No new pharmacokinetic or pharmacodynamic data were submitted with these applications and none were required. The applicant is also the Marketing Authorisation Holder of the reference products (Relpax 20 mg and 40 mg film-coated tablets, PL 00057/0452-0453) and has confirmed that Eletriptan 20 mg and 40 mg film-coated tablets are identical to the reference products, with the same qualitative and quantitative composition and the same manufacturing sites and processes.

Efficacy

No new data on efficacy have been submitted and none are required for this type of application.

Safety

No new data on safety have been submitted and none are required for this type of application.

SmPC, PIL and Labels

The SmPCs, PILs and text versions of the labels are acceptable from a clinical perspective.

Pharmacovigilance System and Risk Management Plan

The Pharmacovigilance System, as described by the applicant, fulfils the requirements and 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 either in the Community or in a third country.

A suitable risk management plan has been provided for these products.

Clinical Expert Report

The clinical expert report has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

Conclusion

The grant of Marketing Authorisations is recommended.

**IV OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT
QUALITY**

The important quality characteristics of Eletriptan 20 mg and 40 mg 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.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL

As the applicant for Eletriptan 20 mg and 40 mg film-coated tablets is the same as the Marketing Authorisation Holder for the reference products and the products are identical, bioavailability studies were not required to demonstrate bioequivalence, and none were provided.

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

No new or unexpected safety concerns arose from these applications.

The SmPCs, PILs and text versions of labelling are satisfactory and consistent with those for the reference products.

BENEFIT-RISK ASSESSMENT

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with eletriptan hydrobromide is considered to have demonstrated the therapeutic value of the compound. The benefit-risk assessment is, therefore, considered to be positive.

Module 6

STEPS TAKEN AFTER INITIAL PROCEDURE - SUMMARY

| Date submitted | Application type | Scope | Outcome |
|------------------|-------------------|---|------------------------|
| 20 November 2013 | Type II variation | To amend section 5.1 (Pharmacodynamics) of the SmPC to more accurately reflect the number of trials and subjects used in the development programme. | Approved – 4 June 2014 |
| | | | |
| | | | |
| | | | |
| | | | |

ANNEX 1 – VARIATION ASSESSMENT REPORT**Recommendation**

Based on the review of the data the RMS considers that the variation to amend section 5.1 of the SmPCs for Eletriptan 20 mg film-coated tablets and Eletriptan 40 mg film-coated tablets could be approved.

Summary of Product Characteristics

Section 4.8 of the SmPC correctly states:

“Eletriptan has been administered in clinical trials to over 5000 subjects, taking one or two doses of Eletriptan 20 or 40 or 80 mg.”

However, some subjects took part in more than one study and individuals were counted once for each study in which they participated. To reflect this it is proposed to amend the current SmPC text from:

“The efficacy of Eletriptan in the acute treatment of migraine has been evaluated in 10 placebo-controlled trials that included about 5000 patients who received Eletriptan at doses of 20 to 80 mg.”

To:

“The efficacy and safety of eletriptan in the acute treatment of migraine has been evaluated in 10 placebo-controlled trials involving more than 6000 patients (all treatment groups) who received eletriptan at doses of 20 to 80 mg.”

Package leaflet and user test

The proposed changes do not impact on the package leaflet.

Labelling

The proposed changes do not impact on the product labelling.

Overall conclusion

This variation is approvable as the changes are clear and aid the healthcare professional by accurately reflecting the number of trials and subjects used in the development programme.