SUMATRIPTAN 50MG TABLETS
SUMATRIPTAN 100MG TABLETS

PL 30306/0008-0009

UKPAR

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LAY SUMMARY

SUMATRIPTAN 50MG TABLETS
SUMATRIPTAN 100MG TABLETS

This is a summary of the Public Assessment Report (PAR) for Sumatriptan 50mg and 100mg Tablets (PL 30306/0008-0009, formerly PL 18866/0048-0049). It explains how the applications for Sumatriptan 50mg and 100mg Tablets were assessed and their authorisations recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Sumatriptan 50mg and 100mg Tablets.

For practical information about using Sumatriptan 50mg and 100mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

Sumatriptan 50mg and 100mg Tablets may be referred to as Sumatriptan Tablets in this report.

What are Sumatriptan Tablets and what are they used for?
Sumatriptan 50 mg and 100 mg Tablets are ‘generic’ medicines. This means that Sumatriptan 50 mg and 100 mg Tablets are similar to reference medicines already authorised in the UK called Imigran 50 and 100 mg Tablets (PL 10949/0222 and 0231), which have been authorised to GlaxoSmithKline in the UK since June 1994.

Sumatriptan Tablets have been developed for the treatment of migraine. The symptoms of migraine may include aura (warning sensations of visual distortion such as flashes of light and zigzag lines or waves).

How do Sumatriptan Tablets work?
The symptoms of migraine are thought to be due to temporary swelling of blood vessels in the head. Medicines like Sumatriptan Tablets are believed to work by reducing the size of these blood vessels. These medicines are called 5HT₁ receptor agonists.

How are Sumatriptan Tablets used?
Sumatriptan Tablets are taken by mouth and must be swallowed whole with water. The tablets should not be chewed or crushed.

The tablets should always be taken exactly as advised by the patient’s doctor. The patient should check with the doctor or pharmacist if he/she is not sure.

Sumatriptan Tablets should not be used in children under 18 years of age, as the safety and effectiveness of the medicine in children has not been established.

There is little experience of Sumatriptan Tablets in patients over 65 years of age so it is not usually prescribed to this age group.

Please read section 3 of the package leaflet (PL) for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Sumatriptan Tablets can only be obtained with a prescription.
What benefits of Sumatriptan Tablets have been shown in studies?
As Sumatriptan Tablets are generic medicines, studies in patients have been limited to tests to determine that Sumatriptan Tablets are bioequivalent to the reference medicines, Imigran 50 mg and 100 mg Tablets (GlaxoSmithKline), respectively. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

In addition, at the time of initial assessment, the Marketing Authorisation Holder provided data from the published literature on sumatriptan.

What are the possible side effects of Sumatriptan Tablets?
Because Sumatriptan Tablets are generic medicines and are bioequivalent to the reference medicines Imigran 50 mg and 100 mg Tablets (GlaxoSmithKline), the benefits and possible side effects are taken as being the same as those of the reference medicines.

For the full list of restrictions, see the package leaflet.

Why are Sumatriptan Tablets approved?
The MHRA concluded that, in accordance with EU requirements, Sumatriptan Tablets have been shown to have comparable quality and to be bioequivalent to Imigran 50 mg and 100 mg Tablets (GlaxoSmithKline). Therefore, the view was that, as for Imigran 50 mg and 100 mg Tablets (GlaxoSmithKline), the benefits outweighs the identified risks.

What measures are being taken to ensure the safe and effective use of Sumatriptan Tablets?
Safety information has been included in the Summary of Product Characteristics and the package leaflet for Sumatriptan 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/reviewed continuously as well.

Other information about Sumatriptan Tablets.
Marketing Authorisations (Sumatriptan 50mg and 100mg Tablets, PL 18866/0048-0049) were first granted in the UK to Rockspring Healthcare Limited on 14 September 2007.

Subsequent to Change of Ownership procedures, the Marketing Authorisations (Sumatriptan 50mg and 100mg Tablets; PL30306/0008-0009) were granted to Actavis Group PTC ehf on 05 March 2008.

The full PAR for Sumatriptan Tablets follows this summary.

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

This summary was last updated in February 2015.
SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted Marketing Authorisations for the medicinal products Sumatriptan 50mg and 100mg Tablets and duplicates to Rockspring Healthcare Limited (PL 18866/0048-0049) on 14 September 2007. The products are prescription-only medicines.

The applications were submitted as abridged applications according to Article 10.1 of Directive 2001/83/EC, as amended, claiming essential similarity to the original products Imigran 50 and 100 mg Tablets (PL 10949/0222 and 0231), which have been authorised to GlaxoSmithKline in the UK since June 1994.

The products contain the active ingredient sumatriptan succinate and are indicated for the acute relief of migraine attacks, with or without aura. Sumatriptan Tablets should only be used where there is a clear diagnosis of migraine.

Sumatriptan is a vascular 5-HT₁ receptor agonist. The specific subtype receptor it activates is present in the cranial and basilar arteries. Activation of these receptors causes vasoconstriction of the dilated arteries. Sumatriptan has also been shown to reduce the activity of the trigeminal nerve, which accounts for its efficacy in treating cluster headaches.

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

Subsequent to Change of Ownership procedures, the Marketing Authorisations (Sumatriptan 50mg and 100mg Tablets; PL 30306/0008-0009) were granted to Actavis Group PTC ehf on 05 March 2008.
Active Substance
INN/Ph.Eur name: Sumatriptan succinate
Chemical name: [3-[2-(Dimethylamino)ethyl]-1H-indol-5-yl]-N-methylmethanesulphonamide hydrogen butanedioate.
Structural formula

\[
\begin{align*}
\text{Molecular formula: } & \quad C_{18}H_{27}N_3O_6S \\
\text{Molecular weight: } & \quad 413.5 \\
\text{Polymorphism: } & \quad \text{There is no evidence of polymorphism.} \\
\text{Chirality: } & \quad \text{There are no chiral centres present so there is no potential for stereoisomerism.}
\end{align*}
\]

General Properties
Characters: White to almost white powder, freely soluble in methanol, sparingly soluble in water and methylene chloride.
Solubility: Freely soluble in water, sparingly soluble in methanol, practically insoluble in methylene chloride.
Melting point: 165-167°C.
pH (5% in water): 4.5-5.3

Sumatriptan succinate is the subject of a European Pharmacopoeia monograph.
A Certificate of Suitability has been provided covering the manufacture and control of the drug substance sumatriptan succinate.
Appropriate stability data have been generated showing the active substance to be a physically and chemically stable drug. The data support a retest period of 36 months.

Other Ingredients
Other ingredients consist of pharmaceutical excipients lactose monohydrate, croscarmellose sodium, lactose anhydrous, microcrystalline cellulose, magnesium stearate, water purified, mannitol, titanium dioxide, talc and glycerol tricetate.
All excipients have a respective European Pharmacopoeia monograph.
Satisfactory certificates of analysis have been provided for all ingredients showing compliance with their respective monograph.
Lactose anhydrous and lactose monohydrate are the only ingredients that come from an animal source. The lactose used to produce both is sourced from healthy animals under the same conditions as milk for human consumption.

**Pharmaceutical development**

The objective of the pharmaceutical development programme was to produce products containing 50mg and 100mg sumatriptan that are tolerable and which could be considered as generic products to the originator products Imigran 50 and 100 mg Tablets.

The rationale for the type of pharmaceutical form developed and formulation variables evaluated during development have been stated and are satisfactory.

The rationale and function of each excipient added is discussed. Levels of each ingredient are typical for a product of this nature and have been optimised on the basis of results from development studies.

Comparative in vitro dissolution profiles have been generated for the proposed and originator products with satisfactory results. Comparative impurity studies have also been undertaken.

**Manufacturing Process**

Satisfactory batch formulae have been provided for the manufacture of both strengths of product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results at pilot-scale. Additionally, a commitment has been provided that the first full-scale commercial production batches will be validated.

**Finished Product Specification**

The finished product specifications proposed for both strengths are acceptable. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

**Container-Closure System**

All strengths of tablet are packaged in either:

1. Polyvinylchloride/aluminium blister strips in pack sizes of 2, 3, 6, 7, 12, 14, 18, 21, 24, 28, 30, 50, 100, 250, 500 and 1000 tablets
2. High-density polyethylene bottle with a low-density polyethylene cap closure in pack sizes of 2, 3, 6, 7, 12, 14, 18, 21, 24, 28, 30, 50, 100, 250, 500 and 1000 tablets.

Satisfactory specifications and certificates of analysis have been provided for all packaging components. All primary packaging complies with the relevant regulations regarding materials for use in contact with food.

The applicant has stated that not all packaging will be marketed in the UK and has provided assurances that they will submit mock-ups before launching any packaging types into the market.

**Stability of the product**

Stability studies were performed on pilot-scale batches of all strengths of finished product and all packaging types, in accordance with current guidelines. All results from stability studies on pilot batches were within specified limits. These data support a shelf-life of 2 years for product stored in the blister strips and 3 years for product stored in the bottle, with no storage conditions.

The applicant has committed to providing stability data for the first three production-scale batches of each strength of finished product.

**Bioequivalence/bioavailability**

Satisfactory Certificates of Analysis have been provided for the test and reference batches used in the bioequivalence study.
SPC, PIL, Labels
The SPC, PIL and Labels are pharmaceutically acceptable.

CONCLUSION
It is recommended that Marketing Authorisations are granted for these applications.

The requirements for essential similarity of the proposed and reference products have been met with respect to qualitative and quantitative content of the active substance. In addition, similar dissolution profiles have been demonstrated for the proposed and reference products.
PRECLINICAL ASSESSMENT

These applications for generic products claim essential similarity to Imigran 50 and 100 mg Tablets (GlaxoSmithKline UK), which have been licensed within the EEA for over 10 years.

No new preclinical data have been supplied with these applications and none are required for applications of this type.
CLINICAL ASSESSMENT

1. INTRODUCTION AND BACKGROUND
These are complex and a standard abridged national applications for Sumatriptan 50mg and 100mg Tablets submitted under Article 10.1 of Directive 2001/83/EC, as amended. The applications cross-refer to Imigran 50 and 100 mg Tablets (GlaxoSmithKline UK), which have been authorised in the EU for more than 10 years.

2. INDICATIONS
For the acute relief of migraine attacks, with or without aura. Sumatriptan Tablets should only be used where there is a clear diagnosis of migraine.

The indications proposed are consistent with those for the originator products and are, therefore, satisfactory.

3. DOSE & DOSE SCHEDULE
For oral use.

Adults:
Sumatriptan Tablets are indicated for the acute intermittent treatment of migraine. Sumatriptan should not be used prophylactically.

It is advisable that sumatriptan be given as early as possible after the onset of migraine attack but it is equally effective at whatever stage of the attack it is administered.

The recommended dose is a single 50mg tablet. Some patients may require 100mg. If the patient has responded to the first dose but the symptoms recur a second dose may be given in the next 24 hours provided that there is a minimum interval of two hours between the two doses and no more than 300mg is taken in any 24 hour period.

Patients who do not respond to the prescribed dose of sumatriptan should not take a second dose for the same attack. Sumatriptan may be taken for subsequent attacks.

Sumatriptan is recommended as monotherapy for the acute treatment of migraine and should not be given concomitantly with other acute migraine therapies. If a patient fails to respond to a single dose of Sumatriptan Tablets there are no reasons, either on theoretical grounds or from limited clinical experience, to withhold products containing aspirin or non-steroidal anti-inflammatory drugs for further treatment of the attack.

The tablets should be swallowed whole with water.

Children (under 18 years of age):
Sumatriptan tablets have not been studied in children under 12 years of age. The available clinical trial data in adolescents (12 to 17 years of age) do not support the use of oral sumatriptan in this age group (see section 5.1). The use of sumatriptan tablets in children and adolescents is therefore not recommended.

Elderly (Over 65):
Experience of the use of sumatriptan in patients aged over 65 years is limited. The pharmacokinetics do not differ significantly from a younger population but until further clinical data are available, the use of Sumatriptan Tablets in patients aged over 65 years is not recommended.

The dose and dose schedule proposed are consistent with those for the originator products and are, therefore, satisfactory.

4. CLINICAL PHARMACOLOGY
With the exception of the bioequivalence study comparing the proposed product to Imigran 100mg Tablets, no formal data are provided and none are required for these applications.
4.1 Bioequivalence
A bioequivalence study was carried out, and the test and reference products shown to be bioequivalent (within the customary 90% confidence intervals) for the appropriate pharmacokinetic criteria.

Design:
Single dose, randomised, cross-over, open-label, laboratory-blind study

Test Product: Sumatriptan 100mg tablets
Reference Product: Imigran 100 mg tablets (GlaxoSmithKline UK)
Subjects: 32 finished the study – 18-55yrs, male and female
Washout: 2 weeks
Sampling: 0, 0.166, 0.33, 0.5, 0.75, 1.0, 1.25, 1.75, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 8.0, 10.0 and 12 hrs post dose.
Parameters: primary were $C_{\text{max}}$, $\text{AUC}_{0-\text{tlast}}$ and $\text{AUC}_{0-\infty}$; secondary were $T_{\text{max}}$ and $T_{1/2}$.

Results:

<table>
<thead>
<tr>
<th></th>
<th>$C_{\text{max}}$ (ng/mL)</th>
<th>$\text{AUC}_{0-\text{tlast}}$ (ng.h/mL)</th>
<th>$\text{AUC}_{0-\infty}$ (ng.h/mL)</th>
<th>$T_{\text{max}}$ (hrs)</th>
<th>$T_{1/2}$ (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sumatriptan 100mg [Test]</td>
<td>54.8 ± 17.4</td>
<td>231 ± 56.7</td>
<td>243 ± 59.4.</td>
<td>1.88</td>
<td>2.54 ± 0.60</td>
</tr>
<tr>
<td>Imigran 100mg [Ref]</td>
<td>52.1 ± 12.3</td>
<td>226 ± 58.3</td>
<td>236 ± 60.0.</td>
<td>1.25</td>
<td>2.35 ± 0.52</td>
</tr>
</tbody>
</table>

Point Estimate: 105%, 102%, 103%, 0.13%, 108%

Ratio 90% CI: 98.0; 113, 96.6; 108, 97.0; 109, -0.25; 0.63, 103; 113

Conclusion: The extent and rates of absorption, time to $T_{\text{max}}$ and $T_{1/2}$ exhibited indicate that two products may be assumed bioequivalent in terms of the customary confidence intervals.

As the two strengths of the proposed product are dose proportional qualitatively and quantitatively, the results of 100mg tablet can be considered applicable to the 50mg tablet.

5. EFFICACY
No new data on the efficacy of sumatriptan are submitted and none are required for this type of application.

6. SAFETY
No new data on the safety of sumatriptan are submitted and none are required for this type of application.

7. EXPERT REPORTS
A clinical expert report is provided, written by an appropriately qualified Doctor. It includes a suitable review of the bioequivalence study.

8. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)
The SPCs are consistent with the approved SPCs for the originator products Imigran 50 and 100 mg Tablets and are satisfactory.

9. PATIENT INFORMATION LEAFLET (PIL)
The PIL has been provided and is consistent the SPC.

10. LABELLING
Labelling text for all strengths are satisfactory. Mock-ups of labelling intended for marketing are satisfactory and comply with current regulations.

The applicant has stated that not all proposed pack sizes will be marketed initially, but has provided assurances that mock-ups will be submitted for assessment before any further pack sizes are marketed.
11. MARKETING AUTHORISATION APPLICATION (MAA) FORMS
The MAA forms are satisfactory.

12. DISCUSSION
Bioequivalence has been satisfactorily demonstrated for the 100mg product in accordance with CPMP criteria. As these products meet all the criteria as specified in the Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98), the results and conclusions of the bioequivalence study on the 100mg strength can be extrapolated to the 50mg strength tablets.

The SPC and PIL are consistent with those approved in the UK for the originator product Imigran 50 and 100 mg Tablets and are satisfactory.

13. MEDICAL CONCLUSION
Marketing Authorisations may be granted for these products.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Sumatriptan 50mg and 100mg 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 Sumatriptan 100mg Tablets and the originator products Imigran 100mg Tablets (GlaxoSmithKline UK). As these products meet all the criteria as specified in the Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98), the results and conclusions of the bioequivalence study on the 100mg strength can be extrapolated to the 50mg strength tablets.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for Imigran Tablets.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The bioequivalence study supports the claim that the applicant’s products and the innovator products are interchangeable. Extensive clinical experience with sumatriptan is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.
SUMATRIPTAN 50MG TABLETS
SUMATRIPTAN 100MG TABLETS

PL 30306/0008-0009

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation applications on 06 September 2004.

2. Following standard checks and communication with the applicant the MHRA considered the applications valid on 21 September 2004.


5. The applications were determined on 14 September 2007.
The following table lists a non-safety update to the Marketing Authorisations (PL 30306/0008-0009) that has been approved by the MHRA since the products were first licensed. The table includes an update that has been added as an annex to this PAR. This is not a complete list of the post-authorisation changes that have been made to these Marketing Authorisations.

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<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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<tr>
<td>01/12/2014</td>
<td>Type 1B</td>
<td>To update sections 4.8 (Undesirable effects), 4.9 (Overdose) and 5.1 (Pharmacodynamic properties) of the Summary of Product Characteristics (SmPC) and consequentially the Patient Information Leaflet (PIL), in line with reference product.</td>
<td>Approved on 30/12/2014</td>
</tr>
</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

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

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
**LABELLING**

The Marketing Authorisation Holder has submitted the text version only and has committed to submitting mock-up livery to the MHRA for approval before packs are marketed.

Labelling for Sumatriptan 50 mg Tablets (PL 30306/0008):

<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARTON 50mg</td>
</tr>
</tbody>
</table>

1. **NAME OF THE MEDICINAL PRODUCT**

Sumatriptan 50mg Tablets
(Sumatriptan succinate)

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

Each coated tablet contains 50mg Sumatriptan as sumatriptan succinate.

3. **LIST OF EXCIPIENTS**

Also contains lactose and mannitol. Please read the enclosed patient information leaflet before use.

4. **PHARMACEUTICAL FORM AND CONTENTS**

<table>
<thead>
<tr>
<th>6 tablets</th>
<th>12 tablets</th>
</tr>
</thead>
</table>

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

For Oral Use Only

Only use as directed by your doctor.

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

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

8. **EXPIRY DATE**

Expiry Date:

9. **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 AUTHORIZATION HOLDER**

   Product Licence Holder:
   Actavis Group PTC ehf, Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland.

12. **MARKETING AUTHORIZATION NUMBER(S)**

   PL 30306/0008

13. **BATCH NUMBER, DONATION AND PRODUCT CODES**

   Batch no.

14. **GENERAL CLASSIFICATION FOR SUPPLY**

   POM

15. **INSTRUCTIONS ON USE**

16. **INFORMATION IN BRAILLE**

   Sumatriptan 50mg Tablets

17. **OTHER**

   READ ENCLOSED LEAFLET - flaps

   Barcode
   Carton reference number
<table>
<thead>
<tr>
<th>1. NAME OF THE MEDICINAL PRODUCT</th>
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<tbody>
<tr>
<td>Sumatriptan 50mg Tablets</td>
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<tr>
<td>(Sumatriptan succinate)</td>
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<table>
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<th>2. NAME OF THE MARKETING AUTHORISATION HOLDER</th>
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<td>Actavis logo</td>
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<table>
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<th>3. EXPIRY DATE</th>
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<table>
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<th>4. BATCH NUMBER</th>
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<tbody>
<tr>
<td>BN [batch number]</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>5. OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foil reference number</td>
</tr>
</tbody>
</table>
Labelling for Sumatriptan 100mg Tablets (PL 30306/0009):

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

CARTON 100mg

---

1. **NAME OF THE MEDICINAL PRODUCT**

Sumatriptan 100mg Tablets  
(Sumatriptan succinate)

---

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

Each coated tablet contains 100mg Sumatriptan as sumatriptan succinate.

---

3. **LIST OF EXCIPIENTS**

Also contains lactose and mannitol. Please read the enclosed patient information leaflet before use.

---

4. **PHARMACEUTICAL FORM AND CONTENTS**

- 6 tablets  
- 12 tablets

---

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

For Oral Use Only  
Only use as directed by your doctor.

---

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

---

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

---

8. **EXPIRY DATE**

Expiry Date:

---

9. **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

Product Licence Holder:
Actavis Group PTC ehf, Reykjavikurvegur 76-78,
220 Hafnarfjordur, Iceland.

12. MARKETING AUTHORISATION NUMBER(S)

PL 30306/0009

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

Batch no.

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sumatriptan 100mg Tablets

17. OTHER

READ ENCLOSED LEAFLET - flaps

Barcode
Carton reference number
MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER foil 100mg

1. NAME OF THE MEDICINAL PRODUCT

Sumatriptan 100mg Tablets
(Sumatriptan succinate)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Actavis logo

3. EXPIRY DATE

Exp [mm yyyy]

4. BATCH NUMBER

BN [batch number]

5. OTHER

Foil reference number
## Annex 1

**Reference:** PL 30306/0008, Application 0020  
**Product:** Sumatriptan 50mg Tablets  
**Marketing Authorisation Holder:** Actavis Group PTC ehf  
**Active Ingredient(s):** Sumatriptan succinate  
**Type of Procedure:** National  
**Submission Type:** Variation  
**Submission Category:** Type IB  
**EU Procedure Number:** Not applicable

**Reason:**  
To update sections 4.8 (Undesirable effects), 4.9 (Overdose) and 5.1 (Pharmacodynamic properties) of the Summary of Product Characteristics (SmPC), and consequentially the Patient Information Leaflet (PIL), in line with reference product.

**Linked/Related Variation(s) or Case(s):**  
The Assessment Report refers to the Collection ID 158664 and covers the following submissions PL 30306/0009 - 0020.

**Supporting Evidence**  
Revised SmPC fragments and PIL text have been provided.

**Evaluation**  
The proposed SmPC update is acceptable.  
Consequential updates to the leaflet are also acceptable.

**Conclusion**  
The amendment to the SmPC fragment and PIL can be approved.

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

**Decision** - Approved (30/12/2014).