GALPHARM MIGRAINE RECOVERY 50MG TABLETS
PL 16028/0139

UKPAR

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LAY SUMMARY

The Medicines Healthcare and products Regulatory Agency granted Galpharm Healthcare Limited a Marketing Authorisation for the medicinal product Galpharm Migraine Recovery 50mg Tablets (PL 16028/0139) on 12th May 2010. This pharmacy-only medicine (P) and is used to relieve migraine attacks (with or without aura), in people who have been diagnosed with migraine.

Galpharm Migraine Recovery 50mg Tablets contains the active ingredient sumatriptan succinate, which belongs to a group of medicines known as triptans (5HT1 Receptor antagonists). The tablets are believed to work on the imbalance of the body’s natural chemicals which have caused the blood vessels in the head to temporarily swell. The tablets help to relieve the headache and other symptoms of a migraine, such as feeling sick and sensitivity to light and sound.

This application is identical to a previously granted application for Migraleve Ultra 50mg Tablets authorised to TEVA UK Limited (PL 00289/0586), approved on 15th May 2006.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Galpharm Migraine Recovery 50mg Tablets outweigh the risks; hence a Marketing Authorisation has been granted.
SCIENTIFIC DISCUSSION

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**INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the MHRA granted Galpharm Healthcare Limited granted a marketing authorisation for the medicinal product Galpharm Migraine Recovery 50mg Tablets (PL 16028/0139) on the 12th May 2010. The product is a pharmacy-only medicine.

The application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, cross-referring to Migraleve Ultra 50mg Tablets authorised to TEVA UK Limited (PL 00289/0586), approved on 15th May 2006.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated for it.

The product contains the active ingredient sumatriptan succinate which is indicated for the acute relief of migraine attacks, with or without aura.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 16028/0139
PROPRIETARY NAME: Galpharm Migraine Recovery 50mg Tablets
ACTIVE(S): Sumatriptan succinate
COMPANY NAME: Galpharm Healthcare Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC
LEGAL STATUS: P

1. INTRODUCTION
This is a simple, informed consent application for Galpharm Migraine Recovery 50mg Tablets submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is Galpharm Healthcare Limited, Hugh House, Dodworth Business Park, Barnsley, South Yorkshire, S75 3SP, UK.

The application cross-refers to Migraleve Ulta, 50mg, Tablets, approved on 15th May 2006 to the marketing authorisation holder TEVA UK Ltd (PL 00289/0586). The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name(s)
The proposed name of the product is Galpharm Migraine Recovery 50mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product contains sumatriptan succinate, equivalent to 50mg. The medicinal product is presented in blisters composed of transparent or white opaque polyvinylchloride/polyvinylidene chloride/aluminum (PVC/PVdC/Al). The blisters hold 2 film-coated tablets and are packaged with the Product Information Leaflet (PIL) into cardboard outer cartons. All primary product packaging complies with Directive 2002/72/EC (amended), regarding contact with food. Specifications and Certificates of Analysis for all packaging components used have been provided and are satisfactory.

The proposed shelf-life of 3 years with no specific storage conditions are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the products will be available as pharmacy-only medicines (P).

2.4 Marketing authorisation holder/Contact Persons/Company
Galpharm Healthcare Limited, Hugh House, Dodworth Business Park, Barnsley, South Yorkshire, S75 3SP, UK.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.
2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

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

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product with the exception of an additional test for moisture.

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

2.10 TSE Compliance
With the exception of lactose monohydrate, magnesium stearate and gelatin, no materials of animal or human origin are included in the product. This is consistent with the cross-reference product.

A declaration has been provided that lactose used in lactose monohydrate is sourced from healthy animals under the same conditions as that for human consumption. TSE certificates of suitability have been provided for all suppliers of gelatin and one supplier of magnesium stearate (the other supplier has stated that it is sourced from vegetable origins).

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. ENVIRONMENTAL RISK ASSESSMENT
It is stated that the application concerned is a duplicate of an existing marketing authorisation for the same product. It is anticipated that the supply of product from this copy licence would replace supply of the same product from the existing reference licence. In addition, usage of the drug substance resulting from the non-prescription sales of Galpharm Migraine Recovery is expected to represent a very small fraction of the overall usage of sumatriptan given its existing use as a widely available prescription-only medicine.

The applicant's justification for absence of ERA is satisfactory; changes in the environmental risks consequent to the approval of this simple licence are not to be expected and an environmental risk assessment is not required.

5. PHARMACOVIGILANCE SYSTEM
A pharmacovigilance system has been provided with this application and is satisfactory.
6. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

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

8. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

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 two separate user-tests: one for content and language (Migraleve Ultra) and one for layout and format (Ibuprofen 200mg Tablets). The bridging report is satisfactory.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

9. CONCLUSIONS
The data submitted with the application are acceptable. A Marketing Authorisation should be granted.
PRECLINICAL ASSESSMENT

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

No new clinical data have been supplied with this application and none are required for an application of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

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

EFFICACY
Sumatriptan succinate is a well known drug and has been used in the treatment of migraine for many years. This application is identical to previously granted application for Migraleve Ultra 50mg Tablets (PL 00289/0586), granted to TEVA UK Limited on the 15th May 2006.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product which, in turn, has been shown to be interchangeable with the innovator product. Extensive clinical experience with sumatriptan succinate is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.
## STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the marketing authorisation application on 16\textsuperscript{th} March 2009.</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 20\textsuperscript{th} March 2009.</td>
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<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 1\textsuperscript{st} June 2009, 19\textsuperscript{th} February 2010 and 14\textsuperscript{th} April 2010.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 2\textsuperscript{nd} September 2009, 17\textsuperscript{th} March 2010 and 7\textsuperscript{th} May 2010.</td>
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## STEPS TAKEN AFTER ASSESSMENT

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SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Galpharm Migraine Recovery 50mg Tablets is as follows:

1 NAME OF THE MEDICINAL PRODUCT
Galpharm Migraine Recovery 50mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains 50mg sumatriptan base (as sumatriptan succinate).

Excipients: Lactose monohydrate 70 mg/ tablet.

For a list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Film-coated tablet.

Peach, oblong shaped cores debossed with “5” and “0” on one side and scoreline on each side.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Sumatriptan 50 mg tablets are indicated for the acute relief of migraine attacks, with or without aura.

Sumatriptan 50 mg tablets should only be used where there is a clear diagnosis of migraine.

4.2 Posology and method of administration
Adults (18-65 years of age)

The recommended dose is a single 50 mg tablet that should be swallowed whole with water. It is advisable that a Sumatriptan 50 mg tablet be taken as soon as possible after the onset of a migraine attack although it is effective at whatever stage of the attack it is taken.

If there is a response to the first tablet but the symptoms recur, a second tablet may be taken. However, this must be at least 2 hours after the first tablet. No more than two 50 mg tablets (total dose 100 mg) may be taken in any 24 hour period.

If there is no response to the first tablet, a second tablet should not be taken for the same attack.

Children and Adolescents
Not to be used in children or adolescents under 18 years of age.

The safety and effectiveness of Sumatriptan 50 mg tablets in children have not been established.

Elderly (over 65 years of age)
Not to be used in those over 65 years of age.
Experience of the use of Sumatriptan 50 mg tablets in patients over 65 years is limited.
4.3 Contraindications

Sumatriptan 50 mg tablets must not be used prophylactically.

Hypersensitivity to sumatriptan succinate or to any of the excipients (see section 6.1).

Hypersensitivity to sulphonamides.

Previous myocardial infarction, or those who have ischaemic heart disease, coronary vasospasm (Prinzmetal’s angina), cardiac arrhythmias, peripheral vascular disease or symptoms or signs consistent with ischaemic heart disease.

History of cerebrovascular accident (stroke) or transient ischaemic attack (TIA/mini-stroke).

Known hypertension.

Hepatic or renal impairment.

History of seizures or other risk factors which lower the seizure threshold.

Concurrent treatment with the following medications is contra-indicated:

- Ergotamine or derivatives of ergotamine (including methysergide) (see Section 4.5, Interactions).
- Monoamine oxidase inhibitors (MAOIs). Sumatriptan 50 mg tablets must not be used within 2 weeks of discontinuation of therapy with MAOIs.
- Any 5-HT1 receptor agonist (triptan).

Sumatriptan 50 mg tablets are not to be used to treat the following rare variants of migraine:

- Hemiplegic migraine – migraine with aura including unilateral motor weakness.
- Basilar migraine – migraine with aura symptoms originating from the brain stem and/or both hemispheres such as double vision, difficulty in articulating words, clumsy and uncoordinated movements, tinnitus, reduced level of consciousness.
- Ophthalmoplegic migraine – migraine headache with involvement of one or more ocular cranial nerves resulting in weakness of the muscles controlling eye movement.

4.4 Special warnings and precautions for use

Sumatriptan 50 mg tablets should only be used where a clear diagnosis of migraine has been made by a doctor or a pharmacist. For pharmacy supply, patients should have an established pattern of migraine (a history of five or more migraine attacks occurring over a period of at least 1 year).

Sumatriptan 50 mg tablets should not be taken concomitantly with other migraine therapies containing any triptan, ergotamine or derivative of ergotamine.

If a migraineur fails to respond to the first tablet of Sumatriptan 50 mg tablets, the attack may be treated with simple analgesics. Further, the diagnosis of migraine should be reconsidered with a doctor.

The recommended dose of Sumatriptan 50 mg tablets should not be exceeded.

Migraineurs whose typical headaches persist for longer than 24 hours should seek advice from their doctor.

Migraineurs in whom the pattern of symptoms has changed, or whose attacks have become more frequent, more persistent, or more severe, or who do not recover completely between attacks, should seek advice from their doctor.

Anyone with atypical symptoms which include, but are not limited to, unilateral motor weakness, double vision, clumsy and uncoordinated movements, tinnitus, reduced level of consciousness, seizure-like movements, or recent onset of rash with headache should seek advice from their doctor.

Patients whose migraine symptoms appear for the first time after age 50 should seek advice from their doctor as there may be a more serious underlying cause.
Migraineurs who experience four or more migraine attacks per month should be referred to a doctor for ongoing management.

It should be noted that migraineurs may be at risk of certain cerebrovascular events (e.g. cerebrovascular accident, transient ischaemic attack).

Following administration, sumatriptan can be associated with transient symptoms including chest pain and tightness that may be intense and involve the throat (see Section 4.8, Undesirable effects). Typically, such symptoms develop within 30 minutes of treatment and last for less than 2 hours. Where such symptoms are thought to indicate ischaemic heart disease, medical evaluation should be obtained immediately and no further doses of Sumatriptan 50 mg tablets should be taken until considered appropriate by a doctor.

Sumatriptan 50 mg tablets should not be used by migraineurs in whom unrecognised cardiac disease is likely without a prior risk assessment by a doctor or pharmacist (see Section 4.3, Contra-indications).

Special consideration should be given to post-menopausal women and men over 40. Risk factors for heart disease include hypercholesterolaemia, regular smoking, marked obesity, diabetes or a family history of early heart disease (father/brother developed heart disease before the age of 55, mother/sister developed heart disease before the age of 65). Anyone who has three or more of these risk factors is not suitable for pharmacy supply of sumatriptan. These evaluations may not identify everyone who has cardiac disease and, in very rare cases, serious cardiac events have occurred without underlying cardiovascular disease.

There have been rare post marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following the use of a selective serotonin reuptake inhibitor (SSRI) and sumatriptan. Serotonin syndrome has been reported following concomitant treatment with triptans and serotonin noradrenaline reuptake inhibitors (SNRIs).

If concomitant treatment with Sumatriptan and an SSRI/SNRI is clinically warranted, appropriate observation of the patient is advised.

Undesirable effects may be more common during concomitant use of triptans and herbal preparations containing St John’s Wort (Hypericum perforatum).

Patients with known hypersensitivity to sulphonamides may exhibit an allergic reaction following administration of sumatriptan. Reactions may range from cutaneous hypersensitivity to anaphylaxis. Although evidence of cross-sensitivity is limited, treatment with Sumatriptan 50 mg tablets is contraindicated in these patients (see Section 4.3, Contra-indications).

Women with migraine who are taking the combined oral contraceptive have an increased risk of stroke and should seek advice from their doctor if migraine attacks started recently (within the last 3 months), migraine symptoms have worsened or they have migraine with aura.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
4.5 Interaction with other medicinal products and other forms of interaction

Studies in healthy subjects show that sumatriptan does not interact with propranolol, flunarizine, pizotifen or alcohol.

Sumatriptan has the potential to interact with MAOIs, ergotamine and derivatives of ergotamine. The increased risk of coronary vasospasm is a theoretical possibility and therefore concomitant administration with MAOIs and ergotamines is contra-indicated. (see Section 4.3, Contraindications).

Prolonged vasospastic reactions have been reported with ergotamine. As these effects may be additive, 24 hours should elapse before sumatriptan can be taken following any ergotamine-containing preparation. Conversely, ergotamine-containing preparations should not be taken until 6 hours have elapsed following sumatriptan administration.

Rarely, an interaction may occur between sumatriptan and SSRIs (see Section 4.4, Special Warnings and special precautions for use). There is a risk of pharmacodynamic interaction between sumatriptan and tricyclic antidepressants.

There have been rare post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following the use of SSRIs and Sumatriptan. Serotonin syndrome has also been reported following concomitant treatment with triptans and SNRIs (see section 4.4).

Undesirable effects may be more common during concomitant use of triptans and herbal preparations containing St John’s Wort (Hypericum perforatum).

4.6 Pregnancy and lactation

Sumatriptan 50 mg tablets is not to be used in pregnancy or when breastfeeding unless on the advice of a doctor.

Post-marketing data from the use of sumatriptan during the first trimester in over 1,000 women are available. Although these data contain insufficient information to draw definitive conclusions, they do not point to an increased risk of congenital defects. Experience with the use of sumatriptan in the second and third trimester is limited.

Evaluation of experimental animal studies does not indicate direct teratogenic effects or harmful effects on peri- and postnatal development. However, embryofetal viability might be affected in the rabbit (see section 5.3).

Administration of sumatriptan should only be considered if the expected benefit to the mother is greater than any possible risk to the fœtus.

It has been demonstrated that following subcutaneous administration sumatriptan is secreted into breast milk. Infant exposure can be minimised by avoiding breast feeding for 24 hours after treatment.

4.7 Effects on ability to drive and use machines

Drowsiness may occur as a result of migraine or its treatment with sumatriptan.

Caution is recommended in patients performing skilled tasks, e.g. driving or operating machinery

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (>1/10), common (>1/100, <1/10), uncommon (>1/1000, <1/100), rare (>1/10,000, <1/1000) and very rare (<1/10,000) including isolated reports.
Immune System Disorders
Very rare: Hypersensitivity reactions ranging from cutaneous hypersensitivity (such as urticaria) to anaphylaxis.

Nervous System Disorders
Common: Tingling, dizziness, drowsiness.
Very rare: Seizures, although some have occurred in patients with either a history of seizures or concurrent conditions predisposing to seizures there are also reports in patients where no such predisposing factors are apparent. Nystagmus, scotoma.

Eye Disorders
Very rare: Flickering, diplopia, reduced vision. Loss of vision (usually transient). However, visual disorders may also occur during a migraine attack itself.

Cardiac Disorders
Very rare: Bradycardia, tachycardia, palpitations, cardiac arrhythmias, transient ischaemic ECG changes, coronary artery vasospasm, myocardial infarction (see Contra-indications, Special Warnings and special precautions for use).

Vascular Disorders
Common: Transient increases in blood pressure arising soon after treatment. Flushing.
Very rare: Hypotension, Raynaud’s phenomenon.

Gastrointestinal Disorders
Common: Nausea and vomiting occurred in some patients but it is unclear if this is related to Sumatriptan or the underlying condition.
Very rare: Ischaemic colitis.
Not known: Diarrhoea.

Musculoskeletal and Connective Tissue Disorders
The following symptom is usually transient and may be intense and can affect any part of the body including the chest and throat:
Common: Sensations of heaviness.
Very rare: Neck stiffness.
Not known: Arthralgia.

Psychiatric disorders
Not known: Anxiety.

Skin and subcutaneous tissue disorders
Not known: Hyperhidrosis.

General Disorders and Administration Site Conditions
The following symptoms are usually transient and may be intense and can affect any part of the body including the chest and throat:
Common: Pain, sensations of heat, pressure or tightness.
The following symptoms are mostly mild to moderate in intensity and transient:
Common: Feelings of weakness, fatigue.

Investigations
Very rare: Minor disturbances in liver function tests have occasionally been observed.

4.9 Overdose
In the event of an overdose, medical advice should be sought immediately.

There have been some reports of overdosage with Sumatriptan 50 mg tablets. Doses in excess of 400 mg orally were not associated with side effects other than those mentioned in Section 4.8, Undesirable effects.

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If overdosage occurs, the patient should be monitored for at least 10 hours and standard supportive treatment applied as required.

It is unknown what effect haemodialysis or peritoneal dialysis has on the plasma concentrations of Sumatriptan 50 mg tablets.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: selective serotonin (5-HT1) agonists
ATC code: N02CC01

Sumatriptan has been demonstrated to be a specific and selective 5-hydroxytryptamine-1 (5-HT1B/D) receptor agonist with no effect on other 5-HT receptor (5-HT2-5-HT7) subtypes. The vascular 5-HT1B receptor is found predominantly in cranial blood vessels and mediates vasoconstriction. In animals, sumatriptan selectively constricts the carotid arterial circulation but does not alter cerebral blood flow. The carotid arterial circulation supplies blood to the extracranial and intracranial tissues such as the meninges and dilatation of and/or oedema formation in these vessels is thought to be the underlying mechanism of migraine in man.

In addition, evidence from animal studies suggests that sumatriptan inhibits trigeminal nerve activity. Both these actions (cranial vasoconstriction and inhibition of trigeminal nerve activity) may contribute to the anti-migraine action of sumatriptan in humans.

Sumatriptan relieves headache and other symptoms of migraine including nausea, and sensitivity to light and sound. Clinical response for relief of migraine headache begins around 30 minutes following a 50 mg oral dose.

Sumatriptan remains effective in treating menstrual migraine i.e. migraine without aura that occurs between 3 days prior and up to 5 days post onset of menstruation. Sumatriptan should be taken as soon as possible after the onset of a migraine headache.

5.2 Pharmacokinetic properties
Following oral administration, sumatriptan is rapidly absorbed, 70% of maximum concentration occurring at 45 minutes. After a 50 mg dose, the mean maximum plasma concentration is 32 ng/ml. Mean absolute oral bioavailability is 14% partly due to presystemic metabolism and partly due to incomplete absorption.

Plasma protein binding is low (14-21%), mean volume of distribution is 170 litres.

The major metabolite, the indole acetic acid analogue of sumatriptan is mainly excreted in the urine, where it is present as a free acid and the glucuronide conjugate. It has no known 5-HT1 or 5-HT2 activity. Minor metabolites have not been identified.

The elimination phase half-life is approximately 2 hours, although there is an indication of a longer terminal phase. Mean total plasma clearance is approximately 1160 ml/min and the mean renal plasma clearance is approximately 260 ml/min. Non-renal clearance accounts for about 80% of the total clearance. Sumatriptan is eliminated primarily by oxidative metabolism mediated by monoamine oxidase A.

The pharmacokinetics of oral sumatriptan do not appear to be significantly affected by migraine attacks.

5.3 Preclinical safety data
Sumatriptan was devoid of genotoxic and carcinogenic activity in in vitro systems and animal studies.

In a rat fertility study, oral doses of sumatriptan resulting in plasma levels approximately 200 times those seen in man after a 100 mg oral dose were associated with a reduction in the success of insemination.
This effect did not occur during a subcutaneous study where maximum plasma levels achieved approximately 150 times those in man by the oral route. In rabbits, embryolethality, without marked teratogenic defects, was seen. The relevance for humans of these findings is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Core
- Lactose monohydrate
- Croscarmellose sodium
- Cellulose, microcrystalline
- Silica colloidal anhydrous
- Magnesium stearate
Coating – Opadry peach
- Hypromellose
- Titanium dioxide E171
- Lactose monohydrate
- Macrogol
- Glycerol triacetate
- Iron oxide red E172
- Iron oxide yellow E172
- Iron oxide black E172

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
Transparent or white opaque PVC/PVdC aluminium blisters. Blister packs of 2 film-coated tablets.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Galpharm Healthcare Limited
Hugh House
Upper Cliffe Road
Dodworth Business Park
Dodworth
Barnsley
South Yorkshire
S75 3SP

8 MARKETING AUTHORISATION NUMBER(S)
PL 16028/0139

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
12/05/2010

10 DATE OF REVISION OF THE TEXT
12/05/2010
GALPHARM MIGRAINE RECOVERY 50MG TABLETS
PL 16028/0139

PATIENT INFORMATION LEAFLET

This medicine is used to relieve migraine attack both with or without aura in people who have been diagnosed as having migraine.

Do not take this medicine if you:
- Have had an allergic reaction to any of the ingredients in this medicine.
- Are pregnant or breast feeding.
- Have high blood pressure.
- Have had a stroke or ever had a transient ischemic attack (TIA).
- Have had a heart attack.
- Have had a history of depression, bipolar disorder or self-harm.
- Have had any condition that could interfere with your ability to take this medicine.

Before taking this medicine,
- Check with your doctor or pharmacist before taking this medicine.
- Take with or after food if you have any concerns.
- Take as directed by your doctor.
- Do not exceed the recommended dose.
- Do not take if you are pregnant or breast feeding.

If you have any concerns or questions, please see your doctor or pharmacist.

If you experience any side effects,
- Please contact your doctor or pharmacist immediately.
- Do not stop taking this medicine without discussing it with your doctor or pharmacist.

If you have any concerns or questions,
- Please contact your doctor or pharmacist immediately.
- Do not stop taking this medicine without discussing it with your doctor or pharmacist.

CAUTION:
- This medicine is not recommended for children under the age of 12 years.
- This medicine is not recommended for those with a history of glaucoma.
- This medicine is not recommended for those with a history of liver disease.
- This medicine is not recommended for those with a history of kidney disease.
- This medicine is not recommended for those with a history of diabetes.
- This medicine is not recommended for those with a history of peptic ulcer.

If you have any concerns or questions,
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If you experience any side effects,
3 HOW TO TAKE THIS MEDICINE

Check the table below to see how much medicine to take:

- For one use only.
- Do not exceed more than the stated dose shown in the table.
- Take the tablet whole with a drink of water.

Children and Adolescents under the age of 18 years

This medicine should not be taken by children and adolescents under the age of 18 years. Contact your doctor.

Adults aged 18 to 65 years

- Adults aged 18 to 65 years
- Take one tablet as soon as possible at the first sign of migraine headache.
- If your symptoms persist, you may take a second tablet after 2 hours.
- You must leave at least 2 hours before the first tablet.
- If this tablet does not provide any relief, do not take a second tablet.

Adults over the age of 65 years

This medicine should not be taken by adults over the age of 65 years. Contact your doctor.

Special Warnings whilst taking the medicine

- The medicine is only to relieve migraine symptoms. Do not use it to prevent an attack. Don’t take it until you know if it is a migraine or a different headache.
- If you do not feel better from the pain within 2 hours, take another tablet or contact your doctor.
- If you are taking an anticoagulant, contact your doctor.
- If you are taking any other medicines, contact your doctor.
- It is advisable to take the medicine for at least 1 hour before meals.
- Do not exceed more than the stated dose shown in the table.

4 POSSIBLE SIDE-EFFECTS

The product can cause side-effects, like all medicines, although they don’t affect everyone and are usually mild.

If you experience any of the following, stop using the medicine and seek immediate medical help:

Very rare side effects less than 1 in 10,000 people
- Allergic reaction: Signs of swelling, including rash (such as hives, swollen lymph glands), breathing difficulty, trouble breathing, swelling of the face, lips, or throat. Seek medical advice immediately.
- Severe central nervous system effects, including headache, including head pain.

If you experience any of the following effects, stop using the medicine and contact your doctor:

Very rare side effects less than 1 in 10,000 people
- Rash, eczema, itching, redness, blisters, or skin lesions.

5 STORING THIS MEDICINE

Keep the product out of reach and sight of children.

6 FURTHER INFORMATION

What’s this medicine?

The active ingredient in this medicine is 10 mg Sumatriptan sodium succinate, a selective serotonin receptor agonist. Other ingredients are lactose monohydrate, colloidal silicon dioxide, microcrystalline cellulose, magnesium stearate, hypromellose, titanium dioxide E171, lactose monohydrate, magnesium stearate, titanium dioxide E171, and red E120 and black E172.

What the medicine looks like

The product is available as a box of 3 tablets, which are each coated, scored tablets shaped film-coated tablets containing 10 mg of Sumatriptan sodium succinate. Each film-coated tablet contains: 5 mg and 10 mg. The tablets are coated with a red and black E172.

Marketing Authorisation Holder: Deltamax Healthcare Ltd, Hugh House, Uppor Oken Road, Oxdenburn Business Park, Wetherby, West Yorkshire, LS23 7SP.


Label approved MIVIVY

7 INFORMATION ON MIGRAINE

Most migraines affect 2% of the population. However, sometimes they may occur in people with a family history. Triggers can be all sorts of things. For example:

- Diet: Eating too fast, irregular meals, chocolate, cheese, and red wine.
- Emotional: Smoking and smoking others, drinking coffee, VOM, and/or dashing TV, loud noise, strong smells.
- Psychological: Stress, anxiety, rage.
- Weather, etc.
- Other: Periods, menstruation, pain, sleep, exercise, sleep, exercise, sleep, exercise, sleep.

With migraines, it is important to consult a doctor or pharmacist if you feel that you may be having a migraine attack. It may help if you have a migraine diary note down and date when and where you have a migraine attack. This may help you to identify the trigger factors. It is important to identify and try to avoid any trigger factors that may trigger your migraine attack.

For further sources of help and information:

Migraine Migraine Association London W1B 4ED Tel: 01234 567890. www.migraine.org.uk
GALPHARM MIGRAINE RECOVERY 50MG TABLETS
PL 16028/0139

LABELLING

CARTON
BLISTER FOIL