Guidance for Pharmacists on the Safe Supply of Sumatriptan 50mg Tablets

Pharmaceutical Society of Ireland

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Contents

1. Introduction

Sumatriptan 50mg Tablets are licensed as a pharmacy-only medicine for the treatment of adults aged 18 to 65 years, for the acute treatment of migraine attacks with or without aura, where a clear diagnosis of migraine has been previously made by a doctor.

The purpose of this guidance is to assist pharmacists in the safe supply of Sumatriptan 50mg Tablets, in line with the product's marketing authorisation. Due to the need to confirm the patient's diagnosis of migraine and the counselling requirements for the appropriate use of this product, Sumatriptan 50mg Tablets **must only be supplied by the pharmacist.**

2. Guidance

The supply of Sumatriptan 50mg Tablets must only be made by a pharmacist following a structured consultation with the patient. When this medicine is supplied the pharmacist must be satisfied that, in the exercise of his or her professional judgment, the supply of such a medicine is safe and appropriate for the individual patient.

In order to determine the appropriateness of the supply, the pharmacist must consult with the information in the product's Summary of Product Characteristics (SmPC) which is available on the Health Products Regulatory Authority's (HPRA) website (www.hpra.ie). This includes the;

- Therapeutic indications
- Contraindications
- Special warnings
- Precautions for use
- Interactions

The PSI expects that pharmacists have referred to the appropriate educational resources and materials, prior to supplying Sumatriptan 50mg tablets to patients. In particular pharmacists must ensure that they can competently assess the health needs of each patient in need of Sumatriptan, for example by considering cardiovascular risk factors and medication overuse headache, as well as advising on the dosing regimen and how to take the tablet. There are other factors that need to be considered by pharmacists when supplying Sumatriptan; pharmacists are obliged to assess their own understanding and knowledge of Sumatriptan supply and upskill if needed.

3. Patient Counselling

Pharmacists as experts in medicines have a unique opportunity to support patients in the rational use of non-prescription medicines. The supervision of a pharmacist is necessary to ensure the correct medicine is selected, and appropriate advice and support is provided to the patient or their representative. It also ensures that the medicine is being used to treat the correct condition and not masking or delaying the diagnosis of a more serious condition which may require immediate referral to a doctor or other healthcare professional. This provides timely access to healthcare for patients and reduces the burden on other healthcare services.

The supply of non-prescription Sumatriptan 50mg Tablets must only be carried out by the pharmacist, who must confirm that the patient has a migraine with or without aura (as distinct from other headaches/migraine types), and previously diagnosed by a doctor. If a supply is deemed appropriate, patient counselling should include information and advice appropriate to that supply.

The supply of non-prescription medicines by a pharmacist must also comply with Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which states that, in relation to the sale or supply of any non-prescription medicine, a registered pharmacist must be satisfied that the purchaser is aware of the appropriate use of the medicine, that it is being sought for that purpose and that it is not intended for abuse and/or misuse.

In order to facilitate the safe use of Sumatriptan 50mg Tablets, pharmacists should consider making a record of the supply, for example in the Patient Medication Record (PMR). Pharmacists should also consult with and consider using any support materials as provided by the Marketing Authorisation Holder.

4. Storage of Sumatriptan 50mg Tablets

As a 'pharmacy-only' medicine, in accordance with legislation, these medicines must be stored in a part of the pharmacy premises to which the public does not have access.[1]

5. Pharmacovigilance

Any suspected adverse reactions to a medicinal product should be reported to the HPRA. There are several options in place for reporting suspected adverse reactions to the HPRA, as follows:

- By following the links ('Report an Issue' tab) to the online reporting options accessible on the HPRA website homepage (www.hpra.ie);
- Using the downloadable report form also accessible from the HPRA website, which may be completed manually and submitted to the HPRA via 'freepost';
- Using the traditional 'yellow card' report, which also utilises a freepost system. 'Yellow cards' are available from the HPRA Pharmacovigilance department on request;
- By telephone to the HPRA Pharmacovigilance section (01 676 4971).

6. Policies and Procedures

Superintendent and supervising pharmacists must ensure that documented policies and procedures are in place, which address the supply of Sumatriptan 50mg Tablets, in the pharmacies under their control. These documents should address all issues identified in this guidance and be reviewed and updated in line with further guidance or any other relevant information in this area. Superintendent and supervising pharmacists must ensure that there is adequate staff training in place to ensure compliance with policies and procedures and all staff are aware that they must refer requests for Sumatriptan 50mg Tablets to the pharmacist.

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1 Regulation 5(1)(ea) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended)

7. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Is the pharmacist and all relevant staff members aware of the licensed indications for Sumatriptan 50mg Tablets?				
Are members of staff aware that all requests for Sumatriptan 50mg Tablets must be referred to the pharmacist?				
Does the pharmacist carry out a thorough consultation with each patient to determine if Sumatriptan 50mg Tablets are safe and suitable for them to use?				
Does the pharmacist counsel the patient to ensure that they know how to safely use Sumatriptan 50mg Tablets and are aware of the maximum dose and when they should seek advice from their doctor?				
Are Sumatriptan 50mg Tablets stored in a part of the pharmacy premises to which the public does not have access?				
Are there written policies and procedures in place for all aspects of the supply of Sumatriptan 50mg Tablets?				
Are the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the relevant policies and procedures?				