Public Assessment Report

Prescription Only Medicine to Pharmacy Reclassification

Sildenafil 50mg Film-coated Tablets

Sildenafil (50mg)

PL 16028/0165 – 0001

GALPHARM HEALTHCARE LIMITED

TABLE OF CONTENTS

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK Government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (https://yellowcard.mhra.gov.uk/).

Alternative format versions of this report are available on request from reclassification@mhra.gov.uk

1. Background on deciding where medicines are available

The role of MHRA

MHRA regulates medicines and medical devices in the UK, on behalf of the UK Licensing Authority. This means that MHRA decides whether medicines are available:

- on prescription only - 'prescription only medicine' (POM)
- bought from pharmacies - 'pharmacy medicine' (P)
- bought from other shops - 'general sales list medicine' (GSL)

What is re-classification of a medicine?

Making a change on where a medicine is available is called 're-classification'. This is sometimes referred to as 'switching'. To decide on this change, MHRA may:

- take advice from the Commission on Human Medicines and its Expert Advisory Groups[1]
- take advice from a group ('stakeholder group') of health professionals and representatives of people affected by the classification change
- run a public consultation

To be reclassified from POM to P, a medicine must:

- be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used correctly
- be generally used correctly (i.e. not frequently or to a wide extent used correctly)
- not contain substances or preparations of substances where the activity of the product or
  its side effects require further investigation
- not normally be prescribed by a doctor for injection (parenteral administration)

What evidence is needed?

A company or organisation can ask MHRA for a medicine to be available as a pharmacy medicine or a general sale medicine. To do this, they need to get together evidence to show that the medicine

a) is likely to be used appropriately, and

b) with relatively little danger to the public.

This evidence needs to focus on the risk to the public. This includes evidence on the possible abuse or misuse of the medicine. The evidence may include:

- clinical studies
- evidence showing acceptable level of side effects
- advice of experts
- views of relevant health professionals and their professional bodies
- views of relevant public associations and individuals with an interest in the medicine under consideration

[1] The Commission on Human Medicines (CHM) is an advisory non-departmental public body, sponsored by the Department of Health. The CHM advises ministers on the safety, efficacy and quality of medicines. The CHM is supported in its work by Expert Advisory Groups (EAGs), covering various areas of medicine. The CHM's views are sought on reclassifications when more complex or new reclassifications of medicines are being proposed.

Who makes the final decision?

The final decision on whether to approve a change is made by the MHRA, on behalf of the UK Licensing Authority.

2. About Sildenafil 50mg Film-coated Tablets

Sildenafil 50mg Film-coated Tablets is a medicine to be taken by mouth for use in adult men with erectile dysfunction.

The full name of the medicine is Sildenafil 50mg Film-coated Tablets. In this document, we will call it 'Sildenafil Tablets'.

The Medicines and Healthcare Products Regulatory Agency (MHRA) considers this product sufficiently safe to be sold without prescription only from pharmacies, by or under the supervision of a pharmacist. This report outlines the evidence that the MHRA reviewed and which led to the decision to approve the application.

What is in Sildenafil Tablets?

Each tablet of the product contains 50mg of sildenafil citrate.

What are Sildenafil Tablets used for?

Sildenafil belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by blocking the phosphodiesterase enzyme, which normally breaks down a substance known as cyclic guanosine monophosphate (cGMP). During sexual stimulation, cGMP is produced in the penis, where it causes the muscle in the spongy tissue of the penis (the corpora cavernosa) to relax, allowing the flow of blood into the corpora, producing the erection. By blocking the breakdown of cGMP, sildenafil improves erectile function. Sexual stimulation is still needed to produce an erection.

NHS Choices provides health advice about erectile dysfunction:
http://www.nhs.uk/conditions/Erectile-dysfunction/Pages/Introduction.aspx

Who has made the proposal?
The licence holder[2], Galpharm Healthcare Limited, applied to make Sildenafil Tablets available through pharmacies.

3. Proposed Terms of Reclassification

What are the details of this change?

Sildenafil Tablets will be made available through pharmacy outlets under the following conditions:

a) For oral use in the form of tablets
b) For use in adult men with erectile dysfunction
c) Maximum strength: 50mg
d) Maximum dose: 50 mg

[2] A licence holder or marketing authorisation holder is the company with legal authorisation to make the medicine available to patients

e) Maximum daily dose: 50mg
f) Maximum pack size: 8 tablets

4. How the application was assessed

A medicine will be non-prescription unless it fulfils the criteria for prescription control as set out below.

Prescription only status will apply where:

- a direct or indirect danger exists to human health, even when used correctly, if used without medical supervision
- there is frequently incorrect use which could lead to direct or indirect danger to human health
- further investigation of activity and/or side-effects is required
- the product is normally prescribed for parenteral administration (by injection)

In the UK these criteria are laid down in the Human Medicines Regulations 2012, regulation 62(3)[3].

Assessment of suitability for Pharmacy availability

Viagra Connect, a sildenafil-containing product to treat erectile dysfunction was approved as a P medicine in 2017 with identical conditions of supply to those proposed for Sildenafil Tablets. There have been no additional safety concerns since the launch of this product in March 2018.

5. Further details on the application

Risk Management Plan

The application contained a risk management plan (RMP). RMPs contain information on a medicine's safety profile and one or more of the following:

- How any risks identified in the safety profile will be prevented or minimised in patients
- Plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine
- Risk factors for side effects
- Measuring the effectiveness of measures taken to prevent or minimise risks

Viagra Connect was reclassified as a P product under the following conditions for risk minimisation measure:

- The main risks associated with the product and proposed additional warnings on the labelling and patient information leaflet
- A pharmacist training guide
- A checklist that can be used for the supply of the product

[3] The Human Medicines Regulations 2012. http://www.legislation.gov.uk/uksi/2012/1916/contents/made

- A survey-based study to assess the utility and effectiveness of the above proposed pharmacy risk minimisation material in conveying the key messages to pharmacists and how these impact on self-reported pharmacy practice

Since the data collection period of the study was completed during the processing of this application a separate study was not required to be undertaken as part of this reclassification. However, any findings from the results of the Viagra Connect study that require changes to the terms of the Marketing Authorisation for Viagra Connect will also apply to this product. The remaining risk minimisation measures are aligned with those of Viagra Connect.

6. Reasons for not seeking advice from the Commission on Human Medicines

No major issues have been identified in the assessment of this application for Sildenafil Tablets as a P medicine based on the following reasons:

- Viagra Connect, a sildenafil-containing product to treat erectile dysfunction was approved as a P product in 2017
- The proposed indication, dose, route of administration, strength, duration of treatment and maximum pack size are as per Viagra Connect
- CHM were consulted on the reclassification of Viagra Connect to a P product. No additional changes have been made to the product information of Sildenafil Tablets which would require additional advice from CHM
- Since the reclassification of Viagra Connect, no additional safety concern has been raised as a result of its availability as a P product

7. Conclusion

The MHRA has taken the decision to approve Pharmacy legal status for Sildenafil Tablets under the following conditions:

a) For oral use in the form of tablets
b) For use in adult men with erectile dysfunction
c) Maximum strength: 50mg
d) Maximum dose: 50 mg tablet
e) Maximum daily dose: 50mg
f) Maximum pack size: 8 tablets

Medicines and Healthcare products Regulatory Agency
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