Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Sildenafil 25 mg film-coated tablets
Sildenafil 50 mg film-coated tablets
Sildenafil 100 mg film-coated tablets

sildenafil citrate

PL 54022/0013 - 0015

Mobius Healthcare Limited

LAY SUMMARY

Sildenafil 25 mg film-coated tablets
Sildenafil 50 mg film-coated tablets
Sildenafil 100 mg film-coated tablets
sildenafil citrate

This is a summary of the Public Assessment Report (PAR) for Sildenafil 25 mg, 50 mg and 100 mg film-coated tablets. It explains how these products 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 these products.

These products will be referred to as Sildenafil in this lay summary for ease of reading.

For practical information about using Sildenafil, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Sildenafil and what are they used for?
These applications are the same as Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 43542/0111 - 0113) which are already authorised.

The Company responsible for Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 43542/0111 - 0113) has agreed that its scientific data can be used as the basis for the grant of an identical licences for Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 54022/0013 - 0015).

Sildenafil are treatment for adult men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

How do Sildenafil work?
Sildenafil contains the active substance sildenafil (as citrate) which belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) inhibitors. It works by helping to relax the blood vessels in the patient's penis, allowing blood to flow into their penis when they get sexually excited. Sildenafil tablet will only help the patient to get an erection if they are sexually stimulated.

How are Sildenafil used?
The pharmaceutical form of these medicines is a film-coated tablet, and the route of administration is oral (by mouth).

The usual starting dose is 50 mg.

The patient should *not* take Sildenafil more than once a day.

The patient should take Sildenafil tablet about one hour before they plan to have sex.
The patient should swallow the tablet whole with a glass of water.

If the patient feels that the effect of Sildenafil is too strong or too weak, they should talk to their doctor or pharmacist.

Sildenafil will only help the patient to get an erection if they are sexually stimulated. The amount of time Sildenafil takes to work varies from person to person, but it normally takes between half an hour and one hour. The patient may find that Sildenafil takes longer to work if they take it with a heavy meal.

If Sildenafil does not help the patient to get an erection, or if their erection does not last long enough for them to complete sexual intercourse, they should tell their doctor.

The tablet can be divided into equal halves for ease of swallowing but should not be used to divide the dose.

For further information on how Sildenafil are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patient should always take this medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Sildenafil have been shown in studies?
Sildenafil are considered identical to the previously authorised products with the same benefits and risks. No new studies have been provided for Sildenafil, however, reference is made to the studies for Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 43542/0111 - 0113).

What are the possible side effects of Sildenafil?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of these medicines.

Sildenafil are considered to be identical to the previously authorised products with the same benefits and risks.

Why were Sildenafil approved?
It was concluded that Sildenafil are considered to be identical to the previously authorised products with the same benefits and risks. Therefore, MHRA decided that the benefits of Sildenafil are greater than the risks and authorised that these medicines are approved for use.

What measures are being taken to ensure the safe and effective use of Sildenafil?
As for all newly authorised medicines, a Risk Management Plan (RMP) has been developed for Sildenafil. The RMP details the important risks of Sildenafil, how these risks can be minimised, any uncertainties about Sildenafil (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Sildenafil:

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• Non-arteristic anterior ischaemic optic neuropathy (NAION)
Missing information	• None

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Sildenafil are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Sildenafil
Marketing Authorisations for Sildenafil were granted in the United Kingdom (UK) on 22 April 2025.

The full PAR for Sildenafil follows this summary.

This summary was last updated in June 2025.

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) approved the applications for Sildenafil 25 mg, 50 mg and 100 mg film-coated tablets (PL 54022/0013 - 0015).

The products are approved for the following indication:
Treatment of men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

In order for Sildenafil to be effective, sexual stimulation is required.

Sildenafil 25 mg, 50 mg and 100 mg film-coated tablets contain the active substance sildenafil (as citrate).

Sildenafil is an oral therapy for erectile dysfunction. In the natural setting, i.e. with sexual stimulation, it restores impaired erectile function by increasing blood flow to the penis.

The physiological mechanism responsible for erection of the penis involves the release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. Nitric oxide then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (cGMP), producing smooth muscle relaxation in the corpus cavernosum and allowing inflow of blood.

Sildenafil is a potent and selective inhibitor of cGMP specific phosphodiesterase type 5 (PDE5) in the corpus cavernosum, where PDE5 is responsible for degradation of cGMP. Sildenafil has a peripheral site of action on erections. Sildenafil has no direct relaxant effect on isolated human corpus cavernosum but potently enhances the relaxant effect of NO on this tissue. When the NO/cGMP pathway is activated, as occurs with sexual stimulation, inhibition of PDE5 by sildenafil results in increased corpus cavernosum levels of cGMP. Therefore, sexual stimulation is required in order for sildenafil to produce its intended beneficial pharmacological effects.

These are national abridged applications approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as informed consent applications. The applications cross-refer to the reference products Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 43542/0111 - 0113).

No new non-clinical or clinical data have been supplied, and none are required for these informed consent applications.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the applications are for identical versions of already authorised products, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

National marketing authorisations for Sildenafil 25 mg, 50 mg and 100 mg film-coated tablets were granted in the United Kingdom (UK) on 22 April 2025.

II. EXPERT REPORT

The applicant cross-refers to the data for Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 43542/0111 - 0113; Euro-Link Pharma Limited), to which these applications are claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

SUMMARIES OF PRODUCT CHARACTERISTICS (SmPCs)

The SmPCs are in line with those for Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 43542/0111 - 0113), dated 18/10/2022, 19/02/2025, and 19/02/2025, respectively.

PATIENT INFORMATION LEAFLET

A leaflet text and mock-up has been provided which has been aligned with that for Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets (PL 43542/0111 - 0113), dated for January 2024.

LABEL

Label text and mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specifications

The sources of the active substances are in line with the cross-reference products. The proposed drug substance specification is consistent with the details registered for the cross-reference products.

IV.2. Drug Products

Name

The products have been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes

Sildenafil 25 mg, 50 mg, and 100 mg film-coated tablets are packaged in PVC/Aluminium foil blister packs and are available in the following pack-sizes:

- *25 mg and 100 mg:* 1, 2, 4, 8, 12 or 24 tablets.
- *50 mg*: 2, 4, or 8 tablets.

Not all pack sizes may be marketed.

The appearance of the products is identical to that of the cross-reference products.

The proposed shelf life of the product is 3 years, without any special storage conditions, is acceptable.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

Legal status

Prescription only medicine (POM).

Manufacturers
The proposed manufacturing sites are consistent with the details registered for the cross-reference products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative compositions
The composition of the proposed products is consistent with the details registered for the cross-reference products.

Manufacturing process & control of critical steps
The proposed manufacturing processes and process controls are consistent with the details registered for the reference products and the maximum batch size is stated.

Finished product release/shelf life specifications
The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference products.

No excipients of animal or human origin are used in the final products.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin

These products do not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS

As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS

As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent applications) no new clinical data have been supplied and none are required.

VII. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference products. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference products and positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference products.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

TABLE OF CONTENTS OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or Reference Regulator (RR) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**