Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Tadalafil 10 mg film-coated Tablets

tadalafil

PL 21880/0344

Medreich PLC

LAY SUMMARY

Tadalafil 10 mg film-coated Tablets
tadalafil

This is a summary of the Public Assessment Report (PAR) for Tadalafil 10 mg film-coated Tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Tadalafil in this lay summary for ease of reading.

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

What is Tadalafil and what is it used for?
This application is the same as Tadalafil 10 mg film-coated Tablets (PL 21880/0231) which is already authorised. The company responsible for Tadalafil 10 mg film-coated Tablets (PL 21880/0231) is the same company that is the holder of Tadalafil 10 mg film-coated Tablets (PL 21880/0344).

Tadalafil is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

How does Tadalafil work?
Tadalafil contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Following sexual stimulation Tadalafil works by helping the blood vessels in the patient's penis to relax, allowing the flow of blood into their penis. The result of this is improved erectile function. Tadalafil will *not* help the patient if they do *not* have erectile dysfunction.

It is important to know that the patient will *not* get an erection just by taking Tadalafil. This medicine works with their body's natural function to get an erection only when they are sexually stimulated. The patient and their partner will need to engage in foreplay, just as they would if they were not taking a medicine for erectile dysfunction.

How is Tadalafil used?
The pharmaceutical form of this medicine is a film-coated tablet, and the route of administration is oral (by mouth).

Tadalafil are for oral use in men *only*.

The patient should take one tablet as needed, at least 30 minutes before sexual activity.

The patient should swallow the tablet whole with some water. The tablets can be taken with or without food. The patient should *not* take more than 1 tablet a day.

The patient can get an erection, when sexually stimulated, in 30 minutes. Tadalafil may still be effective up to 36 hours after taking the tablet.

This medicine is intended for use prior to anticipated sexual activity. It is *not* recommended for continuous daily use. The patient should talk to their doctor if they feel they need to take this medicine every day.

The patient should talk to their pharmacist or doctor if they have taken Tadalafil as directed and are still not able to get and keep an erection.

For further information on how Tadalafil is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can be obtained without a prescription.

The patient should always take the 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 Tadalafil have been shown in studies?
Tadalafil is considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Tadalafil 10 mg film-coated Tablets (PL 21880/0344); however, reference is made to the studies for Tadalafil 10 mg film-coated Tablets (PL 21880/0231).

What are the possible side effects of Tadalafil?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC 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 this medicine.

Tadalafil is considered to be identical to the previously authorised product with the same benefits and risks.

Why was Tadalafil approved?
It was concluded that Tadalafil is identical to the previously authorised product, Tadalafil 10 mg film-coated Tablets (PL 21880/0231). Therefore, the MHRA decided that the benefits of Tadalafil are greater than the risks and authorised that this medicine is approved for use.

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

There are no safety concerns associated with use of Tadalafil.

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 Tadalafil 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 this application and are satisfactory.

Other information about Tadalafil
A Marketing Authorisation for Tadalafil was granted in the United Kingdom (UK) on 19 February 2025.

The full PAR for Tadalafil follows this summary.

This summary was last updated in June 2025.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) approved the application for Tadalafil 10 mg film-coated Tablets (PL 21880/0344).

The product is approved for the following indications in adult men:
Erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual activity.

In order for Tadalafil 10 mg film-coated Tablets to be effective, sexual stimulation is required.

The active substance, tadalafil is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type-5 (PDE5). When sexual stimulation causes the local release of nitric oxide, inhibition of PDE5 by tadalafil produces increased levels of cGMP in the corpus cavernosum. This results in smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection. Tadalafil has no effect in the absence of sexual stimulation.

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers to the reference product, Tadalafil 10 mg film-coated Tablets (PL 21880/0231).

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

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, 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 this product at all sites responsible for the manufacture, assembly and batch release of this product.

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

A national marketing authorisation for Tadalafil 10 mg film-coated Tablets was granted in the United Kingdom (UK) on 19 February 2025.

II. EXPERT REPORT

The applicant cross-refers to the data for Tadalafil 10 mg film-coated Tablets (PL 21880/0231, held by Medreich PLC), to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is generally in line with that for Tadalafil 10 mg film-coated Tablets (POM) and in line with the analogous P product Cialis Together 10 mg tablets (PL 53886/0076) dated 31/10/2024.

PATIENT INFORMATION LEAFLET (PIL)

A leaflet text and mock-up has been provided, which has been aligned with the analogous P product Cialis Together 10 mg tablets (PL 53886/0076) dated 01/2023.

LABEL

Label text and mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specification

The source of the active substance is in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

IV.2. Drug Product

Name

The product has been named in line with current requirements.

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

Tadalafil 10 mg film-coated Tablets are packaged in aluminium-PVC/PE/ACLAR blister packs and are available in pack-sizes of 2, 4, and 8 film-coated tablets.
Not all pack sizes may be marketed.

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

The proposed shelf life of the product is 36 months, 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

Pharmacy (P) medicine.

Manufacturers

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

Qualitative and quantitative compositions

The composition of the proposed product is consistent with the details registered for the cross-reference product.

Manufacturing process & control of critical steps
The proposed manufacturing processes and process controls are consistent with the details registered for the reference product 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 product.

TSE Compliance
With the exception of lactose monohydrate, no excipients of animal or human origin are used in the final products.

The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.

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

This product does not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS

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

VI. CLINICAL ASPECTS

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) 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 product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product, apart from the reclassification from POM to P which was introduced as part of this initial marketing authorisation. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

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

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

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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 SmPC and/or PIL available on the MHRA website.

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