



Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Naproxen 500mg Tablets

naproxen

PL 28444/0268

Activase Pharmaceuticals Limited

LAY SUMMARY

Naproxen 500mg Tablets naproxen

This is a summary of the Public Assessment Report (PAR) for Naproxen 500mg 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 Naproxen Tablets in this lay summary for ease of reading.

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

What is Naproxen Tablets and what is it used for?

This application is the same as Naproxen 500mg Tablets (PL 21880/0111) which is already authorised.

The Company responsible for Naproxen 500mg Tablets has agreed that its scientific data can be used as the basis for the grant of an identical licence for Naproxen Tablets.

Naproxen Tablets is used for treatment of:

- rheumatoid arthritis or other rheumatic or musculoskeletal disorders (ailments that cause pain and stiffness in muscles, bones and joints)
- women, while having period pain
- acute gout

How does Naproxen Tablets work?

Naproxen is one of a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Naproxen reduces inflammation and pain in the joints and muscles.

How is Naproxen Tablets used?

The pharmaceutical form of this medicine is a tablet and the route of administration is oral (by mouth).

Naproxen Tablets should be swallowed whole with a glass of water, with food. The patient should take their tablets at the same time each day.

The patient should make sure that they have enough to drink (stay well hydrated) when they are taking Naproxen. This is particularly important for people who have problems with the kidneys.

While a patient is taking Naproxen Tablets their doctor will want to see the patient to check they are on the right dose for them and look for any side effects. This is particularly important if the patient is elderly.

Recommended dose:

Adults

Muscle, joint or tendon problems and Period pain

The usual starting dose is 500 mg, followed by one 250 mg tablet every 6 to 8 hours as needed.

Arthritis and ankylosing spondylitis

The usual dose is between 500 mg and 1000 mg.

The dose can be taken all at once, or half the dose may be taken twice a day.

Gout

The usual starting dose is 750 mg, then 8 hours later 500 mg followed by one 250 mg tablet every 8 hours as needed.

Elderly and patients with liver and kidney problems

The doctor will decide the right dose for the patient, it will usually be lower than for other adults.

Children over 5 years, rheumatoid arthritis

The usual dose is 10 mg per kilogram of body weight each day.

The total daily dose is split into two doses, to be given 12 hours apart.

Medicines such as Naproxen Tablets may be linked with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with higher doses and long-term treatment.

Patients should not take more than the recommended dose or exceed the length of the treatment.

For further information on how Naproxen Tablets 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 only be obtained with 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 Naproxen Tablets have been shown in studies?

Naproxen Tablets is considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Naproxen Tablets, however, reference is made to the studies for Naproxen 500mg Tablets.

What are the possible side effects of Naproxen Tablets?

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.

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

Why was Naproxen Tablets approved?

The MHRA decided that the benefits of Naproxen Tablets are greater than the risks and recommended that this medicine is approved for use.

What measures are being taken to ensure the safe and effective use of Naproxen Tablets?

As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Naproxen Tablets. The RMP details the important risks of Naproxen Tablets, how these risks can be minimised, any uncertainties about Naproxen Tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Naproxen Tablets.

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 Naproxen Tablets 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 Naproxen Tablets

A marketing authorisation was granted in the UK on 25 March 2024.

The full PAR for Naproxen Tablets follows this summary.

This summary was last updated in May 2024.

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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) considered that the application for Naproxen 500mg Tablets (PL 28444/0268) could be approved.

The product is approved for the following indications:

- the treatment of rheumatoid arthritis and other rheumatic or musculoskeletal disorders, dysmenorrhoea and acute gout.

Naproxen is a non-steroidal anti-inflammatory analgesic compound with antipyretic properties as has been demonstrated in classical animal test systems. Naproxen exhibits its anti-inflammatory effect even in adrenalectomised animals, indicating that its action is not mediated through the pituitary-adrenal axis.

Naproxen inhibits prostaglandin synthetase (as do other NSAIDs). As with other NSAIDs, however, the exact mechanism of its anti-inflammatory action is not known.

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 Naproxen 500mg Tablets (PL 21880/0111).

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 was granted in the UK on 25 March 2024.

II. EXPERT REPORT

The applicant cross-refers to the data for Naproxen 500mg Tablets, 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 in line with that for Naproxen 500mg Tablets, dated 09/2018.

PATIENT INFORMATION LEAFLET

A leaflet mock-up has been provided which has been aligned with that for Naproxen 500mg Tablets, dated for 08/2018.

LABEL

Label 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

Naproxen 500mg Tablets are available in a tamper evident container comprised of polyethylene and polypropylene in pack sizes of 28, 30, 56, 60, 84, 100, 250, 500 and 1000 tablets.

Naproxen 500mg Tablets are also available in a PVDC-PVC blister pack in pack sizes of 28, 30, 56, 60, 84 and 100 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 with the recommended storage conditions store in a dry place below 25°C, protect from light and keep container tightly closed.

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

The supplier of lactose 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. 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 European Medicines Agency (EMA) 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