



# **Public Assessment Report**

## **National Procedure**

### **Diclofenac 1% Gel**

#### **diclofenac sodium**

**PL 36065/0011**

**Phagecon – Serviços e Consultoria  
Farmacêutica, Lda.**

## LAY SUMMARY

### **Diclofenac 1% Gel diclofenac sodium**

This is a summary of the Public Assessment Report (PAR) for Diclofenac 1% Gel. 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 Diclofenac Gel in this lay summary for ease of reading.

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

#### **What is Diclofenac Gel and what is it used for?**

This application is the same as Diclofenac 1% Gel (PL 19255/0019), which is already authorised.

The Company responsible for Diclofenac 1% Gel has agreed that its scientific data can be used as the basis for the grant of an identical licence for Diclofenac Gel.

Diclofenac Gel acts as anti-inflammatory and analgesic agent in the treatment of:

- mild to moderate muscle pains
- contusions
- post-traumatic pain

Diclofenac 1% Gel is intended to adults and adolescents aged 14 years and over.

#### **How does Diclofenac Gel work?**

Diclofenac Gel contains the active substance diclofenac sodium. Diclofenac is a phenylacetic acid derivative. It leads to inhibition of cyclooxygenase activity, which, then, leads to the inhibition of prostaglandin synthesis and other inflammation mediators.

#### **How is Diclofenac Gel used?**

The pharmaceutical form of this medicine is a gel and the route of administration is application to the skin.

#### **Adults and adolescents aged 14 years and over**

The patient or caregiver should apply a thin layer of Diclofenac Gel on the affected area, 3 to 4 times daily according to the need of the situation (2-4g, quantity as big as a cherry or a walnut) and rub gently. The treatment duration depends on the indications and on the response to the treatment. It is recommended that the treatment should be evaluated 7 days after its start.

In adolescents aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient or caregiver is advised to consult a doctor.

#### **Children under the age of 14 years**

Diclofenac Gel must not be used in children under the age of 14 years, since there are no data on the safety and efficacy in this group of patients.

**Patients with liver or kidney insufficiency**

No dosage adjustment is necessary in these patients.

**Elderly**

The usual adult dosage may be used.

**Method of administration**

This medicine should be applied on healthy skin only.

After application, the patient or caregiver should wash their hands, unless these are being treated.

For further information on how Diclofenac Gel 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 use 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 Diclofenac Gel have been shown in studies?**

Diclofenac Gel is considered identical to the previously authorised product with the same benefits and risks. [No new studies have been provided for Diclofenac Gel, however, reference is made to the studies for Diclofenac 1% Gel.

**What are the possible side effects of Diclofenac Gel?**

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

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.

**Why was Diclofenac Gel approved?**

The MHRA decided that the benefits of Diclofenac Gel 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 Diclofenac Gel?**

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

There are no safety concerns associated with use of Diclofenac Gel.

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 Diclofenac Gel 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 for this medicine and are satisfactory.

**Other information about Diclofenac Gel**

A marketing authorisation was granted in the United Kingdom on 31 May 2023.

The full PAR for Diclofenac Gel follows this summary.

This summary was last updated in July 2023.

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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 Diclofenac 1% Gel (PL 36065/0011) could be approved.

Diclofenac Gel is indicated in adults and adolescents aged 14 years and over as anti-inflammatory and analgesic agent in the treatment of:

- mild to moderate muscle pain
- contusions
- post-traumatic pain

The active substance diclofenac (as diclofenac sodium) is a phenylacetic acid derivative. It leads to the inhibition of cyclooxygenase activity, which then leads to the inhibition of the synthesis of prostaglandin and other mediators of inflammation. Diclofenac acts as anti-inflammatory and analgesic agent in the treatment of topical symptoms of rheumatic and non-rheumatic pains of the locomotor apparatus.

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 Diclofenac 1% Gel (PL 19255/0019), currently held by Amdeepcha Limited, which was originally granted in the UK to the Marketing Authorisation Holder Phagecon – Serviços e Consultoria Farmacêutica LDA on 11/04/2019 (PL 36065/0007).

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 United Kingdom on 31 May 2023

## II. EXPERT REPORT

The applicant cross-refers to the data for Diclofenac 1% Gel (PL 19255/0019; Amdeepcha Limited), 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 Diclofenac 1% Gel dated 04/2021.

## PATIENT INFORMATION LEAFLET

A mock-up has been provided which has been aligned with that for Diclofenac 1% Gel, dated for 01/2021. The user test report submitted for PL 36065/0004 has been provided.

**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**

Diclofenac Gel is available in

1. Aluminium tubes each sealed by a membrane, with high density polyethylene caps, in pack sizes of 60 g or 100 g of gel for topical application.
2. Aluminium tubes each sealed by a membrane, with polypropylene caps, in a pack size of 30 g or 50 g of gel for topical application.

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 30 months for the unopened product and 6 months for the product after first opening with storage conditions 'Store below 25°C'.

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**

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

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) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation study in accordance with legal requirements. The results show that the PIL meets the criteria for readability as set out in the guideline on the readability of the label and package leaflet of medicinal products for human use.

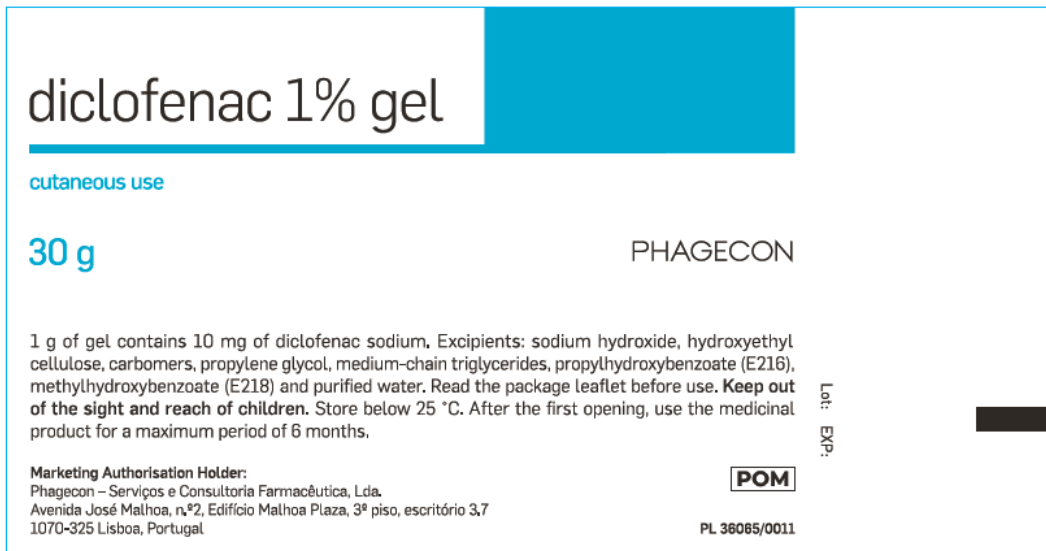
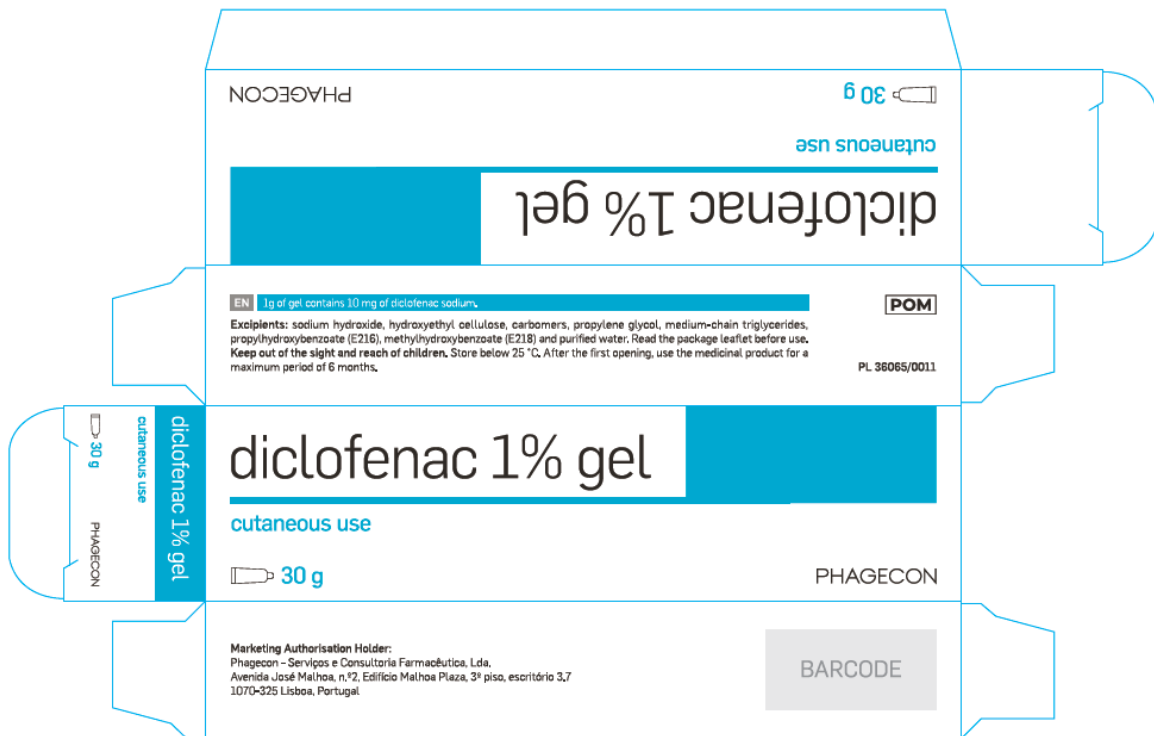
**IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION**

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.

Representative copies of the labels at the time of licensing are provided below.



## TABLE OF CONTENT 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 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.

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