



Public Assessment Report

Pharmacy to General Sales List Reclassification

Voltarol Back & Muscle Pain Relief 1.16% Gel

Diclofenac Diethylammonium (DDEA) 1.16% w/w

PL 44673/0156

GSK Consumer Healthcare (UK) Trading Limited

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1 Introduction

Voltarol Back & Muscle Pain Relief 1.16% Gel can be used for the local symptomatic relief of pain and inflammation in: trauma of the ligaments, muscles and joints e.g. due to sprains, strains and bruises; localised forms of soft tissue rheumatism, in adults and children aged 14 years and over.

Each 100 grams of the product contains 1.16 grams of the active ingredient diclofenac diethylammonium.

The licence holder¹, GSK Consumer Healthcare (UK) Limited, applied to make 120 g pack size of Voltarol Back & Muscle Pain Relief 1.16% Gel available as a General Sales List medicine for sale through general retail outlets (see Background for definition).

The Medicines and Healthcare Products Regulatory Agency (MHRA) considers this product sufficiently safe to be sold on general sale. This report outlines the evidence that the MHRA reviewed and which led to the decision to approve the application.

2 Background

Diclofenac diethylammonium reduces substances in the body that cause pain and swelling and therefore acts to relieve pain and reduce inflammation (it is a non-steroidal anti-inflammatory drug [NSAID]).

Pharmacy medicines can be supplied without prescription only from pharmacies, by or under the supervision of a pharmacist. General Sales List medicines can be sold or supplied in other retail outlets other than pharmacies by someone who is not a pharmacist.

GSL legal status for a 30g pack size of Voltarol Back & Muscle Pain Relief 1.16% Gel was first approved in 2004. Subsequently, GSL legal status was approved for a 50g pack size in 2008 and 100g pack size in 2013.

In line with the other pack sizes, the 120 g pack size of Voltarol Back & Muscle Pain Relief 1.16% Gel can be used for the local symptomatic relief of pain and inflammation in: trauma of the ligaments, muscles and joints e.g. due to sprains, strains and bruises; localised forms of soft tissue rheumatism, in adults and children aged 14 years and over.

3 Proposed Terms of Reclassification

GSK Consumer Healthcare (UK) Limited proposed to make Voltarol Back & Muscle Pain Relief 1.16% Gel available through general retail outlets with the following terms of reclassification:

- a) Pack size: 120g
- b) For use in adults and children aged 14 years and over for the local symptomatic relief of pain and inflammation in: trauma of the ligaments, muscles and joints e.g. due to sprains, strains and bruises; localised forms of soft tissue rheumatism.

¹ A licence holder or marketing authorisation holder is the company with legal authorisation to make the medicine available to patients.



- c) Dose: Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 3-4 times a day. A period of at least 4 hours should be left between applications. The dose should not be applied more than 4 times in a 24-hour period.
- d) Route of administration: applied locally² to the skin
- e) Strength: 100 g of gel contains 1.16g (1.16% w/w) diclofenac diethylammonium
- f) Duration of treatment: up to 7 days.

4 General Sales List Criterion

Under the provisions of The Human Medicines Regulations 2012, regulation 62(5), General Sales List is appropriate for medicines that can, with reasonable safety, be sold or supplied by someone other than a pharmacist.

The term “with reasonable safety” has been defined as: “where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the purchaser.”

5 Assessment of suitability for General Sales List availability

The MHRA assessed the application against the General Sales List criterion, as stated in section 4.

5.1 Hazard to health

5.1.1 Safety Profile

The safety and efficacy of the active substance diclofenac diethylammonium (DDEA) has been assessed for the existing pack sizes for the product. The safety and efficacy of the product is well established. There is no new data of concern for this application to add the 120g pack size.

Similarly, the pharmacokinetic³ data for the product has been assessed for the existing pack sizes. The pharmacokinetics of DDEA in gel formulation are well known.

There is little risk of a more sinister condition being masked; the condition for which the product may be used for the 120g pack is unchanged from that with the existing pack sizes.

The maximum duration of use is limited to 7 days, unchanged from that for the existing pack sizes of the product. The summary of product characteristics (SPC)⁴ states ‘If symptoms persist after 7 days or get worse at any time, medical advice should be sought. Not to be used for more than 7 days unless recommended by a doctor’. This information is clearly conveyed to the patient in the product information (label and leaflet⁵).

² To apply something locally means to put it on a specific part of the body

³ Pharmacokinetics is the study of how a drug acts in the body; including how and how fast it is: taken into and eliminated from the body, and how long its effect lasts the body.

⁴ The summary of product characteristics is a description of a medicinal product's properties and the conditions attached to its use.

⁵ The label and leaflet (product information) provide information to patients about the medicine, including information on correct use of the medicine.



The 7-day maximum duration of use is consistent with the other DDEA-containing gel formulations currently marketed in the UK. Other products on the UK market containing active substances in the same therapeutic class as DDEA (non-steroidal inflammatory drugs; NSAIDs) and for application to the skin (topical use) allow in some cases up to 14 days maximum duration of use, for example some ibuprofen-containing gels.

5.1.2 Drug Interactions

Drug interactions for the 120g pack size are unchanged from those for the existing pack sizes of the product.

The summary of product characteristics states that the combined use of ibuprofen with aspirin or other NSAIDs may cause an increase in the occurrence of side effects. However, due to the low absorption of the product into the body in normal conditions, the interactions described for oral NSAIDs would not be expected.

The product information advises users to consult their doctor or pharmacist if they are taking other medication and advises against using the product if they are taking diclofenac tablets or other NSAID tablets. In particular, section 2 of the patient information leaflet states “Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without prescription. Do not use Voltarol Back & Muscle Pain Relief 1.16% Gel if you are already taking diclofenac tablets or other NSAID pain/inflammation tablets (eg. aspirin or ibuprofen).” In addition, the outer carton of the of the product includes the warning “Do not use if you are taking diclofenac, aspirin or other NSAIDS such as ibuprofen”.

5.2 Risk of Misuse

5.2.1 Pack Size

The proposed addition of a 120g pack size represents a 20% increase from the currently approved 100g GSL pack size.

Depending on the size of the area to be treated, between 2-4g of gel is applied at a frequency of 3-4 times daily. In a typical treatment day, a consumer will apply between 6g and 16g (maximum recommended) of gel. A week’s treatment will require between 42g and 112g. A week’s treatment at the maximum recommended dosage (112g) falls roughly halfway between the currently available maximum GSL pack size (100g) and that of the proposed new pack size (120g). In such a situation, the current maximum pack size of 100g would provide just under the required amount of gel.

If only 2g of gel is applied 3 times daily (the minimum recommended dosage), the largest new proposed pack size (120g) will provide enough product for up to 20 days, which is just under three times the maximum recommended duration of treatment of 7 days. For sports injuries which may recur, the newly proposed GSL pack size of 120g would provide a supply of gel for a more than one injury over the course of the product’s 3-year shelf life.

The product information clearly conveys the 7-day limit to treatment (see section 5.1.1), minimising the risk of misuse/overuse of the product.

5.3 Special Precautions in Handling

There are no special precautions required in handling Deep Relief Anti-Inflammatory Gel.

5.4 Wider sale would be a convenience



The MHRA accepts that a larger pack size (i.e. 120 g) would enable patients who are using the gel to relieve symptoms of a larger affected area to have access to a sufficient amount of medicine from one pack leaving little product left over after applying at the maximum recommended dose. Additionally, repeated sports injuries for example, which may occur over time, could be treated using the larger pack size within the shelf life of the product.

The wider availability of the additional pack size of 120g would enable users to have an increased choice of treatment to better control their symptoms

5.5 Risk Management Plan

The normal practices to monitor the safety of Voltarol Back & Muscle Pain Relief 1.16% Gel are considered sufficient to address the identified and potential risks. The identified risks will be managed using current practices, such as the clear advice in the product information on how to use the product safely and correctly. No additional measures are considered necessary.

6 Reasons for not seeking advice from the Commission on Human Medicines⁶

No major issues have been identified in the assessment of this application. The availability of a 120g pack size as a General Sales List medicine would result in minimal changes based on the following reasons:

1. The proposed use of the medicine, dosing regimen, route of administration, strength, and duration of treatment are the same as those for the currently approved pack sizes of 30 g, 50g and 100g on this licence.
2. The safety and efficacy of the product are well established and there are no new data of concern for this application to add the 120g pack size. The pharmacokinetics of the active substance (DDEA) in gel formulation are well known.
3. The product information clearly communicates the limit to the duration of use of 7 days. The patient information leaflet provides suitable advice to the patient concerning what action to take if symptoms do not improve or worsen within 7 days or if symptoms persist beyond 7 days of treatment.
4. Although a 120-g pack size would provide more than 7 days treatment when used at the minimum recommended dose, other General Sales List products are available for which the largest licensed pack size provides more product than may be used when applying at the lowest of the recommended dosage range and for which the patient information is considered suitable as a risk minimisation measure.

7 Conclusion

The MHRA has taken the decision to approve General Sales List legal status for the 120g pack size of Voltarol Back & Muscle Pain Relief 1.16% Gel.

General Sales List availability of this pack size will be valuable to people who are treating a larger area of their body or repeated occurrences of sports injury.

⁶ The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. Their views are sought on reclassifications when more complex or new reclassifications of medicines are being proposed.



Considering the GSL criterion, and from data provided, the risk of misuse, masking a more sinister condition or abuse/addiction potential is considered small. There are no specific precautions for use in handling the product in addition to those already approved for the current GSL product. The proposed indication has already been accepted as suitable for self-diagnosis and treatment without the intervention of a pharmacist.

**Medicines and Healthcare products Regulatory Agency,
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