Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Montelukast 4 mg Granules

(montelukast sodium)

Product Licence Number: PL 36687/0448

Torrent Pharma (UK) Ltd

LAY SUMMARY

Montelukast 4 mg Granules

(montelukast sodium)

This is a summary of the Public Assessment Report (PAR) for Montelukast 4 mg Granules. 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 Montelukast Granules in this lay summary for ease of reading.

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

What are Montelukast Granules and what are they used for?
This product has been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 19 November 2019 (DE/H/5969/001/DC). This is known as the MR/DC Decision Reliance Procedure.

A doctor has prescribed Montelukast granules to treat child's asthma, preventing asthma symptoms during the day and night.
• Montelukast granules are used for the treatment of 6 months to 5-year-old patients who are not adequately controlled on their medication and need additional therapy.
• Montelukast granules may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
• Montelukast granules also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

A doctor will determine how Montelukast granules should be used depending on the symptoms and severity of your child's asthma.

This application is for a generic medicine. This means that this medicine is the same as, and considered interchangeable with, reference medicines already authorised in the European Union (EU) and the United Kingdom (UK) called Singular paediatric 4 mg granules (Merck Sharp & Dohme Ltd).

How do Montelukast Granules work?
Montelukast Granules contains the active ingredient montelukast sodium, which is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast granules improves asthma symptoms and helps control asthma.

How are Montelukast Granules used?
The pharmaceutical form of this medicine is a granule and the route of administration is oral (by mouth). The sachets should not be opened until ready to use.

Montelukast granules are not intended to be dissolved in liquid. However, a child may take liquids after swallowing the Montelukast granules.

Montelukast granules can be given either directly in the mouth or mixed with a spoonful of cold or room temperature soft food (for example, applesauce, ice cream, carrots and rice).

Mix all of the contents of the Montelukast granules into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food. Be sure the child is given the entire spoonful of the granule/food mixture immediately (within 15 minutes). Never store any granule/food mixture for use at a later time.

Montelukast granules can be taken without regard to the timing of food intake.

This medicine is to be given to a child under adult supervision. A child should take Montelukast granules every evening. It should be taken even when a child has no symptoms or if he/she has an acute asthma attack.

For children 6 months to 5 years of age:
The recommended dose is one sachet of Montelukast 4 mg granules to be taken by mouth each evening.
If a child is taking Montelukast granules, the adult should ensure that the child does not take any other products that contain the same active ingredient, montelukast.

If your child stops taking Montelukast granules
Montelukast granules can treat a child's asthma only if he/she continues taking it.
It is important for a child to continue taking Montelukast granules for as long as a doctor prescribes. It will help control a child's asthma.

If patients have any further questions on the use of this medicine, ask the child's doctor or pharmacist

For further information on how Montelukast Granules are 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 Montelukast Granules have been shown in studies?
Because Montelukast Granules are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Montelukast Granules?
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 behalf of someone else they care for, directly via the Yellow Card scheme at

www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Why were Montelukast Granules approved?
MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

What measures are being taken to ensure the safe and effective use of Montelukast Granules?
A Risk Management Plan (RMP) has been developed to ensure that Montelukast Granules are used as safely as possible. Based on this plan, safety information has been included in the SmPC and the PIL, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Montelukast Granules
A Marketing Authorisation for Montelukast Granules was granted in the United Kingdom (UK) on 16 December 2021.

The full PAR for Montelukast Granules follows this summary.

This summary was last updated in February 2022.

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) considered that the applications for Montelukast 4 mg Granules (PL 36687/0448) could be approved.

The products are approved for the following indications:

Montelukast Granules is indicated in the treatment of asthma as add-on therapy in those 6 months to 5 year old patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom "as-needed" short acting β-agonists provide inadequate clinical control of asthma.

Montelukast Granules may also be an alternative treatment option to low-dose inhaled corticosteroids for 2 to 5 year old patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids (see section 4.2).

Montelukast Granules is also indicated in the prophylaxis of asthma from 2 years of age and older in which the predominant component is exercise-induced bronchoconstriction.

The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene receptors (CysLT) found in the human airway and cause airway actions, including bronchoconstriction, mucous secretion, vascular permeability, and eosinophil recruitment.

This product has been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 19 November 2019 (DE/H/5969/001/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedure, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

This application was approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

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 Marketing Authorisation for Montelukast Granules was granted in the United Kingdom (UK) on 16 December 2021.

II. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPC is in line with current guidelines and are satisfactory.

PATIENT INFORMATION LEAFLET
The PIL is in line with current guidelines and are satisfactory.

LABEL
The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS
MHRA considered that the quality data submitted for this application are satisfactory.

The grant of a marketing authorisation is recommended.

IV. NON-CLINICAL ASPECTS
MHRA considered that the non-clinical data submitted for this application are satisfactory.

The grant of a marketing authorisation is recommended.

V. CLINICAL ASPECTS
MHRA considered that the clinical data submitted for this application are satisfactory.

The grant of a marketing authorisation is recommended.

VI. 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.

VII. USER CONSULTATION
A full colour mock-up of the Patient Information Leaflets (PILs) have been provided with the applications, in accordance with legal requirements.

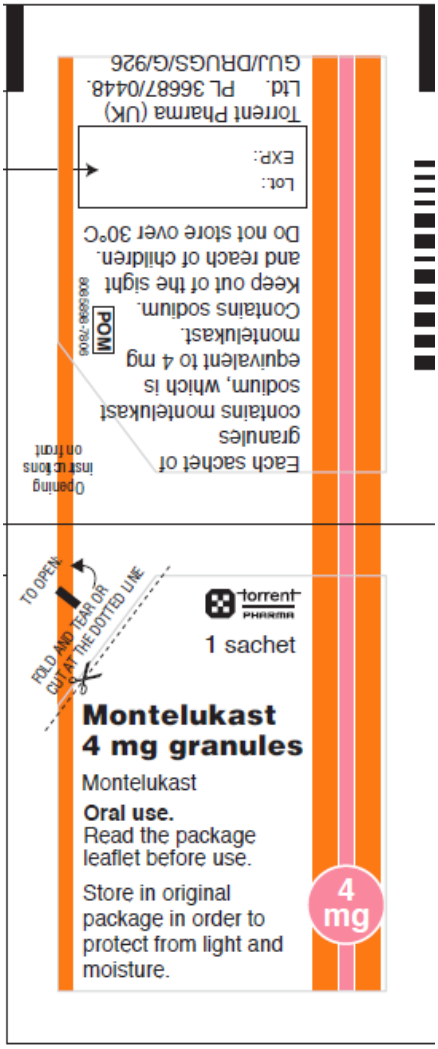
The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Pregabalin capsules (NL/H/3264/001-008/DC). The bridging report submitted by the applicant is acceptable.

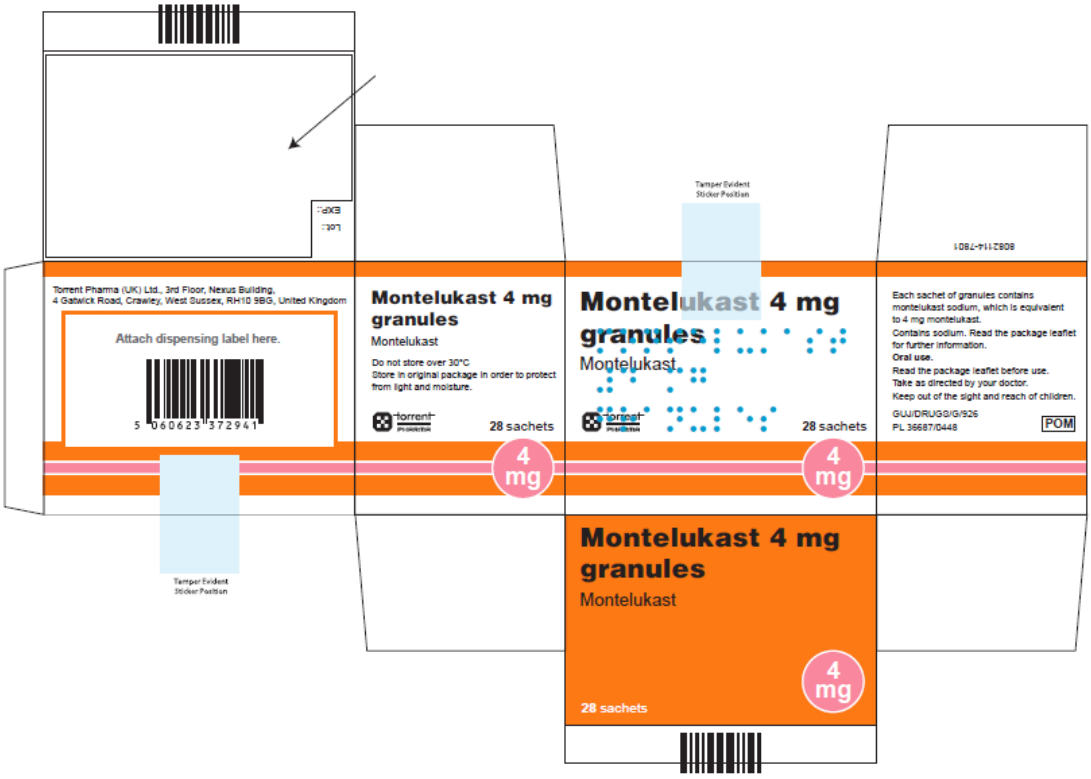
VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

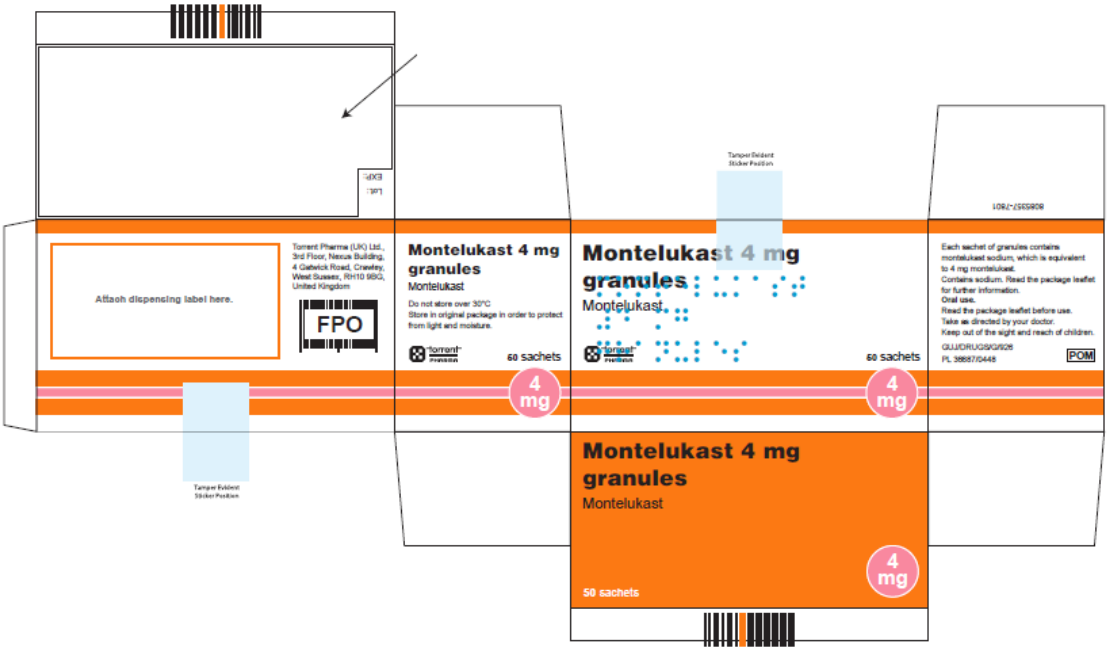
The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

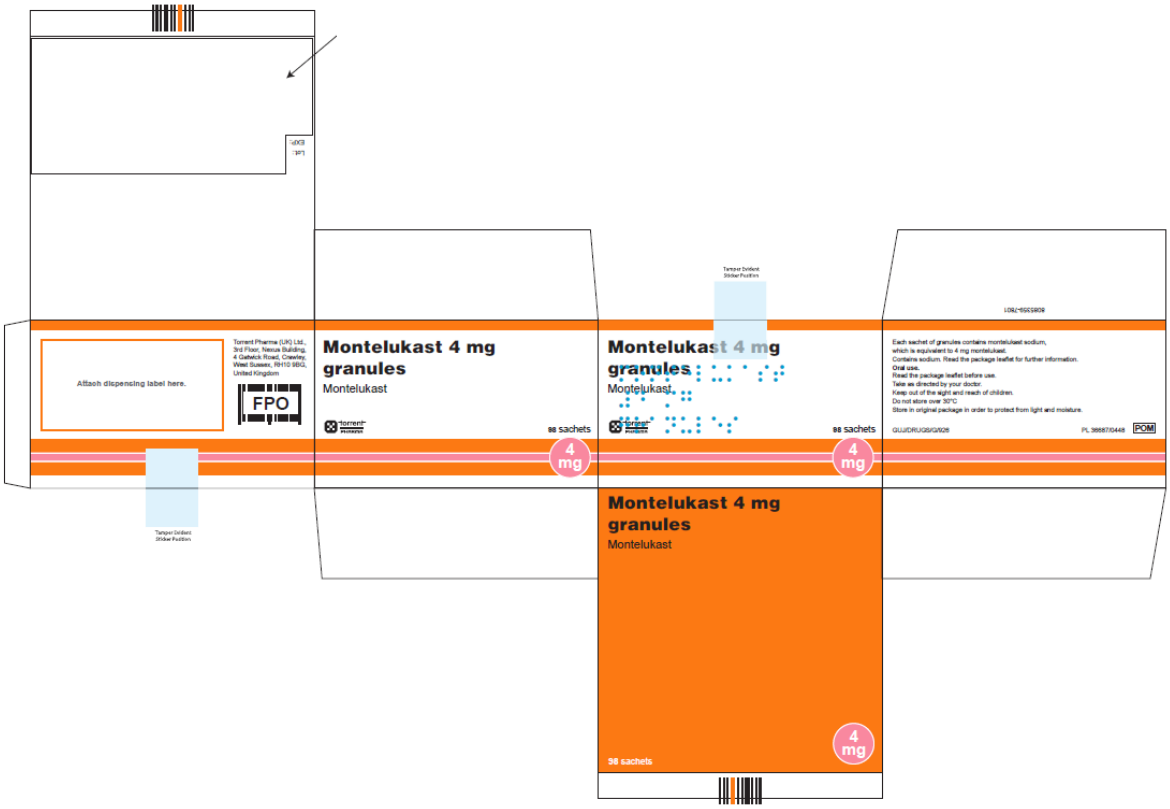
In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

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


Torrent Pharma (UK)
Ltd. PL 36687/0448.
GUJ/DRUGS/G/926
Lot:
EXP:
Do not store over 30°C
and reach of children.
Keep out of the sight
Contains sodium.
montelukast.
equivalent to 4 mg
sodium, which is
contains montelukast
granules
Each sachet of
Opening
instructions
on front
POM
8082-114-7801
TO OPEN
FOLD AND TEAR OR
CUT AT THE DOTTED LINE
torrent PHARMA
1 sachet
Montelukast
4 mg granules
Montelukast
Oral use.
Read the package
leaflet before use.
Store in original
package in order to
protect from light and
moisture.
4
mg


Lot:
EXP:
Torrent Pharma (UK) Ltd., 3rd Floor, Nexus Building,
4 Gatwick Road, Crawley, West Sussex, RH10 9BG, United Kingdom
Attach dispensing label here.
5 060623 372941
Montelukast 4 mg granules
Montelukast
Do not store over 30°C
Store in original package in order to protect from light and moisture.
torrent PHARMA
28 sachets
4 mg
Tamper Evident Sticker Position
Montelukast 4 mg granules
Montelukast
torrent PHARMA
28 sachets
4 mg
8082-114-7801
Each sachet of granules contains montelukast sodium, which is equivalent to 4 mg montelukast.
Contains sodium. Read the package leaflet for further information.
Oral use.
Read the package leaflet before use.
Take as directed by your doctor.
Keep out of the sight and reach of children.
GUJ/DRUGS/G/926
PL 36687/0448
POM
Tamper Evident Sticker Position
Montelukast 4 mg granules
Montelukast
4 mg
28 sachets


Affaoh dispensing label here.
FPO
Montelukast 4 mg granules
Montelukast
60 sachets
4 mg
Montelukast 4 mg granules
Montelukast
50 sachets
Each sachet of granules contains montelukast sodium, which is equivalent to 4 mg montelukast.
Oral use.
POM


Affaoh dispensing label here.
FPO
Montelukast 4 mg granules
Montelukast
98 sachets
4 mg
Montelukast 4 mg granules
Montelukast
98 sachets
Each sachet of granules contains montelukast sodium, which is equivalent to 4 mg montelukast.
Oral use.
POM

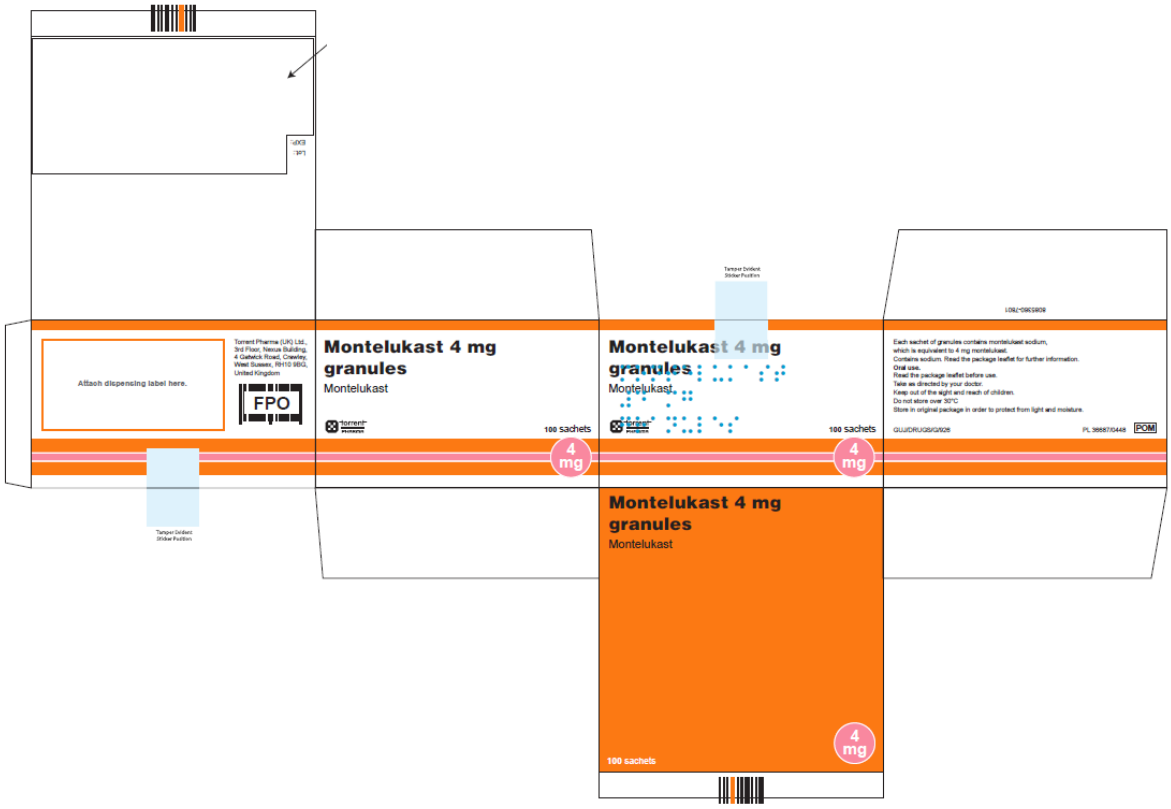

Affaoh dispensing label here.
FPO
Montelukast 4 mg granules
Montelukast
100 sachets
4 mg
Montelukast 4 mg granules
Montelukast
100 sachets
4 mg
Each sachet of granules contains montelukast sodium, which is equivalent to 4 mg montelukast.
Contains sodium. Read the package leaflet for further information.
Oral use.
Read the package leaflet before use.
Take as directed by your doctor.
Keep out of the sight and reach of children.
Do not store over 30°C
Store in original package in order to protect from light and moisture.
PL 36687/0448
POM
Montelukast 4 mg granules
Montelukast
100 sachets
4 mg

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 SmPCs and/or PIL available on the MHRA website.

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