**Public Assessment Report**

**National Procedure**

**<NAME(S) OF PRODUCT(S) FROM SmPC(S)>**

**active substance**

**<PL Number>**

**<MAH Name>LAY SUMMARY**

**<PLEASE NOTE THAT THIS LAY SUMMARY IS INTENDED TO BE INFORMATIVE TO THE PATIENT AND SHOULD CONTAIN NON-PROMOTIONAL INFORMATION TO HELP PATIENTS UNDERSTAND MORE ABOUT THEIR MEDICINES.>**

**product name combined here e.g. Paracetamol 10, 20, and 30 mg Tablets**

active substance

This is a summary of the Public Assessment Report (PAR) for <X>. It explains how this product/these products was/were assessed and its/their authorisation recommended, as well as its/their conditions of use. It is not intended to provide practical advice on how to use this product/these products.

<*If necessary, include shortened name and the following text*:

This product/These products will be referred to as <XX > in this lay summary for ease of reading.> (***Note****: if shortened name is to be used, XX should replace all mentions of X in text below.)*

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

**What is/are <X> and what is/are it/they used for?**

This application/These applications is/are the same as <Y, product name(s) and PL number(s)> which is/are already authorised.

The Company responsible for <Y, product name only> has agreed that its scientific data can be used as the basis for the grant of an identical licence/licences for <X>.

<X is used in the treatment of/X can be used by patients who…>

*<Include the relevant information on indications, e.g. copy the relevant information from PIL section “What X is and what is it used for”. Note that the PL is directed to the patient, rewrite accordingly if necessary.>*

**How does/do <X> work?**

<*Copy the relevant information from Section 1 of the PL “What X is and what is it used for”.>*

**How is/are <X> used?** **<AVOID USING GRAPHICS, TEXT ONLY>**

The pharmaceutical form of this medicine/these medicines is <pharmaceutical form> and the route of administration is <route of administration>.

*<This section should include: pharmaceutical form(s); main dosing recommendations; route/method of administration; duration of treatment if specified; need for any specific monitoring of certain parameters or for diagnostic tests; prescription status.>*

For further information on how <X> is/are used, refer to the PIL and Summary/Summaries of Product Characteristics (SmPC(s)) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

**Either:**

<This/These medicine/medicines can only be obtained with a prescription.>

**Or:**

<This/These medicine/medicines can be obtained without a prescription.>

**Either (if being administered by the patient themselves):**

<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.>

**Or (if being administered by a healthcare practitioner):**

<The patient should ask the administering healthcare practitioner if they have any questions concerning the medicine.>

**What benefits of <X> have been shown in studies?**

<X> is/are considered identical to the previously authorised product/products with the same benefits and risks. |No new studies have been provided for <X>, however, reference is made to the studies for <Y, product name(s) only>.

**What are the possible side effects of <X>?**

For the full list of all side effects reported with this medicine/these medicines, see Section 4 of the PIL or the SmPC(s) 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.

<X> is/are considered to be identical to the previously authorised product/products with the same benefits and risks.

**Why was/were <X> approved?**

The MHRA decided that the benefits of <X> are greater than the risks and recommended that this medicine/medicines is/are approved for use.

**What measures are being taken to ensure the safe and effective use of <X>?**

**<PLEASE COMPILE FROM RELEVANT SECTIONS OF THE RISK MANAGEMENT PLAN>**

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

The following safety concerns have been recognised for <x>:

Important identified risks: <complete as applicable or state “None”>

Important potential risks: <complete as applicable or state “None”>

Missing information: <complete as applicable or state “None”>

<or>

<if applicable: There are no safety concerns associated with use of <x>.>

<if applicable: describe additional risk management measures (also mentioned in the AR), such as obligations to provide educational materials, establish patient registries, or carry out further studies e.g. in specific populations or for long-term safety/efficacy data.>

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 <x> 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/these application(s) and are satisfactory.

**Other information about <X>**

A Marketing Authorisation/Marketing Authorisations was/were granted in the UK on <date of issue of the Marketing Authorisation>.

The full PAR for <X> follows this summary.

This summary was last updated in February 2024.

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1. **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(s) for product name combined here e.g. Paracetamol 10, 20, and 30 mg Tablets (<pl number>) could be approved.

The product(s) is/are approved for the following indications:

*<Include the relevant information on indications, copied from the SmPC(s)>*

<The name(s) of the active substance(s)> is/are….

*<Include a summary of the mechanism of action of each active substance, taken from the national assessment report/Module 2 summaries or Section 5.1 of the SmPC>*

This/These is a/are national abridged application(s) 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(s). The application(s) cross-refers/refer to the reference product(s) cross-reference product name/s and PL number(s).

No new non-clinical or clinical data have been supplied and none are required for this/these informed consent application(s).

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

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

(A) national marketing authorisation(s) was/were granted in the UK on < date of issue of the Marketing Authorisation>.

1. **EXPERT REPORT**

The applicant cross-refers to the data for <name of cross-reference product(s)>, <MAH name of cross-reference product(s)>), to which this/these application(s) is/are claimed to be identical. This is acceptable.

1. **ASSESSOR’S COMMENTS ON THE PRODUCT INFORMATION**

**SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

The SmPC(s) is/are in line with that/those for <name of cross-reference product(s)>), dated <XX/YYYY>.

**Patient Information Leaflet**

A <leaflet text and/or mock-up> has been provided which has been aligned with that for <name of cross-reference product(s)>), dated for <XX/YYYY>.

**Label**

<Label text and/or mock-ups> have been provided.

1. **QUALITY ASPECTS**

**IV.1 Drug Substance**

**Drug substance specification(s)**

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

**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**

<product name(s)> are available in <primary container> in a pack size of <pack sizes>.

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

The proposed shelf life of the product is <months/years> with <no special storage conditions/with the recommended storage condition ‘Do not store above <25/30°C’>/’Store below <25/30°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); Pharmacy (P) medicine; General Sales List (GSL) medicine>.

**Manufacturers**

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

**Qualitative and quantitative compositions**

The composition of the proposed product(s) is/are consistent with the details registered for the cross-reference product(s).

**Manufacturing process & control of critical steps**

The proposed manufacturing processes and process controls are consistent with the details registered for the reference product(s) 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(s).

**TSE Compliance**

With the exception of <state excipient>, no excipients of animal or human origin are used in the final products. *<State whether any EDQM certificates have been provided for the excipients of animal origin>*

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

<If appropriate: Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.>

<If appropriate: Copies of the current TSE certificates for suppliers of gelatin capsules have been provided and are current in accordance with EDQM database.>

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

1. **NON-CLINICAL ASPECTS**

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

1. **CLINICAL ASPECTS**

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

1. **RISK MANAGEMENT PLAN (RMP)**

**Either**

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.

**Or**

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. In addition to routine pharmacovigilance and risk minimisation measures, the following additional < if applicable: pharmacovigilance> <and> < if applicable: risk minimisation> measures have been proposed:

<Insert table of risk minimisation and additional pharmacovigilance measures from part VI ‘II.B Summary of important risks’ of the final RMP in the case folder>.

This is acceptable.

1. **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.

<Or>

A text draft of the Patient Information Leaflet (PIL) was presented. A commitment to provide a mock-up and evidence of user consultation of the PIL to the MHRA prior to marketing was accepted.

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

The quality of the product(s) is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product(s) is/are identical to the cross-reference product(s). The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product(s) 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(s).

In accordance with legal requirements, the current approved UK versions of the SmPCs and PILs for these products 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** |
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