Public Assessment Report

Decentralised Procedure

Potassium Iodate 85 mg Tablets

(Potassium iodate)

UK/H/5190/001/DC

UK licence no: PL 06831/0275

Genus Pharmaceuticals Limited
LAY SUMMARY

On 3rd September 2013, the Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) to Genus Pharmaceuticals Limited for the medicinal product Potassium Iodate 85 mg Tablets (PL 06831/0275, UK/H/5190/001/DC). This is a Pharmacy (P) medicine.

This product contains the active substance potassium iodate. It is a thyroid blocking agent and is used for example after a nuclear accident.

Potassium Iodate tablets are used during a nuclear emergency, when harmful radioactive iodine has been released into the environment. The tablets saturate the thyroid gland (situated in the neck) with iodine, which means that when you breathe in harmful radioactive iodine no more can be absorbed by the thyroid.

Radioactive iodine is especially dangerous to babies and children as they are at a higher risk of developing thyroid disease and/or cancer from breathing it in.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Potassium Iodate 85 mg Tablets outweigh the risks. Hence a Marketing Authorisation has been granted.
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## Module 1
### Information about initial procedure

<table>
<thead>
<tr>
<th><strong>Product Name</strong></th>
<th>Potassium Iodate 85 mg Tablets</th>
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<tbody>
<tr>
<td><strong>Type of Application</strong></td>
<td>Article 10(1), Generic application</td>
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<tr>
<td><strong>Active Substance</strong></td>
<td>Potassium iodate</td>
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<td><strong>Form</strong></td>
<td>Tablets</td>
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<tr>
<td><strong>Strength</strong></td>
<td>85 mg</td>
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| **MA Holder** | Genus Pharmaceuticals Limited  
Park View House  
65 London Road  
Newbury  
Berkshire  
RG14 1JN  
United Kingdom |
| **RMS** | UK |
| **CMS** | Luxemburg |
| **Procedure Numbers** | UK/H/5190/001/DC |
| **Timetable** | Day 178 – 26th July 2013 |
Module 2
Summary of Product Characteristics

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPC) for products that are granted Marketing Authorisations at a national level are available on the MHRA website.
Module 3
Patient Information Leaflet

In accordance with Directive 2010/84/EU the Patient Information Leaflets (PIL) for products that are granted Marketing Authorisations at a national level are available on the MHRA website.
Module 4

Labelling
Oral use. Read the package leaflet before use.

Keep out of the reach and sight of children.

Store in the original package. Do not transfer the tablets to another container.

Potassium iodate is included as a thyroid-blocking agent to prevent the uptake of radioactive iodine into the thyroid gland.

The tablets should be taken as follows: 2 tablets for adults, 1 tablet for children aged 3-12, half a tablet for children aged 1 month to 3 years, and a quarter of a tablet for newborns under 1 month.

Each tablet contains 85mg potassium iodate equivalent to 56mg iodine.

100 tablets
Module 5
Scientific discussion during initial procedure

I INTRODUCTION
Based on the review of the data on quality, safety and efficacy, the Reference Member State (RMS) and Concerned Member State (CMS) considered that the application for Potassium Iodate 85 mg Tablets (PL 06831/0275, UK/H/5190/001/DC), in the prevention of radioactive iodine uptake, for example after a nuclear accident, is now approvable.

This application was submitted under Article 10(1) of Directive 2001/83/EC (as amended), generic application. The application cross refers to Potassium Iodate 85 mg Tablets (PL 00289/0213), originally granted to TEVA UK Limited on 9th October 1991. This reference product is a line extension of Potassium Iodate 170 mg Tablets (Full dossier) which also belongs to the same Marketing Authorisation Holder. The reference licence has undergone a Change of Ownership (CoA) procedure to Cambridge Laboratories Limited (PL 12070/0029) on 5th January 2004 followed by authorisation to the current Marketing Authorisation Holder Alliance Pharmaceuticals Limited (PL 16853/0113) on 18th May 2011.

With the UK as the RMS in this Decentralised Procedure (UK/H/5190/001/DC), Genus Pharmaceuticals Limited applied for a Marketing Authorisation for Potassium Iodate 85 mg Tablets in Luxemburg.

Potassium Iodate is a thyroid-blocking agent. The iodine released from iodide and iodate on absorption from the gut is taken up rapidly and preferentially by the cells of the thyroid gland. Once in the thyroid, it is rapidly incorporated into organic molecules that are synthesised into thyroid hormones and ultimately released into the general circulation.

No new clinical or non-clinical studies were conducted, which is acceptable given that this is a generic application, which refers to an originator product that has been licensed for over 10 years. Bioequivalence studies are not necessary to support this application as the applicant applies for a bio pharmaceutics classification system (BCS-based bio waiver) in line with the bioequivalence guideline (CPMP/EWP/QWP/1401/98 Rev 1/Corr**, Appendix III). The applicant has provided detailed justification and discussion to support this exemption in the clinical dossier.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product type at all sites responsible for the manufacture and assembly of this product.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

The RMS considers that the Pharmacovigilance System as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

A satisfactory Risk Management Plan (RMP) has been provided.
All involved Member States agreed to grant a Marketing Authorisation for the above product at the end of the procedure (Day 178 – 26th July 2013). After a subsequent national phase, the UK granted a Marketing Authorisation for this product on 3rd September 2013 (PL 06831/0275).
II. ABOUT THE PRODUCT

<table>
<thead>
<tr>
<th>Name of the product in the Reference Member State</th>
<th>Potassium Iodate 85 mg Tablets</th>
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<tbody>
<tr>
<td>Name(s) of the active substance(s) (INN)</td>
<td>Potassium iodate</td>
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<tr>
<td>Pharmacotherapeutic classification (ATC code)</td>
<td>Antidotes, ATC code: V03A B21</td>
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<td>Reference Member State</td>
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<td>Concerned Member States</td>
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<td>Marketing Authorisation Number(s)</td>
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<td>Name and address of the authorisation holder</td>
<td>Genus Pharmaceuticals Limited</td>
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<td>Park View House</td>
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III SCIENTIFIC OVERVIEW AND DISCUSSION

III.1 QUALITY ASPECTS

DRUG SUBSTANCE

rINN /Chemical Name: Potassium Iodate

Molecular Formula: KIO₃

Molecular Weight: 214.0 g/mol

Appearance: White crystalline powder.

Solubility: Slowly soluble in water and insoluble in ethanol (96 per cent).

Full information of the active substance is provided in the dossier.

DRUG PRODUCT

Other Ingredients

Other ingredients consist of the pharmaceutical excipients calcium hydrogen phosphate dihydrate, croscarmellose sodium, microcrystalline cellulose and magnesium stearate.

All excipients comply with their respective European Pharmacopoeia monographs. Satisfactory Certificates of Analysis have been provided for all excipients.

Confirmation has been given that the magnesium stearate used in the tablet is of vegetable origin.

Pharmaceutical Development

The objective of the development programme was to formulate robust, stable tablets containing potassium iodate that could be considered a generic medicinal product of Potassium Iodate 85 mg Tablets (Alliance Pharmaceuticals Limited).

Comparative impurity and dissolution profiles have been presented for the test and reference products.

Manufacture

A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results. Satisfactory process validation data on pilot-scale batches have been provided. The applicant has committed to perform process validation on three consecutive commercial-scale batches prior to marketing the drug product.

Finished Product Specification

The finished product specification is satisfactory. Test methods have been described and adequately validated. Batch data have been provided, which comply with the release specification. Certificates of Analysis have been provided for any working standards used.

Container-Closure System

The finished product is packed in OPA/Aluminium/PVC- Aluminium blisters with pack sizes of 10 or 100 tablets.
Specifications and Certificates of Analysis for all packaging materials have been provided. These are satisfactory. All primary packaging complies with relevant EU legislation regarding contact with food.

**Stability**

Finished product stability studies have been conducted in accordance with current guidelines and in the packaging proposed for marketing.

Based on the results, a shelf-life of 24 months with storage condition “Store in the original package” are set. These are satisfactory.

**Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labelling**

The SmPC, PIL and label are acceptable from a pharmaceutical perspective.

A package leaflet has been submitted to the MHRA together with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC, as amended. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that the package leaflet contains.

The Marketing Authorisation Holder has committed to submit mock-ups for any non-marketed pack size to the relevant regulatory authorities for approval before those packs are marketed.

**Marketing Authorisation Application (MAA) Forms**

The MAA form is satisfactory from a pharmaceutical perspective.

**Expert report**

The pharmaceutical expert report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

**Conclusion**

There are no objections to the approval of this product from a pharmaceutical point of view.

**III.2 NON-CLINICAL ASPECTS**

The pharmacodynamic, pharmacokinetic and toxicological properties of potassium iodate are well known.

No new non-clinical data have been supplied with this application and none are required for applications of this type. The non-clinical expert report has been written by an appropriately qualified person and is a suitable summary of the non-clinical aspects of the dossier.

Suitable justification has been provided for not submitting an environmental risk assessment.

There are no objections to the approval of this product from a non-clinical point of view.
III.3 CLINICAL ASPECTS
This application concerns a generic formulation of potassium iodate which is well-established to block uptake of radioiodine by the thyroid gland in scenarios such as nuclear accident. The clinical overview has provided a satisfactory summary of the known clinical aspects of this active substance.

Bioequivalence studies are not necessary to support this application as the applicant applies for a bio pharmaceutics classification system (BCS-based bio waiver) in line with the bioequivalence guideline (CPMP/EWP/QWP/1401/98 Rev 1/Corr**, Appendix III). The applicant has provided detailed justification and discussion to support this exemption in the clinical dossier.

Expert Report (Clinical Overall Summary)
A clinical overall summary, written by an appropriately qualified physician, has been provided. This is a satisfactory.

Marketing Authorisation Application form (MAA)
The MAA form is satisfactory from a clinical perspective.

Summary of Product Characteristics (SmPC)
The SmPC is satisfactory from a clinical perspective and consistent with that for the reference product.

Patient Information Leaflet (PIL)
The PIL is satisfactory from a clinical perspective and consistent with the SmPC.

Labelling
The Labelling is satisfactory from a clinical perspective.

Conclusion
There are no objections to the approval of this product from a clinical point of view.
IV. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
The important quality characteristics of Potassium Iodate 85 mg Tablets are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL
Potassium iodate is well known worldwide with respect to its overall pharmaco-toxicological, clinical properties and its use. A BCS-based bio waiver, in accordance with the revised EMA guideline, is sought and consequently no comparative pharmacokinetic study has been conducted.

No new or unexpected safety concerns arose from this application.

The SmPC and PIL are satisfactory and consistent with those for the reference product. Satisfactory labelling has been submitted.

RISK-BENEFIT ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with potassium iodate is considered to have demonstrated the therapeutic value of the product. The risk-benefit balance is considered to be positive.
Module 6

STEPS TAKEN AFTER INITIAL PROCEDURE - SUMMARY

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<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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