Public Assessment Report

UK PAR

Propiverine 15 mg film-coated tablets
Zidrok 15 mg film-coated tablets

(Propiverine hydrochloride)

UK Licence No: PL 40739/0071

Ennogen Healthcare Limited
LAY SUMMARY

Propiverine 15 mg film-coated tablets
Zidrok 15 mg film-coated tablets

(Propiverine hydrochloride)

This is a summary of the Public Assessment Report (PAR) for Propiverine 15 mg film-coated tablets/Zidrok 15 mg film-coated tablets (PL 40739/0071). It explains how the application for Propiverine 15 mg film-coated tablets/Zidrok 15 mg film-coated tablets was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Propiverine 15 mg film-coated tablets/Zidrok 15 mg film-coated tablets. For ease of reading, the product may be referred to as ‘Propiverine/Zidrok tablets’ in this lay summary.

For practical information about using Propiverine/Zidrok tablets, patients should read the package leaflets or contact their doctor or pharmacist.

What is Propiverine/Zidrok tablets and what is it used for?
Propiverine/Zidrok tablets is a ‘generic’ medicine. This means that Propiverine/Zidrok tablets is similar to a ‘reference’ medicine already authorised in the UK (EU) called Mictonorm 15 mg Coated Tablets (PL 15072/0002; APOGEPHA Arzneimittel GmbH).

Propiverine/Zidrok tablets is used to treat the symptoms of:
- urinary incontinence (uncontrollable) and/or
- increase urinary frequency (very frequent urination) and
- urge to urinate

These are manifested in patients with:
- An overactive bladder, whose cause is not clear (idiopathic detrusor overactivity), or
- A nerve disorder of emptying the bladder (neurogenic detrusor overactivity, detrusor hyperreflexia)

This occurs with disorders of the spinal cord, such as spinal injury or a congenital malformation of the spinal cord and spinal column (meningomyelocele).

How does Propiverine/Zidrok tablets work?
This medicine contains the active substance, propiverine hydrochloride. Propiverine/Zidrok tablets is a drug for relaxing the bladder muscles (bladder spamolytic).

How is Propiverine/Zidrok tablets used?
Propiverine/Zidrok tablets are film-coated and taken by mouth. The tablets should be taken (without chewing) with sufficient liquid (preferably a glass of water) before eating.

The patient’s doctor will decide on the duration of the treatment. The patient should always take this medicine exactly as his/her doctor or pharmacist has advised. The patient should check with his/her doctor or pharmacist if unsure.

Please read section 3 of the package leaflets for detailed information on dosing recommendations, the route of administration and the duration of treatment.

Propiverine/Zidrok tablets can only be obtained with a prescription.
What benefits of Propiverine/Zidrok tablets have been shown in studies?
As Propiverine/Zidrok tablets is a generic medicine, studies in patients have been limited to tests to determine that Propiverine/Zidrok tablets are bioequivalent to the reference product called Mictonorm 15 mg Coated Tablets (PL 15072/0002; APOGEPHA Arzneimittel GmbH. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Propiverine/Zidrok tablets?
As Propiverine/Zidrok tablets is a generic medicine of the reference medicine Mictonorm 15 mg Coated Tablets (PL 15072/0002; APOGEPHA Arzneimittel GmbH), the benefits and possible side effects are taken as being the same as those of the reference medicine.

For the full list of all side effects reported with Propiverine/Zidrok tablets (see Section 4 of the package leaflets).

For the full list of restrictions, see the package leaflets.

Why is Propiverine/Zidrok tablets approved?
It was concluded that, in accordance with EU requirements, Propiverine/Zidrok tablets has been shown to have comparable quality and clinical characteristics to the reference product Mictonorm 15 mg Coated Tablets (PL 15072/0002; APOGEPHA Arzneimittel GmbH). Based on this evaluation, the MHRA concluded that the benefits of Propiverine/Zidrok tablets outweigh the identified risks and recommended Propiverine/Zidrok tablets for approval.

What measures are being taken to ensure the safe and effective use of Propiverine/Zidrok tablets?
A Risk Management Plan has been developed to ensure that Propiverine/Zidrok tablets is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics (SmPC) and the package leaflets for Propiverine/Zidrok Tablets, 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 and healthcare professionals will be monitored and reviewed continuously as well.

Other information about Propiverine/Zidrok tablets
A Marketing Authorisation was granted in the UK to Ennogen Healthcare Limited on 10 April 2018.

The full PAR for Propiverine/Zidrok tablets follows this summary.

For more information about treatment with Propiverine/Zidrok tablets, read the package leaflets, or contact your doctor or pharmacist.

This summary was last updated in June 2018.
TABLE OF CONTENTS

I Introduction .......................................................... Page 5
II Quality aspects ......................................................... Page 5
III Non-clinical aspects .................................................... Page 8
IV Clinical aspects ........................................................ Page 8
V User consultation ....................................................... Page 12
VI Overall conclusion, benefit/risk assessment and recommendation Page 12
Steps taken after authorisation-summary .................................. Page 26
Scientific Discussion

I INTRODUCTION
Based on the review of the data on quality, safety and efficacy, the MHRA granted Ennogen Healthcare Limited a Marketing Authorisation for the application for Propiverine 15 mg film-coated tablets/Zidrok 15 mg film-coated tablets (PL 40739/0071) on 10 April 2018. For the ease of reading, the product may be referred to as ‘Propiverine/Zidrok tablets’ in this scientific discussion.

Propiverine/Zidrok tablets is a Prescription Only Medicine (POM) and is indicated for the symptomatic treatment of urinary incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome or neurogenic detrusor overactivity (detrusor hyperreflexia) from spinal cord injuries, e.g. transverse lesion detrusor overactivity.

The application for Propiverine/Zidrok tablets was submitted under Article 10(1) of Directive 2001/83/EC, as amended, claiming to be a generic medicinal product of the reference medicinal product Mictonorm Dragees 15 mg Film-coated Tablets (Apogepha Arzneimittel GmbH), authorised in Germany on 20 October 1989. The corresponding reference product in the UK is Mictonorm 15 mg Coated Tablets (PL 15072/0002; APOGEPHA Arzneimittel GmbH), which was first authorised on 23 April 1998.

The active substance, propiverine hydrochloride, inhibits calcium influx and modulation of intracellular calcium in urinary bladder smooth muscle cells, causing musculotropic spasmolysis. Inhibition of the efferent connection of the nervus pelvicus is due to anticholinergic action.

A bioequivalence study was submitted to support the application comparing the applicant’s test product Propiverine hydrochloride film coated tablets (x 2 tablets) with the reference product Mictonorm 15 mg tablets (APOGEPHA Arzneimittel GmbH, Germany; x 2 tablets), under fasting conditions. The applicant has stated that the bioequivalence study was conducted in accordance with Good Clinical Practice (GCP).

With the exception of the bioequivalence study, no new non-clinical or clinical data were submitted, which is acceptable given that the application was based on a being generic medicinal product of an originator product that has been in clinical use for over 10 years.

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

No new or unexpected safety concerns arose during review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of Propiverine/Zidrok tablets outweigh the risks and a Marketing Authorisation was granted.

II QUALITY ASPECTS
II.1 Introduction
The submitted documentation concerning the proposed product is of sufficient quality and meets the current EU regulatory requirements.

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

The product is white, round, biconvex film-coated tablets. Each film-coated tablet contains 15 mg of propiverine hydrochloride, as the active substance. The product also contains pharmaceutical excipients in the tablet core namely, colloidal anhydrous silica, pregelatinised starch, calcium hydrogen phosphate...
dihydrate, microcrystalline cellulose and magnesium stearate. In addition, the tablet coating, Opadry II 85F18378, contains polyvinyl alcohol, titanium dioxide (E171), macrogol 3350 and talc. Appropriate justification for the inclusion of each excipient has been provided.

The finished product is supplied in polyvinylchloride/aluminium foil blisters, in pack sizes of 28, 30, 49, 50, 98 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis for the primary packaging materials have been provided. All primary packaging complies with current European regulations concerning materials in contact with foodstuff.

II.2 DRUG SUBSTANCE

Propiverine hydrochloride

INN: Propiverine hydrochloride
Chemical name: α-Phenyl-α-propoxybenzeneacetic acid 1-methyl-4-piperidinyl ester

Structure

\[
\text{\includegraphics[width=0.5\textwidth]{structure.png}}
\]

Molecular formula: \(C_{23}H_{29}NO_3\cdot\text{HCl}\)
M: 403.95
Appearance: White to off-white crystalline powder.
Solubility: Practically insoluble in ethyl acetate, diethyl ether and n-hexane
Slightly soluble in acetone
Sparingly soluble in acetonitrile
Soluble in water, anhydrous ethyl alcohol
Freely soluble in methyl alcohol, chloroform and glacial acetic acid.
Chirality: Propiverine hydrochloride does not exhibit optical isomerism
Polymorphism Propiverine hydrochloride does not exhibit polymorphism.

Propiverine hydrochloride is not the subject of a European Pharmacopoeia monograph.

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Batch analysis data, complying with the proposed specifications, are provided.

Satisfactory Certificates of Analysis have been provided for all working standards used.
Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 MEDICINAL PRODUCT

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious, stable, film-coated tablets, each containing 15 mg of propiverine hydrochloride, which were comparable in performance to Mictonorm 15 mg Coated Tablets (APOGEPHA Arzneimittel GmbH). Suitable pharmaceutical development data have been provided for this application.

Comparative in vitro dissolution profiles have been provided for this product and the reference product. The dissolution profiles were satisfactory.

All the excipients in the tablet core comply with their respective European Pharmacopoeia monographs. The tablet coating, Opadry II 85F18378 and its constituents (titanium dioxide (E171), talc, polyvinyl alcohol) are controlled to a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients. None of the excipients contain materials of animal or human origin.

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

Manufacturing Process

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 with full production-scale batches that have shown satisfactory results.

Control of Finished Product

The finished product specification is acceptable. Test methods have been described that have been validated adequately. Batch data complying with the release specifications have been provided. Certificates of Analysis have been provided for all working standards used.

Stability of the Product

Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. Based on the results, a shelf life of 5 years, with no special storage instructions has been accepted.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

Bioequivalence/Bioavailability

Satisfactory Certificates of Analysis have been provided for the test and reference batches used in the bioequivalence study.

II.4 Discussion on chemical, pharmaceutical and biological aspects

It is recommended that a Marketing Authorisation is granted for this product from a quality point of view.
III NON-CLINICAL ASPECTS

III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of propiverine hydrochloride are well known, no new non-clinical studies are required and none have been provided.

The non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology for propiverine hydrochloride.

Pharmacology
No new data have been submitted and none are required for this type of application. Refer to Section III.1, Introduction, above.

III.2 Pharmacokinetics
No new data have been submitted and none are required for this type of application. Refer to Section III.1, Introduction, above.

III.3 Toxicology
No new data have been submitted and none are required for this type of application. Refer to Section III.1, Introduction, above.

III.4 Ecotoxicity/Environmental Risk Assessment (ERA)
Suitable justification has been provided for non-submission of an Environmental Risk Assessment. Since Propiverine/Zidrok tablets are intended for generic substitution, this will not lead to an increase of the environmental exposure. An environmental risk assessment is therefore not deemed necessary. An environmental risk assessment is therefore not deemed necessary.

III.5 Discussion of the non-clinical aspects
It is recommended that a Marketing Authorisation is granted, from a non-clinical point of view.

IV. CLINICAL ASPECTS

IV.1 Introduction.
The clinical pharmacology of propiverine hydrochloride is well-known. No new clinical pharmacokinetic data is provided or required for this application.

The applicant’s clinical overview has been written by an appropriately qualified person and is considered acceptable.

IV.2 Pharmacokinetics
The pharmacokinetic (PK) profile of propiverine hydrochloride is well known.

In support of the application, a bioequivalence study was submitted. Details of the study are provided below.

An open-label, randomised, single-dose, two-treatment, two-period, two-sequence, crossover bioequivalence study comparing the applicant’s test product Propiverine hydrochloride film coated tablets and the reference product Mictonorm 15 mg tablets (APOGEPHA Arzneimittel GmbH, Germany) in healthy subjects, under fasting conditions.

Subjects were administered a single dose (30 mg; 2 film-coated tablets) of either treatment with 240 ml of water, after at least a 10 hour fast. Blood sampling was performed pre- and up to 96 hours post dose
in each treatment period. The washout period between the treatment arms was 7 to 14 days. The pharmacokinetic results are presented below.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Propiverine Test</th>
<th>Propiverine Reference</th>
<th>Propiverine N-Oxide Test</th>
<th>Propiverine N-Oxide Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>geom. mean</td>
<td>arith. mean</td>
<td>SD</td>
<td>range</td>
</tr>
<tr>
<td>AUC0-tlast [ng/ml]</td>
<td>495.17</td>
<td>539.36</td>
<td>232.78</td>
<td>183.91 – 1277.68</td>
</tr>
<tr>
<td>Cmax [ng/ml]</td>
<td>43.88</td>
<td>47.73</td>
<td>19.59</td>
<td>15.42 – 103.48</td>
</tr>
<tr>
<td>tmax [h]</td>
<td>-</td>
<td>1.72</td>
<td>0.86</td>
<td>1.00 – 5.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUC0-tlast [ng/ml]</td>
<td>506.84</td>
<td>552.38</td>
<td>232.61</td>
<td>172.81 – 1257.21</td>
</tr>
<tr>
<td>Cmax [ng/ml]</td>
<td>43.69</td>
<td>47.38</td>
<td>19.44</td>
<td>15.79 – 104.46</td>
</tr>
<tr>
<td>tmax [h]</td>
<td>-</td>
<td>1.93</td>
<td>0.68</td>
<td>1.00 – 4.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUC0-tlast [ng/ml]</td>
<td>12895.01</td>
<td>13490.31</td>
<td>4309.94</td>
<td>7140.49 - 29495.93</td>
</tr>
<tr>
<td>Cmax [ng/ml]</td>
<td>1397.81</td>
<td>1444.09</td>
<td>382.72</td>
<td>684.44 - 2784.00</td>
</tr>
<tr>
<td>tmax [h]</td>
<td>-</td>
<td>1.22</td>
<td>0.71</td>
<td>0.50 - 4.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUC0-tlast [ng/ml]</td>
<td>13004.41</td>
<td>13564.73</td>
<td>4166.54</td>
<td>6926.09 - 26590.46</td>
</tr>
<tr>
<td>Cmax [ng/ml]</td>
<td>1334.54</td>
<td>1378.29</td>
<td>345.68</td>
<td>673.13 - 2107.99</td>
</tr>
<tr>
<td>tmax [h]</td>
<td>-</td>
<td>1.64</td>
<td>0.87</td>
<td>0.50 - 4.00</td>
</tr>
</tbody>
</table>

The percentage of AUC$_{0-\infty}$ which was extrapolated was less than 20% in both periods for all subjects in both periods, indicating that the sampling schedule was sufficient to characterize the concentration curves.

**Bioequivalence**

**Propiverine**

<table>
<thead>
<tr>
<th>Variable</th>
<th>point estimator</th>
<th>confidence limits***</th>
<th>ANOVA-log CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC0-tlast (ratio test/reference)</td>
<td>0.98*</td>
<td>0.91 - 1.05*</td>
<td>18.19</td>
</tr>
<tr>
<td>Cmax (ratio test/reference)</td>
<td>1.00*</td>
<td>0.94 - 1.08*</td>
<td>17.90</td>
</tr>
<tr>
<td>tmax [h] (difference test-reference)</td>
<td>-0.25**</td>
<td>-0.49 - 0.00 **</td>
<td>-</td>
</tr>
</tbody>
</table>
Conclusion
In line with the guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**), the 90% confidence intervals of the test/reference ratio for $C_{\text{max}}$ and $\text{AUC}_{0-\text{tlast}}$ values lie within the acceptable limits (80.00% to 125.00%). Thus, the data support the claim that the applicant’s test product (x 2 tablets, 30 mg), is bioequivalent to the reference product, Mictonorm 15mg tablets (x 2 tablets, 30 mg; APOGEPHA Arzneimittel GmbH, Germany), under fasting conditions.

IV.3 Pharmacodynamics
The clinical pharmacodynamics properties of propiverine hydrochloride are well-known. No new pharmacodynamic data were submitted and none are required for this type of application.

IV.4 Clinical Efficacy
The clinical efficacy of propiverine hydrochloride is well-known. No new efficacy data are presented or are required for this type of application.

IV.5 Clinical Safety
No new safety data were submitted and none are required for this type of application. The safety profile of propiverine hydrochloride is well-known. No new or unexpected safety issues arose from this application.

IV.6 Risk Management Plan
The MAH has submitted a Risk Management Plan (RMP), in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Propiverine/Zidrok tablets.

A summary of safety concerns is listed in the table below:

Table: Summary of safety concerns

<table>
<thead>
<tr>
<th>Summary of safety concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important identified risks</td>
</tr>
<tr>
<td>Use in patients with obstruction of the bowel</td>
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<tr>
<td>Use in patients with a significant degree of bladder outflow obstruction where urinary retention may be anticipated</td>
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<tr>
<td>Use in patients with myasthenia gravis</td>
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<tr>
<td>Use in patients with intestinal atony</td>
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<tr>
<td>Use in patients with severe ulcerative colitis</td>
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<tr>
<td>Use in patients with toxic megacolon</td>
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<tr>
<td>Use in patients with uncontrolled angle closure glaucoma moderate</td>
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<tr>
<td>Use in patients with tachyarrhythmias</td>
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<tr>
<td>Risk of acute angle-closure glaucoma in individuals predisposed with narrow angles of the anterior chamber</td>
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<tr>
<td>Use in patients receiving potent FMO inhibitors</td>
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<tr>
<td>Use in combination with other drugs metabolised by CYP 3A4</td>
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<tr>
<td>Important potential risks</td>
</tr>
<tr>
<td>Misuse</td>
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<tr>
<td>Missing information</td>
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<tr>
<td>Use in children</td>
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<tr>
<td>Use in pregnancy</td>
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<tr>
<td>Risk of hallucinations</td>
</tr>
<tr>
<td>Use in patients with moderate or severe hepatic impairment</td>
</tr>
</tbody>
</table>

Routine pharmacovigilance and risk minimisation activities are planned for all safety concerns which are considered acceptable.
IV.7 Discussion of the clinical aspects
It is recommended that a Marketing Authorisation is granted, from a clinical point of view.

V. USER CONSULTATION
A package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The language used for the purpose of user testing the pack leaflet was English.

The results show that the package leaflet 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.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with propiverine hydrochloride is considered to have demonstrated the therapeutic value of the compound.

The proposed product has been demonstrated to be bioequivalent to the product and the risks and benefits are considered similar.

The benefit/risk assessment is, therefore, considered to be positive.

The grant of a Marketing Authorisation is recommended.
Summary of Product Characteristics (SmPC), Patient Information Leaflets (PILs) and labelling
The SmPC, PILs and labelling are satisfactory and, where appropriate, in line with current guidance.

In accordance with Directive 2010/84/EU, the current version of the SmPC and PILs is available on the MHRA website. The current labelling is presented below:

Propiverine 15 mg film-coated tablets
Propiverine film-coated tablets

15mg

Put dispensing label here

Each film-coated tablet contains 15 mg propiverine hydrochloride equivalent to 13.84 mg propiverine.

For oral administration only. Use as directed by your doctor.

Take before food. To be swallowed whole with water, not to be broken or chewed.

Please read enclosed Patient Information Leaflet before use.

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

49 film-coated tablets

MA Holder:
Environ Healthcare Limited
Unit G2, G3 & G4 Riverside Industrial Estate, Riverside Way, Dartford, DA1 5BS

PL 40739/0071
Zidrok 15 mg film-coated tablets
Zidrok film-coated tablets
(Propiverine Hydrochloride)

Each film-coated tablet contains 15 mg propiverine hydrochloride equivalent to 13.64 mg propiverine.

For oral administration only. Use as directed by your doctor.

Take before food. To be swallowed whole with water, not to be broken or chewed.

Please read enclosed Patient Information Leaflet before use.

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

MA Holder:
Emogen Healthcare Limited
Unit G2, G3 & G4 Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS
Zidrok film-coated tablets
(Propiverine Hydrochloride)

Each film-coated tablet contains 15 mg propiverine hydrochloride equivalent to 13.64 mg propiverine.

For oral administration only. Use as directed by your doctor.

Take before food. To be swallowed whole with water, not to be broken or chewed.

Please read enclosed Patient Information Leaflet before use.

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.
Propiverine 15 mg film-coated tablets  
Zidrok 15 mg film-coated tablets  

(Propiverine hydrochloride)  

PL 40739/0071  

STEPS TAKEN AFTER INITIAL PROCEDURE - SUMMARY  

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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