EPIRUBICIN HYDROCHLORIDE 10 MG AND 50 MG POWDER FOR SOLUTION FOR INJECTION

PL 40378/0153-4

UKPAR

TABLE OF CONTENTS

Lay Summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 11
Steps taken after authorisation – summary	Page 12
Summary of Product Characteristics	Page 13
Patient Information Leaflet	Page 13
Labelling	Page 14

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LAY SUMMARY

On 4th October 2012, the MHRA granted Aptil Pharma Limited Marketing Authorisations (licences) for Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection.

Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection contain the active ingredient epirubicin hydrochloride.

Epirubicin hydrochloride belongs to a group of medicines called anthracyclines, which are used to treat cancer. Epirubicin hydrochloride is a medicine that acts upon cells that are actively growing (such as cancer cells) in such a way as to slow or stop their growth and increases the likelihood that the cells will die. This medicine helps to selectively kill the cancer tissue rather than normal, healthy tissue.

Epirubicin hydrochloride is used to treat a variety of cancers, either alone or in combination with other drugs. The way in which it is used depends upon the type of cancer that is being treated.

When injected into the bloodstream, epirubicin hydrochloride has been found to be useful in the treatment of cancers of the breast, ovaries, stomach, bowel and lung. Epirubicin hydrochloride can be given in the same way to treat cancers of the blood-forming tissues such as malignant lymphomas, leukaemias and multiple myeloma.

In addition, epirubicin hydrochloride can be injected into the bladder through a tube. This is sometimes used to treat abnormal cells or cancers of the bladder wall. It can also be used after other treatments to try to prevent such cells from growing again.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of taking Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection outweigh the risks and Marketing Authorisations were granted.

EPIRUBICIN HYDROCHLORIDE 10 MG AND 50 MG POWDER FOR SOLUTION FOR INJECTION

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SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction	Page 4
Pharmaceutical assessment	Page 5
Non-clinical assessment	Page 8
Clinical assessment (including statistical assessment)	Page 9
Overall conclusions and risk benefit assessment	Page 10

INTRODUCTION

The MHRA granted Marketing Authorisations for the medicinal products Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection (PL 40378/0153-4) to Aptil Pharma Limited on 4th October 2012. These prescription-only medicines (POM) have produced responses in a wide range of neoplastic conditions, including breast, ovarian, gastric, lung and colorectal carcinomas, malignant lymphomas, leukaemias and multiple myeloma.

Intravesical administration of Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection has been found to be beneficial in the treatment of superficial bladder cancer, carcinoma-in-situ and in the prophylaxis of recurrences after transurethral resection.

These applications for Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection were submitted according to Article 10c (informed consent application) of Directive 2001/83/EC, as amended, cross-referring to Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection, licensed to Apsla Limited on 14th April 2011 (PL 33410/0010-11).

It is considered 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 together with the necessary means for notification of any adverse reaction suspected of occurring.

Satisfactory justification was provided for the absence of a Risk Management Plan.

No new data were submitted nor were they necessary for these 'informed consent' applications because the data are identical to those of the previously granted cross-reference products.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 40378/0153-4
PROPRIETARY NAME:	Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection
ACTIVE(S):	Epirubicin hydrochloride
COMPANY NAME:	Aptil Pharma Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS:	POM

1. INTRODUCTION

These are 'informed consent' applications for Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection (PL 40378/0153-4) submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed Marketing Authorisation Holder (MAH) is Aptil Pharma Limited, 9th Floor, CP House, 97 – 107 Uxbridge Road, Ealing, London W5 5TL.

These applications cross-refer to Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection, licensed to Apsla Limited on 14th April 2011 (PL 33410/0010-11).

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 NAME(S)

The proposed names of the products are Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The products contain 10 mg and 50 mg of epirubicin hydrochloride. The products are sterile, freeze-dried, orange-red coloured, lyophilised cakes (powder for solution for injection). After reconstitution, each vial contains 2 mg/ml epirubicin hydrochloride. The products Epirubicin Hydrochloride 10 mg and 50 mg Powder for Solution for Injection are for intravenous or intravesical administration.

The 10 mg strength presentation is packaged in a 10 ml Type I moulded flint glass vial with a 20 mm bromo butyl rubber stopper and 20 mm aluminium flip-off, tear-off seal.

The 50 mg strength presentation is packaged in a 50 ml Type I moulded flint glass vial with a 20 mm bromo butyl rubber stoppers and 20 mm aluminium flip-off tear-off seal.

There is 1 vial in each pack for both presentations.

The shelf-life of the products as packaged for sale is 2 years with storage conditions 'Store below 30°C. Keep the container in the outer carton'.

The shelf-life of the products after reconstitution is according to directions:
'In-use stability has been demonstrated for 24 hours at 15°C - 25°C and for 48 hours at 2-8°C in water for injections and 0.9 % w/v sodium chloride solution. However from a microbiological point of view, it is recommended that the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8ºC'.

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