population (n=83) (aged from 12 to < 18 years), significantly more patients treated with adefovir dipivoxil achieved the primary efficacy endpoint and obtained significant reductions in serum HBV DNA (23 %) compared to placebo-treated patients (0 %). However, the proportions of subjects who achieved HBeAg seroconversion at week 48 were similar (11 %) between the placebo arm and the adefovir dipivoxil 10 mg arm in adolescent patients.

Overall, the safety profile of adefovir dipivoxil in children was consistent with the known safety profile in adult patients. However, a signal towards a higher rate of decreased appetite and/or food intake was observed in the adefovir arm as compared to the placebo arm. At week 48 and 96, mean changes from baseline in weight and BMI Z scores tended to decrease in adefovir dipivoxil-treated patients. At week 48, all placebo-treated subjects who did not exhibit HBeAg or HBsAg seroconversion, plus all adefovir dipivoxil-treated subjects, were offered the opportunity to receive open-label adefovir dipivoxil from study week 49 through to week 240. A high rate (30%) of hepatic flares was reported following discontinuation of adefovir dipivoxil during the 3 years open-label phase of the study. Furthermore, for the few patients who remained on drug at week 240 (n=12) BMI Z score was lower than typical for their age and gender. Very few patients developed adefovir-associated mutations up to 5 years; however, the number of patients who remained on drugs above week 96 was limited. Due to their limitations, the clinical data available do not allow to draw definitive conclusions on the benefit/risk ratio of the adefovir treatment in children with chronic hepatitis B (see section 4.2).

5.2 Pharmacokinetic properties

Adefovir dipivoxil is a dipivaloyloxymethyl ester prodrug of the active substance adefovir, an acyclic nucleotide analogue which is actively transported into cells where it is converted by host enzymes to adefovir diphosphate.

Absorption
The oral bioavailability of adefovir from 10 mg adefovir dipivoxil is 59 %. Following oral administration of a single dose of 10 mg adefovir dipivoxil to chronic hepatitis B patients, the median (range) peak serum concentration (C_{max}) was achieved after 1.75 h (0.58-4.0 h). Median C_{max} and $AUC_{0-\infty}$ values were 16.70 (9.66-30.56) ng/ml and 204.40 (109.75-356.05) ng·h/ml, respectively. Systemic exposure to adefovir was not affected when 10 mg adefovir dipivoxil was taken with a high fat meal. The t_{max} was delayed by two hours.

Distribution
Preclinical studies show that after oral administration of adefovir dipivoxil, adefovir is distributed to most tissues with the highest concentrations occurring in kidney, liver and intestinal tissues. *In vitro* binding of adefovir to human plasma or human serum proteins is ≤ 4 %, over the adefovir concentration range of 0.1 to 25 µg/ml. The volume of distribution at steady-state following intravenous administration of 1.0 or 3.0 mg/kg/day is 392±75 and 352±9 ml/kg, respectively.

Biotransformation
Following oral administration, adefovir dipivoxil is rapidly converted to adefovir. At concentrations substantially higher (> 4,000-fold) than those observed *in vivo*, adefovir did not inhibit any of the following human CYP450 isoforms, CYP1A2, CYP2D6, CYP2C9, CYP2C19, CYP3A4. Based on the results of these *in vitro* experiments and the known elimination pathway of adefovir, the potential for CYP450 mediated interactions involving adefovir with other medicinal products is low.

Elimination
Adefovir is excreted renally by a combination of glomerular filtration and active tubular secretion. The median (min-max) renal clearance of adefovir in subjects with normal renal function (Cl_{cr} > 80 ml/min) is 211 ml/min (172-316 ml/min), approximately twice calculated creatinine clearance (Cockroft-Gault method). After repeated administration of 10 mg adefovir dipivoxil, 45 % of the dose is recovered as adefovir in the urine over 24 hours. Plasma adefovir concentrations declined in a biexponential manner with a median terminal elimination half-life of 7.22 h (4.72-10.70 h).

Linearity/non-linearity
The pharmacokinetics of adefovir are proportional to dose when given as adefovir dipivoxil over the dose range of 10 to 60 mg. Repeated dosing of adefovir dipivoxil 10 mg daily did not influence the pharmacokinetics of adefovir.

Pharmacokinetic/pharmacodynamic relationship(s)

Gender, age and ethnicity
The pharmacokinetics of adefovir were similar in male and female patients. Pharmacokinetic studies have not been conducted in the elderly. Pharmacokinetic studies were principally conducted in Caucasian patients. The available data do not appear to indicate any difference in pharmacokinetics with regard to race.

Renal impairment
The mean (± SD) pharmacokinetic parameters of adefovir following administration of a single dose of 10 mg adefovir dipivoxil to patients with varying degrees of renal impairment are described in the table below:

Renal Function Group	**Unimpaired**	**Mild**	**Moderate**	**Severe**
Baseline Creatinine Clearance (ml/min)	**> 80 (n=7)**	**50-80 (n=8)**	**30-49 (n=7)**	**10-29 (n=10)**
C_{max} (ng/ml)	17.8±3.2	22.4±4.0	28.5±8.6	51.6±10.3
$AUC_{0-\infty}$ (ng·h/ml)	201±40.8	266±55.7	455±176	1240±629
CL/F (ml/min)	469±99.0	356±85.6	237±118	91.7±51.3
CL_{renal} (ml/min)	231±48.9	148±39.3	83.9±27.5	37.0±18.4

A four-hour period of haemodialysis removed approximately 35 % of the adefovir dose. The effect of peritoneal dialysis on adefovir removal has not been evaluated.

It is recommended that the dosing interval of 10 mg adefovir dipivoxil is modified in patients with creatinine clearance between 30 and 49 ml/min. Adefovir dipivoxil is not recommended in patients with creatinine clearance of < 30 ml/min or in patients on dialysis (see section 4.2 and 4.4).

Hepatic impairment
Pharmacokinetic properties were similar in patients with moderate and severe hepatic impairment compared to healthy volunteers (see section 4.2).

Paediatric population
The pharmacokinetics of adefovir dipivoxil were studied in an efficacy and safety study of a daily dose of 0.25 mg/kg to 10 mg adefovir dipivoxil in children (aged 2 to < 18 years). Pharmacokinetic analysis revealed that adefovir exposure was comparable among 3 age groups, 2 to 6 years (0.3 mg/kg), 7 to 11 years (0.25 mg/kg) and 12 to 17 years (10 mg) and all age groups achieved adefovir exposure in the target range (for efficacy results see section 5.1), which was based on adefovir plasma concentrations in adult patients with chronic hepatitis B with established safety and efficacy profiles.

5.3 Preclinical safety data

The primary dose-limiting toxic effect associated with administration of adefovir dipivoxil in animals (mice, rats and monkeys) was renal tubular nephropathy characterised by histological alterations and/or increases in blood urea nitrogen and serum creatinine. Nephrotoxicity was observed in animals at systemic exposures at least 3-10 times higher than those achieved in humans at the recommended therapeutic dose of 10 mg/day.

No effects on male or female fertility, or reproductive performance, occurred in rats and there was no embryotoxicity or teratogenicity in rats or rabbits administered adefovir dipivoxil orally.

When adefovir was administered intravenously to pregnant rats at doses associated with notable maternal toxicity (systemic exposure 38 times that achieved in humans at the therapeutic dose) embryotoxicity and an increased incidence of foetal malformations (anasarca, depressed eye bulge, umbilical hernia and kinked tail) were observed. No adverse effects on development were seen at systemic exposures approximately 12 times that achieved in humans at the therapeutic dose.

Adefovir dipivoxil was mutagenic in the *in vitro* mouse lymphoma cell assay (with or without metabolic activation), but was not clastogenic in the *in vivo* mouse micronucleus assay.

Adefovir was not mutagenic in microbial mutagenicity assays involving *Salmonella typhimurium* (Ames) and *Escherichia coli* in the presence and absence of metabolic activation. Adefovir induced chromosomal aberrations in the *in vitro* human peripheral blood lymphocyte assay without metabolic activation.

In long-term carcinogenicity studies in rats and mice with adefovir dipivoxil, no treatment-related increase in tumour incidence was found in mice or rats (systemic exposures approximately 10 and 4 times those achieved in humans at the therapeutic dose of 10 mg/day, respectively).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised starch
Croscarmellose sodium
Lactose monohydrate
Talc
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

6.5 Nature and contents of container

Hepsera is supplied in high-density polyethylene (HDPE) bottles with a child-resistant closure. Each bottle contains 30 tablets, silica gel desiccant and fibre packing material.

The following pack sizes are available: outer cartons containing 1 bottle of 30 tablets and outer cartons containing 90 (3 bottles of 30) tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Gilead Sciences Ireland UC
Carrigtohill
County Cork, T45 DP77
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/03/251/001
EU/1/03/251/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 March 2003
Date of latest renewal: 06 March 2008

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigtohill Co. Cork
Ireland

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

- **Obligation to conduct post-authorisation measures**

The MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
The MAH commits to ensure continuous assessment of cross-resistance of adefovir to established and new nucleos(t)ide analogues, and provide reviews of these assessments as new data becomes available. The role of adefovir and add-on lamivudine+adefovir in HBV therapy strategy should be regularly discussed in the light of emerging data.	As data becomes available

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON AND BOTTLE LABELLING

1. NAME OF THE MEDICINAL PRODUCT

Hepsera 10 mg tablets
adefovir dipivoxil

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 10 mg of adefovir dipivoxil.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate, see package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 tablets
90 (3 bottles of 30) tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC. Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Gilead Sciences Ireland UC
Carrigtohill
County Cork, T45 DP77
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/03/251/001 30 tablets
EU/1/03/251/002 90 (3 bottles of 30) tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Hepsera
[outer packaging only]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC {number}
SN {number}
NN {number}

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Hepsera 10 mg tablets
adefovir dipivoxil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hepsera is and what it is used for

What Hepsera is
Hepsera contains the active substance adefovir dipivoxil and belongs to a group of medicines called antiviral medicines.

What it is used for
Hepsera is used to treat chronic hepatitis B, an infection with hepatitis B virus (HBV), in adults. Infection with the hepatitis B virus leads to damage to the liver. Hepsera reduces the amount of the virus in your body, and has been shown to reduce liver damage.

2. What you need to know before you take Hepsera

Do not take Hepsera

- **If you are allergic** to adefovir, adefovir dipivoxil or any of the other ingredients of this medicine (listed in section 6).

- **Tell your doctor at once** if you could be allergic to adefovir, adefovir dipivoxil or any of the other ingredients of Hepsera.

Warnings and precautions
Talk to your doctor before using Hepsera.

- **Tell your doctor if you have had kidney disease**, or if tests have shown problems with your kidneys. Hepsera can affect the way your kidneys work. The risk of this occurring is increased with long-term use of Hepsera. Your doctor should run tests to check your kidneys and liver are working properly, before and during your treatment. Depending on the results, your doctor may change how often you take Hepsera.

- If you are over 65 years of age your doctor may monitor your health more closely.

- **Don’t stop taking Hepsera** without your doctor’s advice.

- **After stopping Hepsera tell your doctor immediately** about any new, unusual or worsening symptoms that you notice after stopping treatment. Some patients have had symptoms or blood tests indicating that their hepatitis has worsened after stopping treatment with Hepsera. It's best for your doctor to monitor your health after stopping treatment with Hepsera. You may need blood tests for several months after treatment.

- **Once you start taking Hepsera:**

    - **look out for possible signs of lactic acidosis** – see section 4, Possible side effects.
    - **your doctor should order blood tests every three months** to check your medicine is keeping your chronic hepatitis B infection under control.

- **Take care not to infect other people.** Hepsera does not reduce the risk of passing on HBV to others through sexual contact or blood contamination. You must continue to take precautions to avoid this. A vaccine is available to protect those at risk from becoming infected with HBV.

- If you are HIV positive this medicine will not control your HIV infection.

Children and adolescents

- **Do not use Hepsera in children** or adolescents under 18 years of age.

Other medicines and Hepsera

- Do not take Hepsera if you are taking any medicines containing tenofovir.

- **Tell your doctor or pharmacist** if you are taking, have recently taken or might take any other medicines, including medicines and herbal products obtained without a prescription.

- **It is especially important to tell your doctor** if you are taking or have recently taken any of the following medicines which may damage your kidneys, or interact with Hepsera:

    - vancomycin and aminoglycosides, used for bacterial infections
    - amphotericin B, for fungal infections
    - foscarnet, cidofovir or tenofovir disoproxil fumarate, for viral infections
    - pentamidine, for other types of infection.

Hepsera with food, drink and alcohol

Hepsera can be taken with or without food (see section 3).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **Tell your doctor immediately if you are pregnant** or planning to become pregnant. It is not known whether Hepsera is safe to use during human pregnancy.

- **Use an effective method of contraception** to avoid becoming pregnant if you are a woman of child-bearing age taking Hepsera.

- **Do not breast-feed while taking Hepsera.** It is not known whether the active substance in this medicine passes into breast milk.

Driving and using machines
Hepsera should not affect your ability to drive or use any tools or machinery.

Hepsera contains lactose
If you are lactose-intolerant, or if you have been told that you have an intolerance to some sugars, talk to your doctor before taking Hepsera.

Hepsera contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Hepsera

Always take this medicine exactly as your doctor has told you. This is to make sure that your medicine is fully effective and to reduce the development of resistance to the treatment. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is one 10 mg tablet each day, taken orally with or without food.
- **A different dose** may be given to patients with **kidney problems**.

If you take more Hepsera than you should

If you accidentally take too many Hepsera tablets, contact your doctor or nearest hospital immediately.

If you forget to take Hepsera

It is important not to miss a dose.

- **If you do miss a dose** of Hepsera, take it as soon as you can, and then take your next scheduled dose at its regular time.
- **If it is nearly time for your next dose,** skip the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet (two doses close together).
- **If you are sick (vomit) less than 1 hour after taking Hepsera** take another tablet. You do not need to take another tablet if you are sick more than 1 hour after taking Hepsera.

If you stop taking Hepsera

- **Tell your doctor immediately about any new,** unusual or worsening symptoms that you notice after stopping treatment. See section 2 for more details.
- **Don't stop taking Hepsera** without your doctor's advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very rare side effects *(may affect up to 1 in 10,000 people)*

- **Lactic acidosis is a serious but very rare side effect of taking Hepsera.** It can cause too much lactic acid in the blood and enlargement of the liver. Lactic acidosis occurs more often in women, particularly if they are very overweight. People with liver disease may also be at risk.

Some of the signs of lactic acidosis are:

- Feeling sick (nausea) and sickness (vomiting)
- Stomach pain

→**Contact your doctor at once** if you get any of these symptoms. They are the same as some of the common side effects of Hepsera. If you do get any of them, it is unlikely to be serious, but you need to check. Your doctor will monitor you regularly while you take Hepsera.

Uncommon side effects *(may affect up to 1 in 100 people)*

- Damage to kidney tubule cells

Common side effects *(may affect up to 1 in 10 people)*

- Headache
- Feeling sick (nausea)
- Diarrhoea
- Digestive problems including wind or discomfort after eating meals
- Stomach pain
- Kidney problems, as shown by blood tests

→Tell a doctor or pharmacist if you are worried about any of these.

Very common side effects *(may affect more than 1 in 10 people)*

- Weakness

→Tell a doctor or pharmacist if you are worried about this.

Side effects before or after having a liver transplant

Some patients have experienced:

- Rash and itching – common
- Feeling sick (nausea) or being sick (vomiting) – common
- Kidney failure – common
- Kidney problems – very common

→Tell a doctor or pharmacist if you are worried about any of these.

- Also tests may show decreases in phosphate (common) or increases in creatinine (very common) in the blood.

Other possible side effects

The frequency of the following side effects is not known (frequency cannot be estimated from the available data):

- Kidney failure

- Kidney problems may lead to softening of the bones (which causes bone pain and sometimes leads to fractures) and muscle pain or weakness.

- Inflammation of the pancreas (pancreatitis)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hepsera

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.

Do not store above 30ºC. Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hepsera contains

- The active substance in Hepsera is adefovir dipivoxil. Each tablet contains 10 mg of adefovir dipivoxil.

- The other ingredients are: pregelatinised starch, croscarmellose sodium, lactose monohydrate, talc and magnesium stearate.

What Hepsera looks like and contents of the pack

Hepsera 10 mg tablets are round, white to off-white tablets. The tablets are marked with “GILEAD” and “10” on one side and a stylised shape of a liver on the other side. Hepsera 10 mg tablets are supplied in bottles of 30 tablets with silica gel desiccant. The silica gel desiccant is contained in either a separate sachet or a small canister and should not be swallowed.

The following pack sizes are available: outer cartons containing 1 bottle of 30 tablets and outer cartons containing 90 (3 bottles of 30) tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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County Cork, T45 DP77
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Manufacturer

Gilead Sciences Ireland UC
IDA Business & Technology Park
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This leaflet was last revised in {MM/YYYY}.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.